KAMADA LTD
Form 20-F
February 27, 2019

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, 2018

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	Name of Each Exchange on which Registered
Ordinary Shares, par value NIS 1.00 each	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, 2018, the Registrant had 40,295,078 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 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.

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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," 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 focus in the Alpha-1 Antitrypsin ("AAT") deficiency ("AATD") field and on becoming the innovator in this field by developing different therapeutic approaches to AATD independently and through collaborations with strategic partners;

- our expectation that our revenues will grow by approximately 9% to 14% in 2019 compared to our revenues for 2018 and that we will achieve our revenue goal of $125-130 million in 2019;

- our expectation that we will continue to generate gross, operating and net profits as well as positive cash flows during 2019 and beyond;

- our belief that our relationships with our strategic partners will lead to increased revenues and other benefits in the future and that such relationships, including with Takeda Pharmaceutical Company Limited ("Takeda"), which acquired Shire plc ("Shire"), and Kedrion S.p.A ("Kedrion") will continue without disruption;

- our expectation that the minimum aggregate revenue for our AAT intravenous product, Glassia ("Glassia"), for the years 2019 to 2020 under our agreement with Takeda will reach approximately $120 million and may be expanded to $150 million during that period;

- our expectation that our revenues in our Proprietary Products segment will increase until the end of 2020 (following which Takeda will have no obligation to purchase a minimum amount of Glassia from us), that Takeda will begin selling Glassia produced in its own manufacturing facility as early as 2021 and pay us royalties on those sales, and that Takeda will have a production facility approved by the U.S. Food and Drug Administration (the "FDA") by 2021;

- our expectation that as Takeda transitions to producing Glassia in its own facilities, we will incur a substantial reduction in revenues (as well as costs of goods sold), driven by the reduction in Glassia manufacturing, and our intent to partially offset such decrease in revenues by income from royalty payments from Takeda on their sales of Glassia and continued increased sales of Glassia in rest of the world countries through local distributors, increased sales of KEDRAB in the United States and sales of KamRAB and our Anti D IgG product in international markets as well as continued sales of our other proprietary products;

- our ability to continue marketing our anti-rabies immunoglobulin product for prophylaxis treatment of rabies disease in the United States in 2019 in collaboration with Kedrion (under the trademark "KEDRAB" in the U.S.) and our expectations regarding future sales of the product in the U.S. and in other territories (under the trademark "KamRAB");

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- our belief that receiving FDA approval for marketing of our anti-rabies immunoglobulin (under the trademark "KEDRAB" in the U.S.) will assist us in our efforts to register the product in additional countries where it is 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 AAT, anti-rabies immunoglobulin and other proprietary products;

- our belief that U.S.-based and other healthcare providers would seek to continue to diversify their source of anti-rabies immunoglobulin, using our product;

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

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

- 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 will continue to grow;

- the beneficial characteristics of Inhaled AAT for AATD, which we believe may result in our increased profitability pending future marketing approval of the product in target key countries;

- our expectations that our discussions with the FDA regarding the clinical and regulatory pathway for registration in the United States of Inhaled AAT for AATD, will materialize by mid-2019. Pending such agreed pathway we plan on filling for an FDA approval for our Investigational New Drug ("IND") application, which will enable us to initiate a pivotal study for registration thereafter. We intend to use the data from this study, if successful, to resubmit a Marketing Authorization Application ("MAA") in the European Union with the European Medicines Agency (the "EMA") and submit a Biologics License Application ("BLA") with the FDA;

- our ability to successfully attract partners in the development program for Inhaled AAT for AATD and 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;

- 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 plasma and production capacity and therefore increase our profitability;

- the various uses of AAT products to potentially be effective against various diseases, including Graft versus Host Disease ("GvHD"), type-1 diabetes ("T1D") and prevention of lung transplantation rejection and organ preservation, and our ability to generate the needed data to potentially attract strategic partner(s) to collaborate in the further development of these indications;

- our expectation that we will report top-line results from the Phase II clinical study of our intravenous AAT product to prevent lung transplantation rejection by the end of 2019;
- our expectation that we will report interim results from the Phase II clinical study of our intravenous AAT product for GvHD by the end of 2019;
- the timing of, and 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;
- the potential market opportunities for our products and product candidates;
- our plan to develop a recombinant AAT product and its future utilization as a replacement of the plasma derived AAT;
- our expectations regarding the potential actions or inactions of existing and potential competitors of our products;
- legislation or regulation in countries where we sell our products that affect product pricing, reimbursement, access or distribution channels;
- the impact of geographic and product mix on our total revenues and gross profit;
- our ability to obtain and maintain protection for the intellectual property relating to or incorporated into our technology and products;
- the impact of our research and development expenses on our financial results as we continue developing product candidates;
- 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 ended December 31, 2018.

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, 2018, 2017 and 2016 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”). None of the financial information in this Annual Report has

been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP").

Unless otherwise noted, NIS amounts presented in this Annual Report are translated at the rate of $1.00 = NIS 3.748, the exchange rate published by the Bank of Israel as of December 31, 2018.

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. Selected Financial Data

The following table summarizes our consolidated financial data. We have derived the summary consolidated statements of operations data for the years ended December 31, 2018, 2017 and 2016 and the consolidated balance sheets data as of December 31, 2018 and 2017 from our audited consolidated financial statements included elsewhere in this Annual Report. We have derived the summary consolidated statements of operations data for the years ended December 31, 2015 and 2014 and the summary consolidated balance sheet data as of December 31, 2016, 2015 and 2014 from our audited consolidated financial statements not included in this Annual Report.

We have included, in our opinion, all adjustments, consisting only of normal recurring adjustments that we consider necessary for a fair presentation of the financial information set forth in those summary consolidated statements. Our historical results are not necessarily indicative of the results that should be expected in the future, and our interim results are not necessarily indicative of the results that should be expected for the full year.

The summary of our consolidated financial data set forth below should be read together with our consolidated financial statements and the related notes, as well as the section entitled "Item 5. Operating and Financial Review and Prospects," included elsewhere in this Annual Report.

	Year Ended December 31,				
	2018	2017	2016	2015	2014
	(U.S Dollars in thousands, except per share data)				
Consolidated Statements of Operations Data:					
Revenues from Proprietary Products	$90,784	$79,559	$55,958	$42,952	$44,389
Revenues from Distribution	23,685	23,266	21,536	26,954	26,676
Total revenues	114,469	102,825	77,494	69,906	71,065
Cost of revenues from Proprietary Products	52,796	51,335	37,723	30,901	32,617
Cost of revenues from Distribution	20,201	19,402	18,411	23,640	23,406
Total cost of revenues	72,997	70,737	56,134	54,541	56,023
Gross profit	41,472	32,088	21,360	15,365	15,042
Research and development expenses	9,747	11,973	16,245	16,530	16,030
Selling and marketing expenses	3,630	4,398	3,243	3,652	2,898
General and administrative expenses	8,525	8,273	7,353	6,607	7,593
Other expense	311	-	-	-	-
Operating income (loss)	19,259	7,444	(5,481)	(11,424)	(11,479)
Financial income	820	500	469	463	404
Income (expense) in respect of currency exchange and translation differences and derivatives instruments, net	602	(612)	127	625	-
Financial expense	(340)	(162)	(126)	(934)	(2,086)
Income (loss) before taxes on income	20,341	7,170	(5,011)	(11,270)	(13,161)
Taxes on income	(1,955)	269	1,722	-	52
Net income (loss)	22,296	6,901	(6,733)	$(11,270)	$(13,213)
Income (loss) attributable to equity holders	22,296	6,901	(6,733)	$(11,270)	$(13,213)
Income (loss) per share attributable to equity holders:					
Basic	$0.55	$0.18	$(0.18)	$(0.31)	$(0.37)
Diluted	$0.55	$0.18	$(0.18)	$(0.31)	$(0.37)
Weighted-average number of ordinary shares used to compute income (loss) per share attributable to equity holders:					
Basic	40,275,374	37,970,697	36,418,833	36,245,813	35,971,335
Diluted	40,445,417	38,045,097	36,418,833	36,245,813	35,971,335
Consolidated Statements of Cash Flows:					
Cash flows from operating activities	$10,546	$3,608	$1,897	$(13,979)	$(9,918)
Cash flows from investing activities	(5,176)	(15,608)	1,637	11,253	(26,819)
Cash flows from financing activities	(587)	15,320	1,490	(6,355)	(7,640)
Consolidated Balance Sheet Data:					
Cash, cash equivalents, restricted cash and short-term investments	$50,592	$43,019	$28,632	$28,306	$51,896
Trade receivables	27,674	30,662	19,788	23,071	17,514
Working capital [(1)]	87,321	67,486	49,871	57,655	66,206
Total assets	138,116	122,110	99,696	101,992	119,140

Total liabilities	25,740	32,618	32,953	29,485	38,723
Total shareholders' equity	112,376	89,492	66,743	72,507	80,417
Other Data:					
Adjusted net income (loss)[2] [3]	$23,244	$7,384	$(5,663)	$(9,363)	$(9,462)
Adjusted EBITDA[2]	$23,910	$11,450	$(909)	$(6,290)	$(4,940)

(1) Working capital is defined as total current assets minus total current liabilities.

(2) We present adjusted net income (loss) 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 (2) they exclude the impact of non-cash 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. Adjusted net income (loss) and adjusted EBITDA are not recognized terms under IFRS and do not purport to be an alternative to IFRS net income (loss) as an indicator of operating performance or any other IFRS measure. Moreover, because not all companies use identical measures and calculations, the presentation of adjusted net income (loss) or adjusted EBITDA may not be comparable to other similarly titled measures of other companies.

Adjusted net income (loss) is defined as net income (loss), plus non-cash share-based compensation expenses. Our management believes that excluding non-cash charges related to share-based compensation provides useful information to investors because of its non-cash nature, varying available valuation methodologies among companies and the subjectivity of the assumptions and the variety of award types that a company can use under the relevant accounting guidance, which may obscure trends in our core operating performance.

(3) Adjusted EBITDA is defined as net income (loss), plus income tax expense, plus financial expense, net, plus depreciation and amortization expense, plus non-cash share-based compensation expenses, plus or minus income or expense in respect of exchange and translation differences and derivatives instruments not designated as hedging. Management believes that adjusted EBITDA provides useful information to investors for the same reasons discussed above for adjusted net income (loss).

The following tables set forth adjusted net income (loss) and adjusted EBITDA and also reconcile these figures to the IFRS measure net income (loss):

	Year Ended December 31,				
	2018	2017	2016	2015	2014
	(U.S Dollars in thousands)				
Net income (loss)	$22,296	$6,901	$(6,733)	$(11,270)	$(13,213)
Non-cash share-based compensation expenses	948	483	1,071	1,907	3,751
Adjusted net income (loss)	$23,244	$7,384	$(5,663)	$(9,363)	$(9,462)

	Year Ended December 31,				
	2018	2017	2016	2015	2014
	(U.S Dollars in thousands)				
Net income (loss)	$22,296	$6,901	$(6,733)	$(11,270)	$(13,213)
Income tax expense	(1,955)	269	1,722	-	52
Financial expense, net	(480)	(338)	(343)	471	1,682
Depreciation and amortization expense	3,703	3,523	3,501	3,227	2,788
Non-cash share-based compensation expenses	948	483	1,071	1,907	3,751
Income (expense) in respect of translation differences and derivatives instruments, net	(602)	612	(127)	(625)	-
Adjusted EBITDA	$23,910	$11,450	$(909)	$(6,290)	$(4,940)

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

You should consider carefully the risks and uncertainties described below, together with all of the other information in this Annual Report, including the consolidated financial statements and the related notes included elsewhere in this Annual Report. 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. If any of the following risks actually occurs, our business, financial condition, results of operations, and future prospects could be materially and adversely affected.

Risks Related to Our Proprietary Products Segment

Our business is currently highly concentrated on our flagship product, Glassia, and our largest geographic region, the United States. Any adverse market event with respect to such product or the United States would have a material adverse effect on our business.

We rely heavily upon the sales of our AAT intravenous product, Glassia. Revenue from our intravenous AAT products for the treatment of AATD comprised approximately 60%, 64% and 56% of our total revenues for the years ended December 31, 2018, 2017 and 2016, respectively. If Glassia 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 Glassia were to become the subject of litigation and/or an adverse governmental ruling requiring us to cease the manufacturing, export or sales of Glassia, our business would be adversely affected.

In addition, we have a partnership arrangement with Takeda, pursuant to which Takeda is the sole distributor of Glassia in the United States, Canada, Australia and New Zealand. The partnership agreement was originally executed in 2010 with Baxter International Inc. (“Baxter”). During 2015, Baxter assigned all its rights under the partnership agreement to Baxalta US Inc. (“Baxalta”), an independent public company which spun-off from Baxter. In 2016, Shire completed its acquisition of Baxalta, and as a result, all of Baxalta’s rights under the partnership agreement were assigned to Shire. In January 2019, Takeda completed its acquisition of Shire. Revenue derived from our partnership with Takeda, which consists of sales of Glassia, milestone revenue and technology transfer services accounted for approximately 56%, 59% and 52% of our total revenues in the years ended December 31, 2018, 2017 and 2016, respectively. Additionally, we depend upon Takeda for the supply of fraction IV plasma for our production of Glassia to be sold in the United States. If our relationship with Takeda were to deteriorate, our business would be adversely affected. See “—In our Proprietary Products segment, we currently rely on Takeda, which accounts for a significant portion of our total sales, and any disruption to our relationships with Takeda would have an adverse effect on our results of operations and profitability.”

We also rely heavily on sales in the United States, which comprised approximately 66%, 59% and 52% of our total revenues for the years ended December 31, 2018, 2017 and 2016, respectively. If our U.S. sales were significantly impacted by material changes to government or private payor reimbursement, other regulatory developments, competition or other factors, then our business would be adversely affected.

In our Proprietary Products segment, we currently rely on Takeda, which accounts for a significant portion of our total sales, and any disruption to our relationships with Takeda would have an adverse effect on our results of operations and profitability.

Pursuant to our partnership arrangement with Takeda, Takeda is the sole distributor of Glassia in the United States, Canada, Australia and New Zealand. Sales to Takeda accounted for approximately 56%, 59% and 52% of our total revenues in the years ended December 31, 2018, 2017 and 2016, respectively. We also depend upon Takeda for the supply of fraction IV plasma for our production of Glassia to be sold in the United States. 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 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 fail to maintain our relationship with Takeda, we could face significant costs in finding a replacement distributor for the markets Takeda serves for Glassia and a replacement supplier of fraction IV plasma for Glassia. Delays in establishing a relationship with a new distributor and supplier could lead to a decrease in our sales and a deterioration in our market share compared to one or more of our competitors. Any of the foregoing developments could have an adverse effect upon our sales, margins and profitability.

Currently, revenue derived from our relationship with Takeda consists of sales of Glassia. Pursuant to the Exclusive Manufacturing, Supply and Distribution Agreement, as amended, after 2020, Takeda has no obligation to purchase a minimum amount of Glassia. Additionally, we estimate that Takeda will begin selling Glassia produced in its own manufacturing facility as early as 2021, and pay us royalties. As Takeda transitions to producing Glassia in its own facilities, we will incur substantial reduction in revenues (as well as costs of goods sold), driven by the reduction in Glassia manufacturing. While we will receive royalty payments from Takeda based on its Glassia sales until 2040, and we may be able to partially offset the decrease in revenues by expanding sales of other products and in other territories, our revenues will decrease and our operating results may be materially and adversely impacted if we are unable to reduce fixed costs relating to our manufacturing facility in line with any reduction in demand.

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 clinical development and marketing in the United States of KEDRAB, Kedrion is the sole distributor of KEDRAB in the United States. Sales to Kedrion accounted for approximately 10% of our total revenues in the years ended December 31, 2018. As the sales of KEDRAB in the United States become material, we will become dependent on Kedrion for its marketing and sales of KEDRAB in the United States.

We also depend upon a subsidiary of Kedrion for the supply of the hyper-immune plasma which is used for the production of KEDRAB to be sold in the United States. 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 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 fail to maintain our relationship with Kedrion, we could face significant costs in finding a replacement distributor for the sales of KEDRAB in the United States and a replacement supplier of the hyper-immune plasma which is used for the production of KEDRAB. Delays in establishing a relationship with a new distributor and supplier could lead to a decrease in our sales and a deterioration in our market share compared to one or more of our competitors. Any of the foregoing developments could have an adverse effect upon our sales, margins and profitability.

Our Proprietary Products segment operates in a highly competitive market.

We compete with well-established drug companies, including two to four large competitors for each of our products in the Proprietary Products segment. These large competitors include CSL Behring Ltd. ("CSL"), Takeda, and Grifols S.A. ("Grifols"), which acquired a competitor, Talecris Biotherapeutics, Inc. ("Talecris"), in 2011, and Kedrion. 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 for longer periods a deliberate substantial reduction in the price of their products or services. Some of them also have an additional advantage regarding the availability of raw materials, as they own companies that collect plasma and/or plants which fractionate plasma.

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. For example, we believe that our two main competitors in the AAT market are Grifols and CSL. 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. 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's intravenous AAT product is mainly sold in the United States. In 2015, CSL's intravenous AAT product was granted centralized marketing authorization in Europe and CSL launched the product in a few European countries during 2016. There is another, smaller local producer in the French market, LFB S.A. In addition, we estimate that each of Grifols and CSL owns approximately 150 operating plasma collection centers located across the United States.

Similarly, if a new AAT formulation or a new route of administration with a significantly improved characteristics is adopted (including, for example, aerosol inhalation), 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 or products that could be substitutions for AAT products, such as gene therapy. For example, Grifols has completed a limited clinical trial for the development of an inhaled formulation of AAT for the indication of cystic fibrosis. While we believe that 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

In addition, our plasma-derived protein therapeutics face, or may face in the future, competition from existing non-plasma products and other courses of treatments. New treatments, such as gene therapy, small molecules, monoclonal or recombinant products, may also be developed for indications for which our products are now used. We do not currently sell any propriety recombinant products. We have begun developing recombinant version of AAT, but we cannot be certain that such product will ever be approved or commercialized. See "Item 4. Information on the Company — Our Product Pipeline and Development Program — Recombinant AAT." The main advantage of recombinant AAT is its potentially wider availability, and ease of large scale manufacturing. As a result, our product offerings may remain plasma-derived, even if our competitors offer competing recombinant or other non-plasma products or treatments.

Our products involve biological intermediates that are susceptible to contamination, which could adversely affect our operating results.

Plasma and its derivatives, such as fraction IV, 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.

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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 protein 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 to write off small amounts of work-in-process inventories 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 materially in excess of 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. 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 protein therapeutics depends on our continued adherence to current Good Manufacturing Practice regulations.

The manufacturing processes for our products are governed by detailed written procedures and regulations that set forth current Good Manufacturing Practice standards (“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 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.

Our adherence to cGMP regulations and the effectiveness of our quality control systems are periodically assessed through inspections of our manufacturing facility in Beit Kama, Israel by the FDA, the Israeli Ministry of Health (“IMOH”) and regulatory authorities of other countries. Such inspections could result in deficiency citations, which would require us to take action to correct those deficiencies to the satisfaction of the applicable regulatory authorities. If serious deficiencies are noted or if we 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 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.

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 a number of our plasma-derived protein 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 a number of 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 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, we rely to a large extent on Takeda for purposes of most of our regulatory compliance for Glassia and product development and approvals in the United States relating to Glassia. Any failure by Takeda to properly advise us regarding, or properly perform tasks related to, regulatory compliance requirements, could adversely affect us. If

our relationship with Takeda terminated for any reason, we may be unable to maintain regulatory compliance on a cost-effective basis, if at all. Any of these actions could cause direct liabilities, a loss in our ability to market Glassia, or a loss of customer confidence in us or Glassia, 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 production, handling, and distributions of Glassia. 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 products, such as Kedrion in the United States, for purposes of our 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 us.

Any changes in our production processes for our products must be approved by the 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.

In addition, changes in the regulation of our activities, such as increased regulation affecting 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.

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 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 products that generate the majority of our revenues depend on our access to U.S. or European source plasma or its derivative, fraction IV. Our plasma and fraction IV are purchased from third-party licensed suppliers, which are also responsible for the fractionation process, pursuant to multiple purchase agreements. We have entered into a number of plasma supply agreements with various third parties in the United States and Europe, some of which are also strategic partners in the distribution of our proprietary products. 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 approved by 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 licensed and approved by the relevant regulatory authorities, such as the FDA or the EMA. When a new plasma collection center is opened, and on an ongoing basis after its licensure, 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 licensed or lead to the suspension or revocation of an existing license. If we or 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 approved by the FDA, the EMA 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.

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, or 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."

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 raise 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 produce their own source plasma or plasma derivatives, and therefore their products' prices would not be impacted by such prices raise, 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.

We have been required to conduct post-approval clinical trials of Glassia and KedARAB as a condition 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 IV clinical trials. For example, the FDA has required that we conduct Phase IV clinical trials of Glassia, which began in 2015, and for KEDRAB, which began in 2017. Such Phase IV 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. Other products we develop may face similar requirements, which would require additional resources and which may not be successful. We may also receive approval, which is conditional 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 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 Bio Products Laboratories Ltd. ("BPL") and Biotest A.G., which are sold in our Distribution segment, together represented approximately 17% , 17% and 24% of our total revenues for the years ended December 31, 2018, 2017 and 2016, 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 include, among other things, industry or customer demands in excess of machine capacity, labor shortages and changes in raw material flows. 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.

Additionally, if our relationship with either 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 compared to one or more of our competitors.

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.

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 sick funds, 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 health maintenance organizations 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.

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

There can be no assurance that our current ongoing discussions with the FDA regarding the continued development of our Inhaled AAT for AATD product candidate will materialize and result in FDA allowing our pivotal clinical study to proceed under an IND.

We completed a Phase II clinical trial of our Inhaled AAT for AATD in the United States, which met its primary endpoint. However, when we presented the data from the European Phase II/III study to the FDA in April 2016, the FDA expressed concerns and questions about that data, primarily related to the safety and efficacy of Inhaled AAT for the treatment of AATD and the risk/benefit balance to patients based on that data. The FDA's questions and concerns need to be resolved before the agency will allow us to proceed with additional clinical development of Inhaled AAT in the United States. See also "—We may not be able to commercialize our product candidates in development for numerous reasons." In order to address the FDA's concerns and questions, in April 2017, we submitted to the agency the results of the U.S. Phase II data together with a proposed Phase III synopsis. The FDA then provided us with guidance for further development of the synopsis and requested that we submit a complete proposed study protocol for the next phase prior to enabling us to continue clinical development and initiate the Phase III study in the United States. In July 2017, we submitted a full study protocol, and in August 2017, in response to the study protocol and previous submission, the FDA issued a letter stating that it continues to have concerns and questions about the safety and efficacy of the Inhaled AAT for AATD. We provided the FDA with data and information related to their concerns and in April 2018, the FDA issued a response letter providing further guidance regarding the proposed pivotal Phase III protocol, as well as additional questions focused on the Inhaled AAT product characteristics. This correspondence indicated that, while several issues had been addressed, the FDA has continued concerns and questions related to the safety profile of Inhaled AAT for AATD. Following a thorough assessment of the FDA response, we provided the

requested information and data and implemented the proposed changes in the study protocol during the second half of 2018. We will need to receive authorization from the FDA in order to proceed with the clinical development of Inhaled AAT in the United States, including our proposed Phase III clinical trial. However, the FDA may decide that the risk/benefit balance to patients based on the comprehensive data we have submitted does not ease the FDA's concerns and accordingly, the FDA will not approve the IND for our planned Phase III study in the United States of our Inhaled AAT for AATD product candidate.

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

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 II/III clinical trial in Europe for Inhaled AAT for AATD did not meet its primary or secondary endpoints and we subsequently withdrew the MAA in Europe for our Inhaled AAT for AATD.

We have experienced other 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 that:

- 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, 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;
- 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;

- 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 products 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 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. For example, in the past, we have experienced delays in the commencement of clinical trials, such as a delay in patient enrollment for our clinical trials in Europe for Inhaled AAT for AATD and a delay in receiving approval for the commencement of Phase II trials in the United States for Inhaled AAT for AATD until further preclinical testing results were submitted. Furthermore, we will need to address the questions and concerns that the FDA expressed relating to the data from the European Phase II/III study, primarily related to the safety and efficacy and the risk/benefit balance to patients based on that data, before the FDA will allow us to proceed with additional clinical development of Inhaled AAT in the United States, including our planned Phase III pivotal study.

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 particular, new indications for our AAT products that are entering into Phase I and II clinical trials may be found not to be safe and/or efficacious when studied further in Phase III 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 II trials, does not ensure that later clinical trials will be successful. Initial results from Phase I and II clinical trials also may not be confirmed by later analysis or subsequent larger clinical trials. A number of companies in the pharmaceutical industry, including us, have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier clinical trials.

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 contract research organizations, 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 products 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.

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 operate in highly innovative businesses. We currently rely on sales of Glassia for the treatment of AATD for a significant portion of our total revenues. However, our continued growth depends in large part 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 EMA or the FDA, 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." We have experienced delays at various stages of obtaining regulatory approval in the past, and failure to obtain regulatory approval of the Inhaled AAT for AATD product or of any of our other product candidates or additional indications in a timely manner or at all would materially adversely impact our business prospects. For example, the Phase II/III clinical trial in Europe for Inhaled AAT for AATD did not meet its primary or other pre-defined endpoints and, following our discussions with the EMA in regards to the study results, in June 2017, we withdrew the MAA in Europe for our Inhaled AAT for AATD. When we presented the data from the European Phase II/III study to the FDA, the agency expressed concerns and questions about that data, primarily related to the safety and efficacy of our Inhaled AAT for the treatment of AATD and the risk/benefit balance to patients based on that data. The FDA's questions and concerns will need to be resolved before the FDA will allow us to proceed with additional clinical development of Inhaled AAT in the United States, including our planned Phase III pivotal study. See also "—We may not be able to commercialize our product candidates in development for numerous reasons."

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.

Research and development efforts invested in our pipeline of specialty and other products may not achieve 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 and clinical testing, but also highly complex, lengthy and expensive regulatory approval processes, 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: 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 IV AAT (Glassia) for the treatment of T1D, GvHD, lung transplantation rejection, organ preservation and recombinant AAT 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 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, 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.

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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 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. In such cases, then with limited exception, 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.

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.

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 commercialization of any inhaled formulation of AAT, including our second generation AATD product, 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 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.

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, 2018, we may incur losses in the future and thus may never achieve sustained profitability.

As of December 31, 2018, our cash and cash equivalents and short-term investments were $50.6 million. Since inception, we have incurred significant operating losses. Our net profit was $22.3 million and $6.9 million for the years ended December 31, 2018 and 2017, respectively, while for the year ended December 31, 2016 we incurred net losses of $6.7 million. As of December 31, 2018, we had an accumulated deficit of $83.0 million. There can be no assurance that we could continue to generate profitability in future years.

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.

In order to obtain FDA, EMA and other regulatory approvals for product candidates and new indications for existing products, we may be required to enhance the facilities in which 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 future 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. A failure to fund these activities may harm our growth strategy, competitive position, quality compliance and financial condition.

In addition, 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 future 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, 2018, we had cash and short-term investments of approximately $50.6 million, compared to cash and short-term investments of approximately $43.0 million as of December 31, 2017. 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 collaborating agreements), sales of ordinary shares (including our 2005 initial public offering and listing on the Tel Aviv Stock Exchange, our 2013 initial public offering in the United States and listing on Nasdaq and our 2017 underwritten public offering), and the issuance of convertible debentures, our ordinary shares and warrants to purchase our ordinary shares. 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 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.

Raising additional capital would cause dilution to our existing shareholders, and raising debt or funds through collaborations or strategic alliances and licensing arrangements may restrict our operations or require us to relinquish rights.

We have filed a registration statement on Form F-3 with the U.S. Securities and Exchange Commission ("SEC") utilizing a "shelf" registration process, and such shelf registration statement was declared effective on July 13, 2017. Under this shelf registration process, we may offer from time to time up to an aggregate of $100,000,000 of our ordinary shares in one or more offerings. Pursuant to such shelf registration statement, in August 2017, we issued an aggregate of 3,833,334 ordinary shares in an underwritten public offering (including the exercise of the over-allotment option). To the extent that we raise additional funds 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, and the terms may include liquidation or other preferences that adversely affect your rights as a shareholder. 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. The shelf registration statement will remain effective until July 2020. If we do not file a new shelf registration statement prior to July 2020, the existing shelf registration statement will expire and we will not be able to publicly raise capital or issue debt until a new registration statement is filed and becomes effective. There can be no assurance that we will be eligible to file an automatically effective shelf registration statement at a future date when we may need to raise funds publicly.

Risks Related to Our Business and Industry

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 plasma-derived therapeutic protein 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 plasma-derived protein therapeutics 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 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 effected, 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.

Regulatory approval for our products is limited by the FDA 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.

Any regulatory approval of our products is limited to those specific diseases and indications for which our products have been deemed safe and effective by the FDA 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 protein 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 any off-label (i.e., unapproved) uses and departures from the approved administration directions become pervasive and produce results such as reduced efficacy or other adverse effects, the reputation of our products in the marketplace may suffer. In addition, off-label uses may cause a decline in our revenues or potential revenues, to the extent that there is a difference between the prices of our product for different indications.

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 or other regulators. Although regulatory authorities generally do not regulate the behavior of physicians, they do restrict communications by companies 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 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, and corrective actions. Other regulatory authorities may impose separately penalties including, but not limited to, fines, disgorgement of money, operating restrictions, or criminal prosecution.

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. 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 or product development and have an adverse effect on our ability to 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, availability of raw materials, changes in taxation, importation limitations, export control restrictions, changes in or violations of applicable laws, including the U.S. Foreign Corrupt Practices Act (“FCPA”), the U.K. Bribery Act of 2010, pricing restrictions, economic and political instability, disputes between countries, 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. 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.

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 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 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

foreign officials. Additionally, pharmaceutical products are usually marketed through government tenders, and the majority of pharmaceutical companies' clients are Health Maintenance Organizations (“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.

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, or global credit markets, obtaining additional or replacement financing may be more difficult and the cost of issuing new debt could be higher than the costs we incur under our current debt. The higher cost of new debt may limit our ability to have cash on hand for working capital, capital expenditures and acquisitions on terms that are acceptable to us.

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 and worldwide, including global and local economic slowdowns, challenges faced banks and the health of markets for the sovereign debt. Many of our largest markets, including the United States and Europe, 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. 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.

If our manufacturing facility in Beit Kama, Israel were to suffer a serious accident, contamination, force majeure event 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 from the Gaza Strip. All of our revenues in our Proprietary Products segment are 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.

Failure to adequately or timely adapt our manufacturing capacity to match changes in demand for our manufactured products and/or continued manufacturing at or close to our plants maximum capacity may have a material adverse effect on our business.

As our product offerings in our Proprietary Products segment is predicted to increase until 2020, until such date we will be required to produce in higher volumes compare to previous years. A failure to increase our manufacturing volume as needed or continued manufacturing at or close to our plants maximum capacity levels 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.

After 2020, Takeda has no obligation to purchase a minimum amount of Glassia, and we estimate that Takeda will begin selling Glassia produced in its own manufacturing facility as early as 2021 and only paying us royalties. As Takeda transitions to producing Glassia in its own facilities, we will incur a substantial reduction in revenues (as well as costs of goods sold) driven by the reduction in Glassia manufacturing. Our revenues will decrease and our operating results may be materially and adversely impacted if we are unable to reduce fixed costs relating to our manufacturing facility in line with any reduction in demand.

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 regulatory authorities in Israel 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.

If our shipping or distribution channels were to become inaccessible due to an accident, act of terrorism, strike or any other force majeure event, our supply, production and distribution processes could be disrupted.

Our plasma raw materials must be transported at a 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 plasma at these temperatures. If any of our shipping or distribution channels become inaccessible because of a serious accident, act of terrorism, strike or any other force majeure event, we may experience disruptions in our continued supply of plasma and other raw materials, delays in our production process or a reduction in our ability to distribute our plasma-derived protein therapeutics to our customers.

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, 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.

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

The healthcare regulatory environment in the U.S. is currently subject to significant uncertainty and the industry may in the future continue to experience fundamental change as a result of regulatory reform. In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the “healthcare reform law”), a sweeping measure intended to expand healthcare coverage within the United States, primarily through the imposition of health insurance mandates on employers and individuals and expansion of the Medicaid program. The healthcare reform law, among other things: (i) addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; (ii) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations; (iii) established annual fees and taxes on manufacturers of certain branded prescription drugs; (iv) expands the availability of lower pricing under the 340B drug pricing program by adding new entities to the program; and (v) established a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable

brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D. On April 1, 2016, final regulations issued by the Centers for Medicare and Medicaid Services to implement the changes to the Medicaid Drug Rebate Program under the healthcare reform law became effective. In addition, the new law established an abbreviated licensure pathway for products that are drugs made by a living organism or derived from a living organism, commonly referred to as biosimilars, to become FDA-approved biological products, with provisions covering exclusivity periods and a specific reimbursement methodology for biosimilars.

However, some provisions of the healthcare reform law have yet to be fully implemented, and President Donald Trump has vowed to repeal the healthcare reform law. On January 20, 2017, President Trump signed an executive order stating that the administration intended to seek prompt repeal of the healthcare reform law, and, pending repeal, directed the U.S. Department of Health and Human Services and other executive departments and agencies to take all steps necessary to limit any fiscal or regulatory burdens of the healthcare reform law. On October 12, 2017, President Trump signed another executive order directing certain federal agencies to propose regulations or guidelines to permit small businesses to form association health plans, expand the availability of short-term, limited duration insurance, and expand the use of health reimbursement arrangements, which may circumvent some of the requirements for health insurance mandated by the healthcare reform law. The U.S. Congress has also made several attempts to repeal or modify the healthcare reform law. In addition, there is ongoing litigation regarding the implementation and constitutionality of the healthcare reform law. While the law is still in effect pending the ultimate resolution of the litigation, the outcome of the litigation is unknown, and cannot be predicted. There is no guarantee whether the healthcare reform law will remain in effect or be repealed or replaced. 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. We cannot predict what other legislation relating to our business or to the health care industry may be enacted, or what effect such legislation may have on our business, prospects, operating results and financial condition.

In addition, federal, state and foreign governmental authorities are likely to continue efforts to control the price of drugs and reduce overall healthcare costs. These efforts could have an adverse impact on our ability to market products and generate revenues in the United States and foreign countries.

Certain of our business practices could become subject to scrutiny by regulatory authorities, as well as to lawsuits brought by private citizens under federal and state laws. Failure to comply with applicable law or an adverse decision in lawsuits may result in adverse consequences to us.

The laws governing our conduct in the United States are enforceable by criminal, civil and administrative penalties. Violations of laws such as the Federal Food, Drug and Cosmetic Act (the “FDCA”), the Federal False Claims Act (the “FCA”), the Public Health Service Act (the “PHS Act”), the Physician Payments Sunshine Act or a provision of the U.S. Social Security Act known as the “Anti-Kickback Law,” 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 Anti-Kickback Law, 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; therefore, our arrangements with 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 and reported in accordance with the Physician Payments Sunshine Act to avoid any possibility of wrongfully influencing healthcare providers to prescribe or purchase particular products or as a reward for past prescribing. 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 $22,363 per claim. Through the Physician Payments Sunshine Act, the healthcare reform law 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 U.S. physicians and 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. On the other hand, as President Trump has vowed to repeal the healthcare reform law, it is uncertain whether such data collection obligations would be repealed or replaced with new regulations. 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.

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.

To enhance compliance with applicable health care laws, and mitigate potential liability in the event of noncompliance, regulatory authorities, such as the Department of Health and Human Services' Office of Inspector General ("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 not adopted U.S. healthcare compliance and ethics programs that generally incorporate the HHS OIG's recommendations. Even if we do, having such a program can be no assurance that we will avoid any compliance issues.

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 plasma-derived protein therapeutics, are subject to price controls. In the United States, where pricing 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 is often not 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, 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.

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 the new IFRS 15 on revenue from contracts with customers that we adopted in 2018) 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.

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. 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 relevant product 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 new distribution agreements with foreign pharmaceutical manufacturers and may need to amend previously executed agreements or seek a specific exemption from the Israeli Competition Authority for such arrangements, and we may not be successful in negotiating such new agreements or amending such agreements or receiving such exemptions.

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 new collective bargaining agreement with the employees' committee and the Histadrut, which will expire in December 2021. We have experienced labor disputes and work stoppages in the past and in July 2018, during the course of our negotiations with the Histadrut and the employees' committee on the extension of the initial collective bargaining agreement beyond the December 2017 expiration, the employee's committee commenced a labor strike, which continued for approximately one month. As a result of the labor strike, in the year ended December 31, 2018, we had a $1.8 million write-off of indirect manufacturing costs and $0.8 million of process materials scraps. Any future disputes with the 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.

Tax legislation in the United States may impact our business.

On December 22, 2017, the U.S. President signed into law federal tax legislation commonly referred to as the Tax Cuts and Jobs Act. The Tax Cuts and Jobs Act provides for significant and wide-ranging changes to the U.S. Internal Revenue Code. The reforms are complex, and it will take some time to assess the implications thoroughly. While we are not currently a U.S. tax filer there can be no assurance that these tax reforms will not give rise to significant consequences, both immediately and going forward in terms of the our taxation expense. The Tax Cuts and Jobs Act could be subject to potential amendments and technical corrections, any of which could lessen or increase adverse impacts of the law.

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 develop in the future will not, in and of themselves, be patentable. Since many of our patents relate to processes or uses thereof , 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 secured 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 published 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 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 in the United States and many other jurisdictions are typically not published until 18 months after their filing, if at all, 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 make the inventions claimed in our or their issued patents or pending patent applications, or 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. For example, if a third party has also filed a patent application covering an invention similar to one covered in one of our patent applications, we may be required to participate in an adversarial proceeding, known as an “interference proceeding,” declared by the U.S. Patent and Trademark Office (“USPTO”) or its foreign counterparts to determine priority of invention. In 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 reduce 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 expire at various dates between 2019 and 2029. 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 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.

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, held to be unenforceable or circumvented.

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 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 areas relating to critical aspects of our business and technology, including the separation and purification of proteins, the composition of AAT and the use of AAT for different indications, 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 or our strategic partners, we or they could be forced to permanently or temporarily stop or delay manufacturing, exportation or sales of the product or product candidate that is the subject of the dispute or suit.

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.

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 being traded in the United States, as well as in Israel, 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 adversely affect out 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 reduce the market's confidence in our financial statements and negatively affect our share price.

Additionally, as of December 31, 2018, we were no longer an "emerging growth company," as defined in the JOBS Act, and are now required to comply with additional disclosure and reporting requirements, including, but not limited to, being required to comply with the auditor attestation requirements of Section 404 of SOX (and the rules and regulations of the SEC thereunder). These additional reporting requirements may increase our legal and financial compliance costs and cause management and other personnel to divert attention from operational and other business matters to devote substantial time to these public company requirements.

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, including pursuant to the registration statement on Form F-3 that we filed in November 2016;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- recalls and/or adverse events associated with our products;
- the expiration of contractual lock-up agreements with our executive officers and directors; 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 equity research analysts issue unfavorable commentary or downgrade our ordinary shares, the price of our ordinary shares could decline.

The trading market for our ordinary shares relies in part on the research and reports that equity research analysts publish about us and our business. The price of our ordinary shares could decline if one or more securities analysts downgrade our ordinary shares or if those analysts issue other unfavorable commentary or cease publishing reports about us or our business.

Future sales of our ordinary shares in the public market could cause our share price to fall.

Sales by us or the shareholders of a substantial number of our ordinary shares in the public market, either on the Tel Aviv Stock Exchange (the "TASE") or Nasdaq, or the perception that these sales might occur, could depress the market

price of our ordinary shares and could impair our ability to raise capital through the sale of additional equity securities. As of December 31, 2018, we had 40,295,078 ordinary shares outstanding.

We have filed a registration statement on Form F-3 with the SEC utilizing a "shelf" registration process, and such shelf registration statement was declared effective on July 13, 2017. Under this shelf registration process, we may offer from time to time up to an aggregate of $100,000,000 of our ordinary shares in one or more offerings. In August 2017, pursuant to such shelf registration statement, we completed an underwritten public offering of an aggregate of 3,833,334 ordinary shares (including the exercise of the over-allotment option) for total gross proceeds of approximately $17.3 million. The shelf registration statement will remain effective until July 2020.

Furthermore, except for shares held by our affiliates as contemplated by Rule 144 under the U.S. Securities Act of 1933, as amended (the "Securities Act"), all of the ordinary shares that are outstanding as of December 31, 2018, as well as the 2,445,597 ordinary shares issuable upon exercise of outstanding options and the 139,706 restricted shares granted to certain managers , are freely tradable in the United States without restrictions or further registration under the Securities Act. Approximately 28% of our outstanding ordinary shares are beneficially owned by affiliates. These entities could resell the shares into the public markets in the United States in the future in accordance with the requirements of Rule 144, which include certain limitations on volume.

The significant share ownership positions of Leon Recanati, the current Chairman of our board of directors, and the Hahn family may limit our shareholders' ability to influence corporate matters.

Leon Recanati, the Chairman of our board of directors, and the Hahn family (including Jonathan Hahn, a member of our board of directors), owned, directly and indirectly, 9.98% and 9.11% of our outstanding ordinary shares, respectively, as of December 31, 2018. Accordingly, if Leon Recanati and the Hahn family vote the shares that they own or control together, they will be able to significantly influence the outcome of matters required to be submitted to our shareholders for approval, including decisions relating to the election of our board of directors and the outcome of any proposed 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. 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.

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 by individuals who are U.S. Holders (as defined in "Item 10. Additional Information — E. Taxation — United States Federal Income Taxation"), 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 will not be required to report equity holdings under Section 16 of the Exchange Act and will not be 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 SEC and 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 SEC and 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."

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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

Conditions in Israel could adversely affect our business.

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 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. During July and August 2014, Israel engaged in an armed conflict with Hamas in the Gaza Strip, resulting in thousands of rockets being fired from the Gaza Strip and missile strikes against civilian targets in various parts of Israel, which disrupted most day-to-day civilian activity, particularly in southern Israel, the location of our manufacturing facility. In the event that our facilities 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.

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.

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

As of December 31, 2018, we had 408 employees, all of whom were based in Israel. Certain of our 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 response to increased tension and hostilities, there have been since September 2000 occasional call-ups of military reservists, including in connection with the conflicts with Hamas in July and August 2014, and it is possible that there will be additional call-ups in the future. 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 that are 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.

The tax benefits that are 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.

One of our Israeli facilities was granted "Approved Enterprise" status by the Investment Center of the Ministry of Economy and Industry (formerly named the Ministry of Industry, Trade and Labor) of the State of Israel (the "Investment Center"), under the Israeli Law for the Encouragement of Capital Investments, 1959 (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 will apply 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 have 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 is also eligible for tax benefits as a "Privileged Enterprise," which will 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 are scheduled to expire at the end of 2020 and 2023.

In order to remain eligible for the tax benefits of a Privileged Enterprise, 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 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. For example, while we do not expect that the transfer of manufacturing of Glassia to Takeda, or the grant to Takeda of the right to use our technology for such manufacturing, would result in the reduction or loss of these tax benefits, according to the tax ruling that we obtained, we may lose those benefits if it is determined that we do not comply with the conditions set forth in the tax ruling. 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 was 26.5% for 2014 and 2015, it decreased to 25% in 2016 and 24% in 2017, and further decreased to 23% in 2018 and thereafter. 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 corporate tax rate applicable to our Approved/Privileged Enterprise's income, 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 to our Privileged Enterprise's income 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."

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. Most of our directors and executives 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.

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 shareholders 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 whose country of residence does not have a tax treaty with Israel granting tax relief to such shareholders from Israeli tax. 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. See "Item 10. Additional Information — B. Memorandum and Articles of Association — Acquisitions Under Israeli Law."

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.

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 plasma-derived protein therapeutics company focused on orphan indications, with an existing marketed product portfolio and a late-stage product pipeline. Our proprietary products are produced using our advanced proprietary technologies and know-how for the separation and purification of proteins derived from human plasma. We develop and produce our plasma-derived protein therapeutics in our advanced cGMP compliant, FDA-approved production facility located in Beit Kama, Israel. We use our proprietary platform technology and know-how for the extraction and purification of proteins from human plasma to produce AAT in a high purity, liquid form, as well as other plasma-derived proteins. AAT is a protein derived from human plasma with known and newly discovered therapeutic roles given its immuno-modulatory, anti-inflammatory, tissue protective and antimicrobial properties.

During 2017, we established a Strategy Committee of the board of directors, which, with the assistance of an external consulting firm, performed a strategic review of our business. Based on that analysis, we decided to focus our resources in the AATD field, as we believe we have developed extensive commercial, scientific, manufacturing, clinical and regulatory experience (based on multiple clinical trials we performed in the United States and Europe) in that field. Accordingly, we aim to become the leading innovator in this field by developing different therapeutic approaches to AATD independently, or through collaborations with strategic partners. In addition, we focus on increasing sales and profitability through commercial growth of AAT and specific IgGs, focusing on key strategic markets. Lastly , we decided that the development of AAT for indications other than AATD, such as GvHD, Type 1 Diabetes (T1D), lung transplantation rejection and/or the development of new immunoglobulins (IgG) will be performed through strategic collaborations. For that purpose, we are investing in the additional indications/and products, primarily to the point of developing sufficient data, to enable us to attract such strategic partners.

We operate in two segments: the Proprietary Products segment, in which we develop and manufacture plasma-derived therapeutics and have a product line consisting of six pharmaceutical products that we market in more than 15 countries; and the Distribution segment, in which we leverage our expertise and presence in the Israeli market by distributing drugs manufactured by third-parties for use in Israel.

We derived approximately 66%, 59% and 52% of our total revenues in the years ended December 31, 2018, 2017 and 2016, respectively, from sales in the United States, approximately 3%, 5% and 5% of our total revenues in the years ended December 31, 2018, 2017 and 2016, respectively, from sales in Europe, approximately 3%, 5% and 4% of our

total revenues in the years ended December 31, 2018, 2017 and 2016, respectively, from sales in Asia (excluding Israel), approximately 3%, 5% and 5% of our total revenues in the years ended December 31, 2018, 2017 and 2016, respectively, from sales in Latin America and approximately 25%, 26% and 33% of our total revenues in the years ended December 31, 2018, 2017 and 2016, respectively, from sales in Israel.

Our flagship product, Glassia, was the first liquid, ready-to-use, intravenous plasma-derived AAT product approved by the FDA (Glassia is also approved for self-administration). Glassia is an intravenous AAT product that is indicated for chronic augmentation and maintenance therapy in adults with emphysema due to 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. We market Glassia through a strategic partnership with Takeda in the United States, under which the minimum aggregate revenue for Glassia for the years 2019 to 2020 is expected to reach approximately $120 million and may be expanded to $150 million during that period. Pursuant to the Exclusive Manufacturing, Supply and Distribution Agreement, as amended, after 2020, Takeda currently has no obligation to purchase a minimum amount of Glassia. We estimate that Takeda will begin selling Glassia produced in its own manufacturing facility as early as 2021, and pay us royalties based on their sales. As Takeda transitions to producing Glassia in its own facilities, we will incur a substantial reduction in revenues (as well as costs of goods sold) driven by the reduction in Glassia manufacturing, and our revenues and our operating results may be materially and adversely impacted if we are unable to reduce fixed costs relating to our manufacturing facility in line with any reduction in demand. Selling Glassia by Takeda, produced in its own manufacturing facility, may have a negative impact on our financial performance, as despite of the fact that we will be entitled to receive royalties from Takeda, our topline revenues will be substantial reduced. We also market Glassia in other counties through local distributors.

Our second leading product is KamRAB, a prophylactic treatment against rabies infection that is administered to patients after exposure to an animal suspected of being infected with rabies. KamRAB is a protein therapeutic derived from hyper-immune plasma, which is 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. 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, and in August 2017 we received FDA approval for anti-rabies immunoglobulin as a post-exposure prophylaxis against rabies infection. In April 2018, we launched KamRAB in the United States, under the trademark “KEDRAB.” In addition, in November 2017, we signed a supply agreement for marketing of KamRAB with an undisclosed international organization. The agreement extends through 2020 and it may generate total revenues through 2020 for our company in the total amount of approximately $13 million.

In addition to our commercial operation, we invest in research and development of new product candidates and new indication for existing products activities. Our lead product candidate is Inhaled AAT for AATD. We believe that this second generation AAT product is currently the only aerosolized AATD treatment in advanced stages of clinical development. We believe 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. In addition, because Inhaled AAT for AATD would be delivered directly to the affected tissue through a nebulizer using a lower AAT dosage, 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 therefore increase our profitability.

We completed a pivotal Phase II/III clinical trial for Inhaled AAT for AATD in Europe and filed the Marketing Authorization Application (“MAA”) with the EMA in March 2016. The Phase II/III clinical trial in Europe, however, did not meet its primary or other pre-defined endpoints. Following our discussions with the EMA in regards to the study results, in July 2017, we withdrew the MMA in Europe for our Inhaled AAT for AATD, which relied on this single pivotal clinical trial. 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.

In the United States, we completed a Phase II clinical trial of our Inhaled AAT for AATD, which met its primary endpoint. However, when we presented the data from the European Phase II/III study to the FDA in April 2016, the FDA expressed concerns and questions about that data, primarily related to the safety and efficacy of Inhaled AAT for the treatment of AATD and the risk/benefit balance to patients based on that data. We understood that the FDA's questions and concerns need to be resolved before the agency would allow us to proceed with additional clinical development of Inhaled AAT in the United States. In order to address the FDA's concerns and questions, in April 2017, we submitted to the agency the results of the U.S. Phase II data together with a proposed Phase III synopsis. The FDA then provided us in June 2017 with guidance for further development of the synopsis and requested that we submit a complete proposed study protocol for the next phase prior to enabling us to continue clinical development and initiate the Phase III study in the United States. In July 2017, we submitted a full study protocol, and in August 2017, in response to the study protocol and previous submission, the FDA issued a letter stating that it continues to have concerns and questions about the safety and efficacy of the Inhaled AAT. We have provided the FDA with data and information related to their concerns and in April 2018, the FDA issued a response letter providing further guidance regarding the proposed pivotal Phase III protocol, as well as additional questions focused on the Inhaled AAT product characteristics. This correspondence indicated that, while several issues had been addressed, the FDA has continued concerns and questions related to the safety profile of Inhaled AAT for AATD. Following a thorough assessment of the FDA response, we provided the requested information and data and implemented the proposed changes in the study protocol during the second half of 2018. We will need to receive authorization from the FDA in order to proceed with the clinical development of Inhaled AAT in the United States, including our proposed Phase III clinical trial.

In July 2018, we received positive scientific advice from the Committee for Medicinal Products for Human Use ("CHMP") of the EMA related to the development plan for our proposed pivotal Phase III study for our Inhaled AAT for AATD. We requested scientific advice (protocol assistance) from the CHMP following the results of the previous Phase II/III (EU) and Phase II (US) studies conducted by us with respect to a proposed subsequent Phase III study design. The CHMP notified us that it concurred with the overall design of the proposed study, including its objectives, patient population, proposed endpoints and their clinical importance, and the safety monitoring plan. The CHMP had some minor comments, which we intend to address in the final study protocol. Following, and subject to receiving IND approval for such trial from the FDA, we plan to initiate an additional pivotal Phase III clinical trial in the United States and Europe, and submit a BLA in the USA and resubmit the MAA in Europe after such clinical trial is successfully completed, with the data to be collected in such clinical trial. We may seek to attract partners in this development program. See "—Our Product Pipeline and Development Program—Inhaled Formulations of AAT—AATD" and "Risk Factors— Risk Related to Development, Regulatory Approval and Commercialization of Product Candidates."

In the past, we have also completed Phase II clinical studies in Israel for additional novel indications, using formulations of AAT through Inhalation for cystic fibrosis in 2008 and bronchiectasis in 2009. At present, the development of cystic fibrosis and bronchiectasis products is suspended as we prioritize other products.

We also test our liquid, intravenous plasma-derived AAT product for other indications utilizing AATs known and newly-discovered therapeutic roles given its immunomodulatory, anti-inflammatory, tissue-protective and antimicrobial properties:

- Acute Graft versus Host Disease (aGvHD) - In November 2016, we initiated a Phase II/III clinical trial for the treatment of aGvHD in collaboration with Shire (now part of Takeda) in the United States. In June 2017, Shire informed us of its decision not to continue with the study. As the result of this decision, the study was halted. In January 2018, we announced a collaboration with a consortium of prominent hospitals led by Mount Sinai Hospital and initiated an investigator initiated Phase II clinical study to evaluate our AAT product for preemption of steroid refractory aGvHD (SR-aGvHD) utilizing a novel blood biomarker developed algorithm that may identify patients at high risk of developing SR-aGvHD and non-relapse mortality. .

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Lung Transplantation Rejection - We have also initiated a Phase II clinical study with our intravenous AAT product to prevent lung transplantation rejection, and in January 2018, we announced interim results from this study, which showed that our intravenous AAT demonstrated favorable safety and tolerability profile in 10 patients during first six months of treatment, consistent with previously observed results in other indications. In February 2019, we announced additional interim results from such study suggesting improvement in multiple key clinical outcomes. We also announced that top-line results are anticipated in the second half of 2019.

- Type 1 Diabetes (T1D) - In November 2017, we reported the top-line results from the Phase II clinical study conducted in Israel for the indication of newly diagnosed T1D patients. While in the overall study population no significant treatment effect was observed, in the pre-determined subgroup of patients between the ages of 12 and 18 years old, a trend toward better efficacy was demonstrated in the high dose arm of AAT (120 mg/kg) represented in terms of beta-cell function preservation, lower average of total daily insulin usage and a better glycemic control measured by lower average HbA1c. We are currently seeking a strategic partner for collaboration to further product development.

With respect to the development of our AAT product for T1D, GvHD and prevention of lung transplantation rejection, our continued investment would be limited primarily to the point where such further development could generate sufficient data to enable us to attract strategic partner(s) to collaborate in the further development of those programs.

Our Product Portfolio

Our products include plasma-derived protein therapeutics produced in our Proprietary Products segment or licensed products, majority of which are plasma-derived marketed and sold in our Distribution segment in Israel.

Proprietary Products Segment

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

We currently have products that target four product categories: respiratory, immunoglobulins, critical care and other. Our flagship product in the Proprietary Products segment is Glassia, sales of which, for the years ended December 31, 2018, 2017 and 2016, accounted for approximately 75%, 83% and 77% of our total revenues, in the Proprietary Products segment, respectively. Revenue from our intravenous AATD products comprised approximately 60%, 64% and 56% of our total revenues for the years ended December 31, 2018, 2017 and 2016, respectively. During 2018, we launched in the U.S. KEDRAB, our prophylactic treatment against rabies infection, sales of which, for the year ended December 31, 2018, accounted for approximately 13% and 10% of our revenues, in the Proprietary Products segment, and of our total revenues, respectively. Sales of KamRAB and KamRho (D) for the years ended December 31, 2018, 2017 and 2016 accounted for the substantial balance of total revenues in the Proprietary Products segment.

Product	Indication	Active Ingredient	Geography
Respiratory			
Glassia (or Ventia/Respikam in certain countries)	Intravenous AATD	Alpha-1 Antitrypsin (Human)	United States, Israel, Russia, Brazil, Argentina, Uruguay, South Africa, Colombia**
Immunoglobulins			
KamRAB/KEDRAB	Prophylaxis of rabies disease	Anti-rabies immunoglobulin (Human)	United States, Israel, India, Thailand, El Salvador*, South Africa, Bosnia, Afghanistan, Russia*, Mexico*, Georgia*, Ukraine**, Turkey, South Korea and Canada*
KamRho (D) IM	Prophylaxis of hemolytic disease of newborns	Rho(D) immunoglobulin (Human)	Israel, Brazil, India, Argentina, Paraguay, Chile*, Russia, Nigeria, Sri Lanka*, Thailand** and the Palestinian Authority
KamRho (D) IV	Treatment of immune thermobocytopunic purpura	Rho(D) immunoglobulin (Human)	Israel, India*, Sri Lanka* and Argentina*

Snake bite antiserum	Treatment of snake bites by the Vipera palaestinae and the Echis coloratus	Anti-snake venom	Israel*
Other Products			
Human transferrin (diagnostical grade)	Not for human use	Transferrin	United States, Israel, and France

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*We have regulatory approval, but did not market the product in this country in 2018.

** Product was registered, but we have not yet started sales.

Respiratory — 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. 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.

In the United States and Europe, we believe that AATD is currently significantly under-diagnosed and under-treated, as we estimate that only approximately 8% and 2.5-3% of all potential cases of AATD are treated in the United States and Europe, respectively, with an aggregate of up to an estimated 180,000 to 190,000 patients suffering from AATD, of which less than 10% have been diagnosed. According to the Centers for Medicare and Medicaid Services published payment allowance limits for Medicare part B, the average sale price, as of January 2019, of 10 mg of Glassia is $4.696, resulting in an annual cost of between $80,000 and $100,000 per AATD patient. In the United States, in some of the European countries and in Israel, we believe that the majority of the cost of treatment is covered by medical insurance programs.

We estimate that the potential world market for AAT products is significantly larger than current consumption indicates. We believe that the primary reasons for this are the non-availability of AAT products in many countries, under diagnosis of patients suffering from AATD, expensive and protracted registration processes required to commence sales of AAT products in new markets and the absence of insurance reimbursement in various countries. As AATD can be diagnosed with a simple blood test, we expect diagnosis of AATD to continue to increase going forward as awareness of AAT increases. The rate of AATD treated patients has increased in recent years at an estimated annual rate of 6-8%.

Glassia was the first AAT product in the world approved for use in a high purity liquid state, which is ready for infusion and does not require reconstitution and mixing before injection, 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 to self- infusion at home.

Currently, Glassia has been approved in seven countries. It is sold in five of those countries and also is sold in one additional country, where it has not been approved, on a non-registered named-patient basis. The majority of sales of Glassia are in the United States, where Glassia was approved by the FDA in July 2010 and sales began in September 2010. As part of the approval, the FDA requested that we conduct post-approval Phase IV clinical trials, as is common in the pharmaceutical industry, aimed at collecting additional safety and efficacy data for Glassia. In 2010, we submitted our proposed Phase IV clinical trials to the FDA. Such Phase IV clinical trials began in 2015 and are still ongoing. Pursuant to our agreement with Takeda, the Phase IV clinical trials are financed and managed by Takeda, provided that if the cost of such Phase IV 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.

We market Glassia in the United States through our partnership with Takeda. We market Glassia in Israel by ourselves and in the other countries through our local distributors. Sales to Takeda accounted for approximately 56%, 59% and 52% of our total revenues in the years ended December 31, 2018, 2017 and 2016, respectively. We plan to submit Glassia for marketing approval in additional countries. Revenues from our intravenous AATD products have grown from approximately $0.6 million in 2009 to $68.3 million in 2018, representing 61% compound annual growth rate.

Immunoglobulins

KamRAB

KamRAB is a prophylactic treatment against rabies infection that is administered to patients after exposure to an animal suspected of being infected with rabies. KamRAB is a protein therapeutic derived from hyper-immune plasma, which is 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.

According to the World Health Organization, each year, more than 10 million people worldwide are exposed to potential rabies infection. We believe that there are market opportunities for KamRAB in developing countries, as well as in Canada and Australia. In many developing countries, patients do not receive treatment for suspected rabies due to the lack of availability of healthcare resources. In the United States, there are currently two registered anti-rabies immunoglobulin, with one of them controlling the market share and we believe that healthcare providers would seek to diversify their source of supply with our product as an additional FDA approved high-quality product.

We began selling KamRAB in certain countries in Asia and Latin America in 2003, and subsequently obtained regulatory approvals to market KamRAB in seven additional countries, We currently sell KamRAB in eleven countries, including certain countries where registration is not required.

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 II/III clinical trials. See “— Strategic Partnerships — Kedrion.” . In August 2017, we received marketing approval for KamRAB in the United States (under the trademark “KEDRAB”) and in April 2018, KEDRAB was launched in the United States and initial shipments reached healthcare practitioners across the country.

We believe that receiving the FDA approval for marketing the product will assist us in our efforts to register KamRAB in additional countries where KamRAB is not currently registered, which we believe would lead to additional sales worldwide.

In November 2017, we signed a supply agreement for sales of KamRAB outside of the United States with an undisclosed international organization. The agreement extends through 2020 and is expected to generate additional sales for KamRAB.

In November 2018, we received marketing approval for KamRAB in Canada and we expect to start selling the product in Canada as early as 2020 subject to winning supply tenders.

KamRho (D)

KamRho (D) is indicated for (i) the prevention of hemolytic disease of the newborn ("HDN"), which is a blood disease that occurs where the blood type of the mother is incompatible with the blood type of the fetus; and (ii) the treatment of immune thrombocytopenic purpura ("ITP"), which is thought to be an autoimmune blood disease in which the immune system destroys the blood's platelets, which are necessary for normal blood clotting. KamRho (D) is produced from hyper-immune plasma and is administered through intra-muscular injection (KamRho (D) IM) or through intravenous infusion (KamRho (D) IV).

According to academic research, approximately 15% of Caucasian women are Rh-negative and, if left untreated, HDN would affect one percent of all newborns and would be responsible for the death of one baby out of every 2,200 births. In addition, academic research estimates that ITP affects approximately five out of every 100,000 children per year, and two of every 100,000 adults per year worldwide, although some will recover without treatment. We have completed the registration process for Kam Rho (D) in several countries and sell it in eight countries, including Israel, Latin America, Asia, Africa and Eastern Europe.

Snake Bite Antiserum

Our snake bite antiserum product is used for the treatment of humans that 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 is produced from hyper-immune serum that has been derived from horses that were immunized against Israeli viper and Israeli Echis venom. This product is the only treatment on the market for Vipera palaestinae and Echis coloratus snake bites in Israel.

We developed the snake bite antiserum pursuant to an agreement with the Israeli Ministry of Health (IMOH) entered into in March 2009. We completed construction of the production facilities and laboratories for the product, and successfully passed the IMOH inspections. We began production in August 2011 and commenced sales to the IMOH in 2012. The agreement with the IMOH is automatically renewable for up to ten additional one-year periods until December 31, 2020, unless the IMOH has provided us with a prior notice of non-renewal of the agreement, prior any automatic renewal term.

Other Products

We also sell Transferrin, which is used as a cultural medium for diagnostic assays and cell cultures.

Distribution Segment

Our primary products in the Distribution segment include pharmaceuticals for critical use delivered by injection, infusion or inhalation. We leverage our expertise and presence in the plasma-derived protein therapeutics market to distribute products in Israel that we believe complement our products in the Proprietary Products segment. Currently the majority of the products in our Distribution segment are produced from plasma or plasma-derivatives, and are manufactured by European companies. IVIG is our primary product in the Distribution segment, comprising approximately 58%, 54% and 61% of total revenues in the Distribution segment for the years ended December 31,

2018, 2017 and 2016, respectively. Sales of IVIG accounted for approximately 12%, 12% and 17% of our total revenues for the years ended December 31, 2018, 2017 and 2016, respectively.

The following table sets forth our primary products in our 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
PROVOCHOLINE	Diagnosis of bronchial airway hyperactivity in subjects who do not have clinically apparent asthma	METHACHOLINE CHLORIDE
Immunoglobulins		
IVIG 5%	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	Human hepatitis B immunoglobulin
Hepatect CP	Prevent contraction of Hepatitis B by adults and children older than two years	Hepatitis B immunoglobulin (human)
Megalotect	Contains antibodies that neutralize cytomegalovirus 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 4%	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)
Vaccinations		
IXIARO	Active immunization against Japanese encephalitis in adults, adolescents, children and infants aged 2 months and older	Japanese encephalitis purified inactivated vaccine

Our Product Pipeline and Development Program

We are in various stages of pre-clinical and clinical development of new product candidates for our Proprietary Products segment. The following table sets forth our primary product pipeline in our Proprietary Products segment and each such product's stage of development:

1. Orphan drug designation (US & EU);
2. Orphan drug designation (US only).

Inhaled Formulations of AAT

We are in the process of development of inhaled formulations of AAT administered through the use of a nebulizer. The nebulizer was developed by PARI for several indications in the respiratory field, including the treatment of AATD, cystic fibrosis and bronchiectasis.

AATD

We have been able to leverage our expertise gained from the production of Glassia to develop a stable, high purity Inhaled AAT for AATD, an 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 will significantly improve the patient's disease condition and the quality of life of the patients versus current invasive weekly treatment that requires uncomfortable infusion, consumption of time and administration by a medical professional. If approved, Inhaled AAT for AATD is estimated to be the first AAT product that is not required to be delivered intravenously but, instead is administered by a user-friendly, lightweight and silent nebulizer in up to two short daily sessions. We believe that Inhaled AAT for AATD 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 and reducing medical costs. Because of the smaller amount of AAT product 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 therefore increase our profitability.

The current standard care for AATD in the United States and in certain European countries is intravenous 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 II clinical study demonstrating that administration of inhaled formulations of AAT through inhalation results in greater dispersion of AAT to the target lung tissue including the lower lobes and lung periphery. Accordingly, we believe that an inhaled formulation of AAT would require a significantly lower therapeutic dose and 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. In addition, self-administration by inhalation is more convenient than intravenous infusion and would also reduce the burden on healthcare providers to administer treatments.

Inhaled AAT for AATD has been designated as an orphan drug for the treatment of AATD in the United States and Europe.

A double blind placebo controlled and randomized Phase II/III pivotal trial, under EMA guidance, started in January 2010 and 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 daily dose of Inhaled AAT for AATD or equivalent dose of placebo for 50 consecutive weeks. The primary endpoint for 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 other exacerbation measures, lung function, CT scan 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 one year later. A 20% difference between the two groups was required to prove efficacy and is considered to be clinically meaningful and would allow the decision to prescribe 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.

Results from our double blind part of the trial indicated that the primary endpoint was not met, although a potentially encouraging signal was seen in lung function measurement. We reported in September 2014 the results of the study, stating that the primary endpoint of “time to the first moderate or severe exacerbation event” did not show a statistically significant difference between inhaled formulation of AAT and placebo in the Intent-to-Treat (“ITT”) population and that the study did not show statistically significant differences between inhaled formulation of AAT and placebo in the secondary exacerbation endpoints measured in the ITT population.

Despite not meeting the primary or secondary endpoints for the ITT population, lung function parameters, including Forced Expiratory Volume in One Second (“FEV1”) % of Slow Vital Capacity (“SVC”), FEV1 % predicted, FEV1 (liters) and Diffusing capacity (“DLCO”), which were 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.

Our inhaled formulation of AAT therapy showed clinically relevant changes in various lung function measurements for the entire ITT population, a few of which were statistically significant. This suggests evidence of potential therapeutic activity resulting in a clinically relevant and meaningful effect.

Based on such results, we held pre-submission meetings with the European rapporteur and co-rapporteur in December 2014 with regard to filing MAA with the EMA for our Inhaled AAT for AATD. The co-rapporteurs advised that they would consider the entire study data once submitted, including post hoc analysis and will not reject the application simply because the primary endpoint of the study was not met. They agreed that the application fulfills the requirements relating to unmet medical need and benefit to public health and that it may meet the scope of approval if we convincingly prove the positive benefit-risk balance of the product, by the time of MAA filing. The co-rapporteurs have requested the addition of supplemental data analyses that may address the benefit-risk balance and support the already available safety and efficacy data.

We performed these post hoc analyses in accordance with guidance received following the meeting with the European rapporteur and co-rapporteur. Results of the post hoc analyses indicate that after one year of daily inhalation of our Inhaled AAT for AATD, 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 one year effect:

- 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)

Additional data collected throughout the trial for exacerbation symptom score and well-being score. The changes in symptoms of dyspnea and well-being are suggested as those that most influence the change in patients' health, and quality of life status and determine the need for additional therapy. The results showed trends in favor of the AAT-treated group for both dyspnea and well-being but were not statistically significant. The improvement in dyspnea and well-being further correlates with the fact that patients inhaling AAT had better preserved airflow than patients inhaling placebo.

During March 2014, we initiated Phase II trials 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 II/III trial and was designed to incorporate parameters required by the FDA. This Phase II, double-blind, placebo-controlled study explored the 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 inhalation of 80 mg or 160 mg of human AAT or placebo twice daily 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 for the U.S. Phase II clinical trial, 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 II clinical trial, demonstrated a significant increase in endothelial lining fluid ("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 Kamada's previously completed intravenous ("IV") 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 the most efficient way of delivering therapeutic amounts of AAT to the primary sites of potential lung injury. 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 II/III 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 provided by us from the European clinical trial showed 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 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. In addition, 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 we presented the data from the European Phase II/III study to the FDA, the agency expressed concerns and questions about that data, primarily related to the safety and efficacy of Inhaled AAT for the treatment of AATD and the risk/benefit balance to patients based on that data. The FDA's questions and concerns will need to be resolved before the agency would allow us to proceed with additional clinical development of Inhaled AAT in the United States, including our planned Phase III pivotal study. In order to address the agency's concerns and questions, in April 2017, we submitted to the agency the results of the U.S. Phase II data together with a proposed Phase III synopsis. In July 2017, we submitted to the FDA for review a proposed pivotal Phase III protocol for our Inhaled AAT product. In August 2017, in response to the study protocol and previous submission, the FDA issued a letter to us stating that it continues to have concerns and questions about the safety and efficacy of the Inhaled AAT. We have provided the FDA with data and information related to their concerns and in April 2018, the FDA issued a response letter providing further guidance regarding the proposed pivotal Phase III protocol, as well as additional questions focused on the Inhaled AAT product characteristics. This correspondence indicated that, while several issues had been addressed, the FDA has continued concerns and questions related to the safety profile of Inhaled AAT for AATD. Following a thorough assessment of the FDA response, we provided the requested information and data and implemented the proposed changes in the study protocol during the second half of 2018. We are currently in discussions with the FDA with respect to the pivotal Phase III study for Inhaled AAT for AATD, which is designed to address FDA concerns regarding the safety and efficacy. The proposed Phase III pivotal study is intended to treat AATD subjects with Inhaled AAT at a dose of 80 mg once daily for a period of two years, with a placebo arm at a 1:1 ratio. If FDA authorizes our IND, the study is planned to include approximately 220 patients, and is expected to measure lung function as a primary endpoint and lung density as a secondary endpoint.

In July 2018, we received positive scientific advice from the CHMP of the EMA related to the development plan for our proposed pivotal Phase III study for our inhaled AAT for AATD. We requested scientific advice (protocol assistance) from the CHMP following the results of the previous Phase II/III (EU) and Phase II (US) studies with respect to a proposed subsequent Phase III study design. The CHMP notified us that it concurred with the overall design of the proposed study, including its objectives, patient population, proposed endpoints and their clinical importance, and the safety monitoring plan. The CHMP had some minor comments, which we intend to address in the final study protocol.

Upon conclusion of these discussions and subject to filing for an FDA approval for our IND, we intend to initiate the new pivotal Phase III clinical trial in the United States and Europe. In addition, we are considering all strategic options for Inhaled AAT, including engagement with a marketing partner.

AAT by Infusion for Treatment of Graft-Versus-Host Disease

GvHD is a common complication following an allogeneic tissue transplant. It is commonly associated with stem cell transplant, but the term also applies to other forms of tissue graft. Immune cells (white blood cells) in the tissue (the graft) recognize the recipient (the host) as “foreign”. The transplanted immune cells then attack the host's body cells.

GvHD occurs in 30-70% of patients who undergo a medical procedure of allogeneic hematopoietic stem cell transplantation (HSCT), usually as a treatment to leukemia or other blood cancer or blood conditions. HSCT is a stem cell transplantation that is usually derived from an external (allogeneic) bone marrow donor. One of the most common and dangerous complications of HSCT is GvHD. GvHD is expressed in damage to the recipients’ tissues including damage to the liver, gastrointestinal system, skin and mucosal tissues, and is a major cause of death in these patients.

Intravenously administered glucocorticoids, such as prednisone, are the standard treatment in acute GvHD and chronic GvHD. The use of these glucocorticoids is designed to suppress the T-cell-mediated immune onslaught on the host tissues; however, in high doses, this immune-suppression raises the risk of infections and cancer relapse. In addition, more than 50% of patients do not respond well to steroids and consequently have very low survival rates.

Preliminary human and animal studies indicate that AAT may reduce the severity of GvHD, which is one of the key, life threatening complications of allogeneic stem cell transplantation. GvHD could result in significant damage to the recipients’ tissues including damage to the liver, gastrointestinal tract, skin and mucosal membranes. The immuno-modulatory effect of AAT may attenuate inflammation by lowering levels of pro-inflammatory mediators such as cytokines, chemokines and proteases that are associated with this severe disease. GvHD is a disease of unmet medical need and both the disease and current therapy options carry considerable side effects. Given the favorable safety profile of our intravenous AAT product, we will continue to support the clinical development of this potential indication and for possible regulatory submission.

The European Commission, acting on the recommendation from the Committee for Orphan Medicinal Products of the EMA, has designated our proprietary human IV AAT as an orphan medicinal product to treat GvHD. We received Orphan Drug designation from the FDA for our AAT by IV to treat GvHD. The orphan designation allows the awarded pharmaceutical company to benefit from incentives offered by the European Union to develop the designated medicine for the rare indication.

In January 2018, we announced a collaboration with the Mount Sinai Acute GvHD International Consortium (“MAGIC”) for the conduct of a clinical trial assessing the safety and preliminary efficacy of our AAT product as preemptive therapy for patients at high-risk for the development of steroid-refractory acute GvHD (“SR-aGvHD”). The study will be conducted in five U.S. centers, all of which are members of MAGIC, which consists of 23 Bone Marrow Transplantation (“BMT”) centers in the United States, Europe and Asia, and conducts clinical trials to prevent and treat GvHD following BMT. This is an investigator-initiated study, co-funded by Mount Sinai and our company, and is sponsored by the Icahn School of Medicine at Mount Sinai (ISMMS). The study will be initiated in the first quarter of 2018. This study replaces the previously-planned Phase II/III clinical trial that was designed to evaluate IV AAT as a first-line treatment for aGvHD patients.

The open-label, single-arm study will include 30 high-risk patients who will be treated with our IV AAT for 8 weeks with a follow-up period of one year after undergoing BMT. The primary endpoint will measure the proportion of patients who develop SR-aGvHD by day 100 post-BMT. Other endpoints will include safety, severity of GvHD and mortality. Patient enrollment to the study has been initiated and is progressing well at five active sites. We anticipate the completion of enrollment followed by the availability of interim data from this study by the end of 2019.

The Principal Investigator of the study is John Levine, M.D., M.S., Professor of Pediatrics and Medicine, Hematology and Medical Oncology at the Tisch Cancer Institute at ISMMS and Co-Director of MAGIC. The laboratory aspects of the study will be led by James L.M. Ferrara, M.D., Professor of Pediatrics, Oncological Sciences and Medicine,

Hematology and Medical Oncology at the Tisch Cancer Institute at ISMMS, and Co-Director of MAGIC.

The study is based on an innovative approach of early intervention driven by biomarkers. Drs. Ferrara and Levine have developed an algorithm to diagnose patients at risk for non-relapse mortality on day seven following BMT. The MAGIC algorithm utilizes proprietary biomarkers for prediction of mortality risk. Non-relapse mortality is closely related to non-responsiveness to steroids, which are the current standard of care for aGvHD. Early intervention, based on risk prediction and prior to the development of the clinical symptoms of aGvHD, could prevent patients from further disease deterioration. To date, the MAGIC database includes data from over 2,500 BMT recipients. Pursuant to the agreement with ISMMS, we received the exclusive right to develop and commercialize AAT for GvHD using the MAGIC biomarkers.

Further development of this indication would be subject to the trial results, while considering prospective development partners.

AAT for Treatment of Lung Transplantation Rejection

Lung transplantation rejection occurs when the recipient's immune system attacks the transplanted lung resulting in destruction of the transplanted lung tissue. Around 20% of lung transplant recipients will experience an episode of acute rejection within the first year and approximately 48% and 76% of the recipients will experience chronic rejection within five and 10 years respectively. Chronic rejection is also known as BOS (Bronchiolitis Obliterans Syndrome).

A lung transplant is considered only for people with severe, end-stage lung disease, when patients will most likely die without the surgery and no other options are available. The most common lung diseases for which people undergo lung transplant are Chronic Obstructive Pulmonary Disease, Idiopathic pulmonary fibrosis, cystic fibrosis and Idiopathic Pulmonary Arterial Hypertension.

To protect the new lung, patients are prescribed a variety of medications which suppress the body's natural immune response. These medications are called "immunosuppressants," and they are intended to trick the immune system into believing that the new organ is not foreign, and therefore it is not attacked. After transplantation, the patient will have to take immunosuppressant medications for the rest of the patient's life.

In 2015, we entered into collaboration with Takeda on a Phase II clinical trial of our proprietary alpha-1 antitrypsin ("AAT") treatment for the prevention of lung transplantation rejection that is currently performed in Israel. Under the agreement, Takeda and we collaborate in the development and funding of the study.

This Phase II study was initiated in April 2016. In January 2018, we reported the interim results for such Phase II study and in February 2019, we reported additional interim results from such study. Topline results are expected to be published in the second half of 2019. The study is a randomized, open-label, single-site study of 30 lung transplant recipients to evaluate the safety and efficacy of IV AAT on top of standard-of-care (SOC) versus SOC. The study is randomized 2:1 with 20 patients in the treatment group receiving IV AAT treatment every other day for 14 days, then once every two weeks until week eight, followed thereafter by monthly treatments. The ten patients in the control group will be treated with SOC, which includes systemic corticosteroids and immunosuppressants. Following one year of AAT treatment, there will be a one-year follow-up. The primary endpoints of the study include safety and tolerability, the incidence of acute lung transplantation rejection and changes in Forced Expiratory Volume (FEV1) from baseline and overall effect (a measure of Bronchiolitis Obliterans (chronic rejection)). Additional endpoints measured will include various inflammatory biomarkers and functional capacity.

The principal investigator in this study is Prof. Mordechai R. Kramer, M.D., Director of the Institute of Pulmonary Medicine, Rabin Medical Center - Beilinson Hospital. Prof. Kramer, a renowned expert in pulmonary care and a top specialist in his field, is a full Professor at Tel Aviv University, Sackler Faculty of Medicine. He completed several fellowships in the U.S. in pulmonary care and lung transplantation, and has published many articles in leading scientific publications.

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In May 2017, the last patient of the 30 patients to be recruited entered the study and began treatment. In January 2018, we reported interim results which summarize data from the first six months of treatment for the initial 16 patients in the study. Ten of these 16 patients were in the AAT+SOC group, and six were in the SOC arm. To date, six patients have died (four patients in the AAT+SOC arm, and two in the SOC group) from common transplant-related complications unrelated to treatment with IV AAT.

Out of the 10 total patients who lived throughout the six-month treatment period, four experienced acute rejection post transplantation, but survived and their situation improved and stabilized. Two of the patients who experienced the acute rejections were in the AAT+SOC arm, but their situation resolved without the need to change treatment; the other two patients were in the SOC group and their situation resolved, with one of them changing treatment. Moreover, pulmonary function, which is a key indicator of acute or chronic rejection, improved and was found to be stable in all 10 patients who are alive following six months of treatment.

Our AAT demonstrated a favorable safety and tolerability profile, consistent with the results observed in previous clinical studies in different indications. None of the adverse events (AEs) or serious adverse events (SAEs) observed to date were considered to be related to treatment with IV AAT. During the six months of treatment, the six patients in the SOC group had a total of 28 AEs, while the 10 patients in the AAT+SOC arm had a total of 36 AEs. This represents a rate of 3.6 AEs and 2.5 AEs per 100 days of treatment in the SOC and AAT+SOC arms, respectively. Out of the 28 AEs in the SOC group, four were SAEs, while out of the 36 AEs in the AAT+SOC arm, three were SAEs. This represents a rate of 0.51 SAEs and 0.2 SAEs per 100 days of treatment in the SOC and AAT+SOC arms, respectively.

In May 2018, the last patient enrolled in the study completed one year of treatment and began the one-year follow-up period. During this one-year treatment period, none of the adverse events (“AEs”) or serious adverse events (“SAEs”) observed were considered to be related to treatment with IV-AAT. Acute rejection rates and pulmonary infections were similar in both study groups; five events of acute rejection were observed in five AAT+SOC patients (26%) versus four events in three SOC patients (30%), and pulmonary infections were observed in 10 AAT+SOC patients (53%) versus five SOC patients (50%). Pulmonary function showed a trend towards improved FEV1% of predicted value in the AAT+SOC group at week 4 and week 48 post-transplantation compared to the SOC group (at week 4: 59.4 ± 3.8 for AAT+SOC versus 45.6 ± 3.3 for SOC; at week 48: 58.0 ± 13.0 for AAT+SOC versus 52.1 ± 3.9 for SOC). When compared to SOC, treatment with AAT+SOC demonstrated a trend towards a lower percentage of patients with Primary Graft Dysfunction (“PGD”) grade 3 on day 3 (15% of the patients with AAT+SOC versus 30% of the patients with SOC treatment), and a shorter mechanical ventilation time post-surgery (median of 1 day with AAT+SOC versus 4.5 days with SOC treatment). In addition, the AAT+SOC group demonstrated a trend towards improved Six Minute Walk Test (“6MWT”) results at the end of week 48 as compared to the SOC group (445±115 meters for AAT+SOC versus 371±144 meters for SOC). Throughout the one-year treatment period, 44 AEs were reported in the SOC group, while a total of 107 AEs were reported in the AAT+SOC group. This represents a rate of 1.5 and 1.8 AEs per 100 treatment days in the SOC and AAT+SOC groups, respectively. Out of the 44 AEs in the SOC group, 12 were serious adverse events (SAEs), while out of the 107 AEs in the AAT+SOC group, 31 were SAEs. This represents a rate of 0.4 and 0.5 SAEs per 100 treatment days in the SOC and AAT+SOC groups, respectively. During the one-year treatment period of the study, five patients in the AAT+SOC group and two patients in the SOC group, died. During the follow-up period, to date, three additional patients from the AAT+SOC group have died. All deaths were considered as resulting from common transplant-related complications and unrelated to treatment with IV-AAT.

Top-line data from this study is expected by the end of 2019.

AAT by Infusion for Treatment of Newly Diagnosed Type-1 Diabetes

Type 1 Diabetes is an autoimmune disease in which the pancreatic beta cells responsible for secretion of insulin are attacked and destroyed by the immune system. According to estimates by the U.S. Centers for Disease Control, more than 10 million people throughout the world suffer from Type-1 Diabetes with 100,000 new patients diagnosed annually. According to estimates by the American Association for Type-1 Diabetes, approximately three million people in the United States suffer from Type-1 Diabetes, with 30,000 new patients diagnosed annually.

Studies have demonstrated that even though the level of AAT protein in Type-1 Diabetes patients may be normal, the activity of the AAT protein in these patients is significantly lower than in healthy people. Because AAT has proven anti-inflammatory responses, we believe that treatment by AAT protein in the initial stages after diagnosis of Type-1 Diabetes may prevent or may delay the inflammation that is caused by the autoimmune destruction of the pancreatic cells. As a result, we believe that AAT therapeutics may slow the progression of the development of newly diagnosed Type-1 Diabetes and improve prognosis.

In November 2017, we reported topline results of a phase II clinical trial. We also presented this data at the 78th Scientific Sessions of the American Diabetes Association ("ADA") held in Orlando, Florida in June 2018. The 70 patients enrolled in the study, ranging in age from 8 to 25 years old, and recruited within 100 days of diagnosis of T1D, were randomized to three treatment groups in a 1:1:1 ratio; placebo and two doses of AAT, 60 mg/kg or 120 mg/kg. The study's duration was 56 weeks and included three treatment periods. During the first 12 weeks, a once-weekly treatment was given, followed by 8 weeks of treatment given every two weeks, then a follow-up period of 26 weeks, followed by a once-weekly treatment given for 6 weeks, and a final 4-week follow-up period. Study endpoints included beta cell function assessment as measured by change in C-peptide parameters, glycemic control represented by HbA1C levels and insulin daily dose. The key results for the 12- to 18-year-old patient subgroup treated included:

- Better preservation of beta-cell function, demonstrated as a smaller decline of the average (± SEM) Area Under the Curve (AUC) of stimulated (MMTT) C-peptide secretion over time (- 0.18 ± 0.15nmol/L for AAT 120 mg/kg, -0.47 ±0.13 nmol/L for 60 mg/kg, and -0.34 ±0.10 nmol/L for the placebo group; p =0.543), suggesting a slower decline in pancreatic function for the 120 mg/kg treatment arm. Similar differences were noted for Cmax (defined as maximum or peak serum concentration).
- Lower average HbA1c (AAT 120 mg/kg: 6.66±0.32%, AAT 60 mg/kg: 7.85±0.45%, placebo: 8.29±0.52%, p=0.052, in addition the p-value of the comparison between AAT 120 mg/kg and placebo was p=0.048) and a higher percentage of patients who achieved the clinically meaningful target of HbA1c ≤7% (AAT 120 mg/kg: 70%, AAT 60 mg/kg: 29%, placebo: 25%, p=0.073).
- In a post-hoc analysis of insulin daily dose intake a beneficial favorable effect trend was found in the AAT 120 mg/kg treatment group versus placebo, p=0.086.

We are currently seeking a strategic partner for collaboration to further product development.

Recombinant AAT

According to our strategic decision to focus on AATD, and in preparation for future anticipated increased demand for AAT potentially resulting from greater awareness of AAT deficiency, as well as potential additional indications for Alpha 1 Antitrypsin, which are currently in clinical development, we have initiated development activities in the recombinant human Alpha 1 Antitrypsin ("rhAAT") field.

To ensure the success of this project, we have previously developed analytical methods (physicochemical, biochemical, in-vitro, and in-vivo) that will help identify and characterize functional rhAAT. In addition, we have established a significant understanding on several expression systems and finally selected Cellca (CDMO located in Germany, part of Sartorius Stedim BioTech Group) to pursue the cell line development of the rhAAT in Chinese

Hamsters Ovaries (“CHO”) with high productivity and suitable product quality.

Liquid AAT for Liver Preservation Prior to Transplantation

In September 2018, we reported on the extension of an ongoing investigator initiated, proof-of-concept study evaluating the potential benefit of AAT on liver preservation and transplant rejection prevention. We collaborate with Massachusetts General Hospital (MGH), which is conducting and funding the study that is led by James F. Markmann, M.D., Ph.D., Chief, Division of Transplant Surgery, MGH, who is the Claude E. Welch Professor of Surgery at Harvard Medical School. The purpose of the ongoing study is to assess the effect of AAT on liver graft quality and viability and to evaluate the liver graft for markers of Ischemia-Reperfusion Injury (IRI) and tissue damage. Organ preservation methods pre-transplant are continuously improving due to advanced technologies, such as ex-vivo perfusion systems. This study is evaluating the effect of AAT produced by us on a liver graft once administered into an ex-vivo perfusion system.

AAT has been found to have anti-inflammatory, tissue-protective, immune-modulatory, and anti-apoptotic properties. These characteristics may decrease inflammation by lowering levels of pro-inflammatory cytokines and proteases associated with organ injury during harvest and transplantation, the prevalent causes of organ transplant rejection. In the first cohort of the study, organ viability parameters (e.g. liver function tests and hemodynamics, which represent risks for failure or dysfunction after transplantation), inflammatory pathway analysis and histology, were all measured and yielded positive trends. The second cohort of the study will assess the effect of AAT with different dosing.

Strategic Partnerships

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

Takeda (Glassia)

We have a partnership arrangement with Takeda. The partnership agreement was originally executed on August 23, 2010 with Baxter. During 2015, Baxter assigned all its rights under the partnership agreement to Baxalta, an independent public company which spun-off from Baxter. In 2016, Shire completed the acquisition of Baxalta, and as a result, all of Baxalta's rights under the partnership agreement were assigned to Shire. In January 2019, Takeda completed its acquisition of Shire.

The partnership arrangement with Takeda includes three main agreements: (1) a distribution agreement, pursuant to which Takeda is the sole distributor of Glassia in the United States, Canada, Australia and New Zealand; (2) a licensing agreement, which grants Takeda licenses to use our knowledge and patents to produce, develop and sell Glassia and other products administered by transfusion; and (3) an agreement for Takeda to supply us with fraction IV plasma, a plasma derivative, produced by Takeda, as discussed under "— Manufacturing and Supply — Raw Materials — Fraction IV plasma for Glassia." As between us and Takeda, we retain all rights, including distribution rights, to any inhaled formulation of AAT in development, including Inhaled AAT for AATD. On October 5, 2016, we signed a fifth amendment to the distribution agreement with Takeda to extend the period of minimum purchases by Takeda of Glassia until the end of 2020 and increase the minimum purchases under the distribution agreement. Following the amendment, the minimum aggregate revenue for Glassia under such extended agreement for the years 2018 to 2020 is expected to reach approximately $177 million and may be expanded to $228 million during that period, excluding any potential royalty payments under the licensing agreement, which are not expected to begin prior to 2021.

Sales to Takeda accounted for approximately 56%, 59% and 52% of our total revenues for the years ended December 31, 2018, 2017 and 2016, respectively.

Distribution Agreement

Pursuant to the distribution agreement, we received an upfront and milestone payments of $25 million in total related to distribution rights. Additionally, Takeda is obligated to purchase a minimum amount of Glassia per year until the end of 2020. Pursuant to Takeda's minimum purchase obligations, from 2017 until the end of 2020, we are entitled to receive minimum revenues of between $56.8 million and $63.1 million per year from Takeda. We expect that from 2021, Takeda will start marketing Glassia in the United States to be produced at its production facility and pay us royalties on those sales, in accordance with the terms of the technology license agreement. According to the terms of the distribution agreement, following its compliance with its purchasing obligations until the end of 2020, Takeda will have no further obligation to purchase a minimum amount of Glassia; however, Takeda's failure to purchase a specified minimum amount of Glassia over a period of 24 consecutive months until the expiration of the agreement provides us with the right to terminate the agreement. Takeda is also obligated to fund required Phase IV clinical trials related to Glassia up to a specified amount. If the costs of such clinical trials are in excess of this amount, we have agreed to fund a portion of the costs. We do not expect that the cost of the trials will exceed the specified amount. In May 2016 and June 2017, we received milestone payments from Takeda as a result of Takeda achieving an undisclosed sales milestone for Glassia. We have committed to reimburse Takeda for its Glassia marketing efforts up to a limited amount during the years 2017-2020.

The distribution agreement expires in 2040. In addition to customary termination provisions, either party may terminate the agreement, subject to certain exceptions, in whole or solely with respect to one or more countries covered by the distribution agreement, if regulatory approval in one or more countries covered by the distribution agreement is withdrawn or rejected and not reversed. Takeda has the right to terminate the agreement, upon prior written notice and after a period of time, in the event that Glassia is determined to materially infringe upon a third party's intellectual property rights. In addition to the minimum purchase termination right discussed above, we have the right to terminate the agreement upon prior written notice if Takeda infringes upon our intellectual property.

Following termination of the agreement, Takeda is obligated to cease marketing, promoting or otherwise using Glassia and, at our election, sell all remaining inventory of Glassia in the market or back to us at the relevant purchase price.

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. Takeda agreed to pay us royalties at the rates specified in the agreement, which are in the low double digits during the first 15 years of the agreement and decreasing to less than 10% for the remainder of the period, once it begins to sell Glassia of its own production. We do not expect that such production will begin prior to 2021. The technology license agreement sets forth a minimum amount of royalty payments of $5.0 million required to be made by Takeda per year beginning on the first year of commercial sales of Glassia produced by Takeda.

Pursuant to the technology license agreement, we are entitled to receive payments for the achievement of certain milestones for an aggregate of up to $20.0 million, of which we have already received $14.5 million. Of the milestone payments, $15.0 million are development-based milestones related to the transfer of technology to Takeda and $5.0 million are sales-based milestones.

The intellectual property rights for any improvements on the manufacturing process or formulations that we disclose to Takeda 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; (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; or (iv) if the first sale of Glassia produced by Takeda did not occur by June 15, 2017 and Takeda has not used commercially reasonable efforts to sell by that date. Following any termination, other than expiration of the agreement, all licensed rights will revert to us. Upon expiration of the agreement, we are obligated to grant to Takeda a non-exclusive, perpetual, royalty free license.

Kedrion (KEDRAB)

On July 18, 2011, we signed an agreement with Kedrion, an international pharmaceutical company engaged in the manufacture of life saving drugs based on human plasma which complement our products, and which are marketed in Europe, the United States and approximately 40 other countries worldwide. The agreement provides for exclusive cooperation on completing the clinical development, and marketing and distribution of our anti-rabies pharmaceutical, KamRAB, in the United States under the name KEDRAB, if the product is approved. Pursuant to the agreement, Kedrion will bear all the costs of the Phase III clinical trials in the United States of our product for rabies. Costs related to any Phase IV clinical trials, if required, and the FDA Prescription Drug User fee that is required for all FDA new drug approvals, will be divided equally between us and Kedrion. An addendum to the agreement was executed dated as of October 15, 2016, with respect to the performance of a safety clinical trial for the treatment of pediatric patients which we intend to initiate in the United States. According to such addendum, Kedrion and we agreed to equally share the cost of such trial. A second addendum to the agreement was executed dated as of October 11, 2018, with respect to the purchases prices of KEDRAB under the agreement.

In 2014, the Phase III trial was completed and successfully met the trial's primary endpoint of non-inferiority when measured against an IgG reference product, and in September 2016, the BLA was submitted to the FDA. In August 2017, we received FDA approval of anti-rabies immunoglobulin as a post-exposure prophylaxis against rabies infection. In April 2018, we launched KEDRAB in the United States, under the trademark "KEDRAB" See "Item 4. Information on the Company — immunoglobulins — KEDRAB". Sales to Kedrion accounted for approximately 10% of our total revenues for the year ended December 31, 2018.

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.

The term of the agreement is for six years following the receipt of FDA approval, subject to Kedrion's option to extend the agreement by two years. In addition to customary termination provisions, either party can terminate the agreement for any reason prior to the commencement of clinical trials for FDA approval. Kedrion also 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 Biologics License Application 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.

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 Phase I clinical trials of inhaled formulations of AAT, where each of us was responsible for developing and adapting our own product and bore the costs involved.

Pursuant to the Original PARI Agreement, we agreed to pay PARI royalties from sales of inhaled formulations of 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 royalties period"). During the PARI royalties period, PARI is obligated to pay us specified percentages of its annual sales of the "eFlow" nebulizer for use with inhaled formulations of 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 formulations of AAT for two additional indications of lung disease, namely cystic fibrosis and bronchiectasis. At present, the development of cystic fibrosis and bronchiectasis products is suspended as we prioritize other products. 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 formulations of AAT and the "eFlow" nebulizers, respectively, and in the quantities required for all phases of clinical studies worldwide. In addition, PARI will provide to us, at its expense, technical and regulatory support regarding the "eFlow" nebulizer. Sales of the inhaled formulation of AAT for the additional indications will be added to sales of the first two indications covered by the original agreement as the basis for calculating the royalties to be paid by us to PARI.

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 III 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.

In addition, on February 21, 2008, we signed a commercialization and supply agreement with PARI that provides for the supply of the "eFlow" nebulizer and its spare parts to patients who are treated with the inhaled formulation of AAT, 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.

Manufacturing and Supply

We have a production plant located in Beit Kama, Israel. We operate the main production facility on a campaign-basis so that at any time the facility is assigned to produce only one product. The division of facility time among the various products is determined based on orders received, sales forecasts and development needs. During 2014, we completed the build out of a new logistic facility in our plant in Beit Kama that supports our logistic needs. During each year we have routine maintenance shut downs of our plant, which may last up to a few weeks.

Our production plant successfully passed inspection by the FDA in 2010, and our plant and laboratories also successfully passed a quality assurance audit by Brazil, Kenya and Mexico Ministry of Health. In July 2011, a cGMP audit was conducted by the IMOH, following which the plant's main production facility was reapproved, as well as the new facility to produce our snake bite antiserum product, which was planned and constructed between the years 2009 and 2011 with IMOH funding and began operating in August 2011. In each of July 2013, February 2016 and November 2018, the IMOH completed additional successful cGMP audits of our facility and concluded that we comply with cGMP requirements of the IMOH. In February 2017, the EMA completed a successful cGMP audit of our facility in connection with our Inhaled AAT Product with no critical observations, and in March 2017, the FDA completed a successful audit of our facility in connection with our products Glassia and KEDRAB with no critical observations. In July 2018, Health Canada (the department of the government of Canada with responsibility for national public health) completed a successful audit in connection with the KamRAB product, with no critical observations.

Any changes in our production processes for our products must be approved by the FDA and/or similar authorities in other jurisdictions. In 2014, as part of our on-going effort to increase efficiency and profitability, we received approval from the FDA to make changes to the production processes for Glassia, which scale-up the output of our manufacturing facility, and began to produce Glassia using the improved processes.

Raw Materials

The main raw materials in our Proprietary Products segment are plasma and fraction IV. 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 rules, 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.

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We maintain relationships with several suppliers in order to ensure availability and reduce reliance on specific suppliers. We are dependent, however, on a number of 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 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, 2018, 2017 and 2016, we incurred $25.5 million, $19.9 million and $18.4 million of expenses for the purchase of raw materials, respectively.

Fraction IV Plasma for Glassia

On August 23, 2010, in conjunction with the cooperation arrangement with Takeda, we signed an agreement with Takeda for the supply of fraction IV plasma for use in the production of Glassia to be sold in the United States. Under this agreement, Takeda also supplies us with fraction IV plasma to continue the development and trials of Glassia and for the production, sale and distribution of Glassia in jurisdictions other than those which are covered under the exclusive distribution agreement. Takeda receives no payment for the supply of fraction IV plasma to be used by us for the manufacture of Glassia to be sold to Takeda. If we require fraction IV for other purposes, we are entitled to purchase it from Takeda at a predetermined price. While we are dependent on Takeda for the supply of fraction IV plasma, Takeda is currently dependent on us to produce Glassia for sale in the United States, as it does not have its own FDA approved production facility for Glassia. We assume that Takeda will have an FDA approved production facility by 2021. The supply agreement terminates on August 23, 2040, subject to an option for earlier termination in the event of a material breach.

In December 2012, we signed an additional agreement with Takeda to supply additional fraction IV plasma manufactured in its Vienna plant to be used as the raw material in the production of our AAT product. Takeda is obligated to make available to us yearly minimum quantity of fraction IV plasma. The agreement remains in effect until December 31, 2021, subject to earlier termination in the case of a breach, and may be renewed for two consecutive two year periods upon mutual agreement of both parties. Either party may terminate the agreement for any reason with twelve months prior written notice to the other party, provided that as a condition to such termination by Takeda, Takeda is obligated to provide us, upon our request, with fraction IV plasma in the amount equivalent to the previous year’s total amount of fraction IV plasma sold to us in addition to the fraction IV plasma to be sold during the last year of the agreement.

We have an additional fraction IV plasma supplier, which supplies us with fraction IV plasma that is used for production of Glassia marketed in non-U.S. countries. We are in the process of entering into long-term supply agreements for fraction IV plasma with additional companies.

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 KamRAB 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 orders. We continue to seek to enter into long-term supply agreements for hyper-immune plasma with additional plasma-collection companies.

Research and Development

Our research and development activity in the Proprietary Products segment includes conducting pre-clinical and clinical trials, development activities in the rhAAT field, advanced understanding of the mechanism of action of AAT, 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 as well as clinical programs. We incurred approximately $9.7 million, $12 million and $16.2 million research and development expenses in the years ended December 31, 2018, 2017 and 2016, respectively.

Marketing and Distribution

In the Proprietary Products segment, we receive orders for plasma-derived protein therapeutics and, other than for Glassia, requests for participation in tenders for the supply of plasma-derived protein therapeutics from potential distributors and from existing distributors. We sell Glassia to Takeda and to other distributors in additional Non-U.S. countries.

For our other products, we market, in most cases, by means of agreements with local distributors in each country through a tender process and the private market. The tender process is conducted on a regular basis by the distributors, sometimes on an annual basis. For existing customers, our existing relationship does not guarantee additional orders from the same customers in these tenders. The decisive parameter is generally the price proposed in the tender. The distributor purchases plasma-derived protein therapeutics 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 plasma-derived protein therapeutics in the relevant country. The distribution agreements are, in most cases, made for a specific initial period and are subsequently renewed for one-year periods, where the parties have the right to cancel or renew the agreements with prior notice of a number of 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 participation in marketing costs as a part of incentives for distributors. In Israel, we market our plasma-derived protein therapeutics independently to the end user, healthcare providers and medical centers or through a partner company that specializes in the supply of equipment and pharmaceuticals to healthcare providers.

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.

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

We have distribution agreements with each of our two largest suppliers in our Distribution segment to be their exclusive distributor in Israel for a number of their manufactured products; however, we purchase our Distribution segment products from our suppliers on a purchase order basis. We work closely with our suppliers to develop annual forecasts, but these forecasts do not obligate our suppliers to provide us with their products. Additionally, one of our suppliers has the right to convert the agreement into a non-exclusive agreement or terminate the agreement if we do not meet our annual forecasts.

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Customers

For the year ended December 31, 2018, sales to Takeda and Kedrion accounted for 56% and 10%, respectively, of our total revenues. For the year ended December 31, 2017, sales to Takeda and Kupat Holim Clalit, an Israeli healthcare provider, accounted for 59% and 9%, respectively, of our total revenues. For the year ended December 31, 2016, sales to Takeda and Kupat Holim Clalit accounted for 52% and 13%, respectively, of our total revenues.

Takeda and Kedrion are currently our major customers in the Proprietary Products segment. Our other customers in the Proprietary Products segment are our distributors in Argentina, Russia, Thailand, India and Brazil as well as healthcare providers and medical centers in Israel. In other geographies, most of the sales of our products are conducted through local distributors. These arrangements are further described above under "— Marketing and Distribution."

Our primary customers in the Distribution segment are health maintenance organizations and hospitals in Israel, including Kupat Holim Clalit and Kupat Holim Maccabi.

Competition

The worldwide market for pharmaceuticals in general, and biopharmaceutical and plasma products in particular, has in recent years undergone a process of mergers and acquisitions among companies active in such markets. This trend has led to a reduction in the number of competitors in the market, but the strengthening of the remaining competitors, mainly for specific immunoglobulin products.

Proprietary Products Segment

We believe that there are two to four large competitors for each of our products in the Proprietary Products segment. These large competitors include CSL Behring Ltd., Grifols S.A., which acquired a previous competitor, Talecris Biotherapeutics, Inc. in 2011, and Kedrion (other than for KEDRAB). We have not seen significant changes in the activities of our competitors in recent years. Additionally, our strategic alliance with Takeda and Kedrion in the United States has strengthened our Glassia and KEDRAB competitive positioning in the market.

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. Some of them have an additional advantage regarding the availability of raw materials, as they fractionate plasma internally and own plasma collection centers and/or companies that collect or produce raw materials such as plasma.

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

Glassia. We believe that Glassia has two main competitors: Grifols and CSL. We estimate that Grifols' AAT by infusion product for the treatment of AATD, Prolastin, accounts for at least 50% market share in the United States and more than 70% of sales worldwide, and until 2015 it was the only AAT product that was approved for sale in both – key European countries and the United States. In September 2017 Grifols announced that the FDA approved a liquid formulation of its AAT product. CSL'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 launched the product in few selected EU markets during 2016 under the brand name Respreeza. Apart from its sales of the past Talecris product, Grifols is also a local producer of an additional AAT product, Trypsone, which is marketed in Spain and in some Latin American countries, including Brazil. While Takeda is our strategic partner for sales of Glassia, it also serves existing patients in the United States with its own proprietary product, Aralast. As far as we know Takeda is proactively marketing Glassia in the United States, while maintaining existing patients on Aralast. In addition, we are

aware of a smaller local producer of AAT in the French market, Laboratoire Français du Fractionnement et des Biotechnologies, S.A ("LFB"). We do not believe any new suppliers are expected to enter the United States market for AAT by infusion in the near future. As part of the approval of our competitors' intravenous AAT products for the treatment of AATD, they (like us) were required by the FDA to conduct Phase IV clinical trials aimed to collect efficacy data. CSL has released results from its Phase IV trial. As far as we know those results were not accepted by the FDA as prove of required efficacy. To the best of our knowledge, to date, our other competitors have not completed their trials or their results have not been published.

KamRAB/KEDRAB. We believe that there are two main competitors for this anti-rabies product worldwide: Grifols, whose product we estimate comprises over 85% of the anti-rabies market in the United States, and CSL, which sells its anti-rabies product in Europe and elsewhere. Sanofi Pasteur, the vaccines division of Sanofi S.A., has a product registered for the United States market, but the product is primarily sold in Europe and not currently sold in significant quantities in the United States. There are a number of local producers in other countries that make similar anti-rabies products. Most of these products are based on equine serum, which we believe results in inferior products, as compared to products made from human plasma.

KamRho(D). While Kedrion is one of our strategic partners for KamRAB, it is also one of our competitors for KamRho(D). In addition to its sales in the United States, Kedrion also markets a competing product in Italy and has begun to expand into other markets. We believe there are three additional main suppliers of competitive products in this market: Aptevo, Grifols and CSL. There are also local producers in other countries that make similar products mostly intended for local markets.

Distribution Segment

We believe that there are a number of companies active in the Israeli market distributing the products of several manufacturers whose comparable products compete with our products in the Distribution segment. In the Plasma area, these manufacturers include Grifols, Takeda, CSL, Omrix Biopharmaceuticals Ltd. (a Johnson & Johnson company), while in other specialties we may be competing against products produced by some of largest pharmaceutical manufacturers in the world, such as, Novartis AG, AstraZeneca AB, Sanofi UK 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 greater expertise in the Israeli market. 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, including Glassia, 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.

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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, 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;

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 I 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 II 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 III 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 I, Phase II or Phase III 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 $2,400,000, 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.

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, 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. 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 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 IV 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.

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Other U.S. Healthcare Laws and Compliance Requirements

In the United States, our activities are potentially 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 other divisions of the United States Department of Health and Human Services (e.g., the 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 False Claims Act, the privacy and security provisions of the Health Insurance Portability and Accountability Act, 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 Veterans Health Care Act of 1992, each as amended, as well as the "Anti-Kickback Law" provisions of the Social Security Act. 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 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 particular 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 some states that require manufacturers and others to adopt new 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, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical companies for use in sales and marketing, and to 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 U.S. physicians and/or certain teaching hospitals as well as ownership by a physician or a physician's family member in a pharmaceutical manufacturer. 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 Committee of Medicinal Products for Human Use ("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 or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with GCPs and the applicable regulatory requirements and the ethical principles that have their origin in the 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, as a result of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), a Medicare prescription drug benefit (Medicare Part D) became effective at the beginning of 2006. Medicare is the federal health insurance program for people who are 65 or older, certain younger people with disabilities, and people with End-Stage Renal Disease. Medicare coverage and reimbursement for some of the costs of prescription drugs may increase demand for any products for which we receive FDA approval. However, we would be required to sell products to Medicare beneficiaries through entities called "prescription drug plans," which will likely seek to negotiate discounted prices for our products.

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.

As another example, in March 2010, President Obama signed into law the Patient Protection and Affordable Care Act and the Healthcare and Education Reconciliation Act of 2010 (collectively referred to as the "health care reform law"). The health care reform law made significant changes to the United States healthcare system, such as imposing new requirements on health insurers, expanding the number of individuals covered by health insurance, modifying healthcare reimbursement and delivery systems, and establishing new requirements designed to prevent fraud and abuse. In addition, provisions in the health care reform law promote the development of new payment and healthcare delivery systems, such as the Medicare Shared Savings Program, bundled payment initiatives and the Medicare pay for performance initiatives.

The health care reform law and the related regulations, guidance and court decisions have had, and will continue to have, a significant impact on the pharmaceutical industry. In addition to the general reforms briefly described above, provisions of the health care reform law directly address drugs. For example, the health care reform law:

- increases the minimum level of Medicaid rebates payable by manufacturers of brand-name drugs from 15.1% to 23.1%;

- requires Medicaid rebates for covered outpatient drugs to be extended to Medicaid managed care organizations;

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- requires manufacturers of drugs covered under Medicare Part D to participate in a coverage gap discount program, under which they must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible Medicare beneficiaries during their coverage gap period; and

- imposes a non-deductible annual fee on pharmaceutical manufacturers or importers who sell "branded prescription drugs" to specified federal government programs.

On April 1, 2016, final regulations issued by the Centers for Medicare and Medicaid Services to implement the changes to the Medicaid Drug Rebate Program under the healthcare reform law became effective.

Some provisions of the healthcare reform law have yet to be fully implemented, and President Donald Trump has vowed to repeal the healthcare reform law. On January 20, 2017, President Donald Trump signed an executive order stating that the administration intended to seek prompt repeal of the healthcare reform law, and, pending repeal, directed by the U.S. Department of Health and Human Services and other executive departments and agencies to take all steps necessary to limit any fiscal or regulatory burdens of the healthcare reform law. On October 12, 2017, President Trump signed another Executive Order directing certain federal agencies to propose regulations or guidelines to permit small businesses to form association health plans, expand the availability of short-term, limited duration insurance, and expand the use of health reimbursement arrangements, which may circumvent some of the requirements for health insurance mandated by the healthcare reform law. The U.S. Congress has also made several attempts to repeal or modify the healthcare reform law. In addition, there is ongoing litigation regarding the implementation and constitutionality of the healthcare reform law. While the law is still in effect pending the ultimate resolution of the litigation, the outcome of the litigation is unknown and cannot be predicted. It is uncertain whether new legislation will be enacted to replace the healthcare reform law and whether any such legislation would affect coverage and reimbursement for prescription drugs or otherwise include provisions intended to limit the growth of healthcare costs.

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.

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Patents

As of December 31, 2018, we owned for use within our field of business five families of patents or patent applications, which are registered or applied for in the United States and also in the European Union, Russia, Turkey, Israel, certain Latin American countries, Canada, Australia and other countries, seven PCT patent applications and four US provisional applications. At present, one patent protecting our manufacturing process is considered to be material to the operation of our business as a whole. Such patent has been issued in a variety of jurisdictions, including Australia, Austria, Belgium, Canada, Denmark, Estonia, Israel, Finland, France, Germany, Greece, Ireland, Italy, Netherlands, Slovenia, Poland, Spain, Portugal, Sweden, Switzerland, Turkey, the United Kingdom and the United States, and expires in 2024.

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 and their delivery methods. Our patents and patent applications are expected to expire at various dates between 2019 and 2029. 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 invent the inventions claimed in our owned patents or patent applications and/or the first to file said patent applications. In addition, our competitors or other third parties may independently develop similar technologies that don’t 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 GLASSIA, RESPIKAM, KAMRAB, KEDRAB, RESPIRA, KamRHO VENTIA, KAMADA and Rebinolin.

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.”

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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 subsidiary, leases from the Israel Land Administration pursuant to a capitalized long-term lease. Kamada Assets subleases the property to us. The property covers 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. The production plant includes our manufacturing facility, manufacturing support systems, packaging, warehousing and logistics areas, laboratory facilities and an area for the manufacture of snake bite anti-serum, as well as office buildings.

Since January 2017, we have leased approximately 2,200 square meters of a building located in the Kiryat Weizmann Science Park in Rehovot, Israel, which replaced our former Ness Ziona premises. This property houses our head office, our research and development laboratory and additional departments such as our research and development, clinical, medical, regulatory and business development departments.

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.

Organizational Structure

Our significant subsidiaries are set forth below. All subsidiaries are either 100 percent 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
Kamada Biopharma Limited	England and Wales
Kamada Inc.	Delaware
Kamada Ireland Limited	Ireland
Kamada Assets Ltd.	Israel

Legal Proceedings

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.

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 "Item 3. Key Information—A. Selected Financial Data" and 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, 2018, 2017 and 2016 in this Annual Report have been prepared in accordance with IFRS as issued by the IASB. None of the financial information in this Annual Report has been prepared in accordance with U.S. GAAP.

Overview

We are a plasma-derived protein therapeutics company focused on orphan indications, with an existing marketed product portfolio and a late-stage product pipeline. We develop and produce specialty plasma-derived protein therapeutics and currently market these products through strategic partners in the United States and directly, through local distributors, in several emerging markets. We use our proprietary platform technology and know-how for the extraction and purification of proteins from human plasma to produce AAT in a high purity, liquid form, as well as other plasma-derived proteins. AAT is a protein derived from human plasma with known and newly discovered therapeutic roles given its immuno-modulatory, anti-inflammatory, tissue protective and antimicrobial properties. Our flagship product, Glassia, was the first liquid, ready-to-use, intravenous plasma-derived AAT product approved by the FDA (Glassia is also approved for self-administration). We market Glassia through a strategic partnership with Takeda in the United States. In addition to Glassia, we have a product line consisting of five other products which are marketed in more than 15 countries, including Israel, Russia, Brazil, India and other countries in Latin America and Asia. In August 2017, we received FDA approval for anti-rabies immunoglobulin as a post-exposure prophylaxis against rabies infection. In April 2018, we launched, together with Kedrion, KamRAB in the United States, under the trademark "KEDRAB." In addition to our propriety products, we leverage our expertise and presence in the plasma-derived protein therapeutics market by distributing more than 20 complementary products in Israel that are manufactured by third parties.

Our lead product in development is Inhaled AAT for AATD, for which we completed a pivotal Phase II/III clinical trial in Europe and filed the MAA with the EMA in March 2016. The Phase II/III clinical trial in Europe, however, did not meet its primary or other pre-defined endpoints. Following our discussions with the EMA in regards to the study results, in July 2017, we withdrew the MAA in Europe for our Inhaled AAT for AATD, which relied on this single pivotal clinical trial. 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. See "Item 4. Information on the Company—Our Product Pipeline and Development Program—Inhaled Formulations of AAT—AATD." We have also completed a Phase II clinical trial with our Inhaled AAT for AATD in the United States. We are currently in continued discussions with the FDA with respect to a new pivotal Phase III study for Inhaled AAT designed to address both FDA and EMA concerns regarding the safety and efficacy. In July 2018, we received positive scientific advice from the CHMP of the EMA related to the development plan for our proposed pivotal Phase III study for our Inhaled AAT for AATD. The CHMP notified us that it concurred with the overall design of the proposed study, including its objectives, patient population, proposed endpoints and their clinical importance, and the safety monitoring plan. Upon conclusion of the current discussions with the FDA and subject to an approved IND, we intend to initiate the new pivotal Phase III clinical trial in the United States, and resubmit the MAA. However, it is not certain when we will initiate such Phase III clinical trial, as the FDA expressed concerns and questions regarding safety and efficacy, and we are currently in discussions with the FDA regarding the IND approval. See "Risk Factors— Risk Related to Development, Regulatory Approval and

Commercialization of Product Candidates."

Our Segments

We operate in two segments: the Proprietary Products segment, in which we develop and manufacture plasma-derived therapeutics and market them in more than 15 countries, and the Distribution segment, in which we distribute imported drugs in Israel, which are manufactured by third-parties, the majority of which are produced from plasma or its derivative products.

Segment performance is evaluated based on revenues and gross profit (loss). Items that are not allocated to our segments consist mainly of research and development costs, sales and marketing expenses, general and administrative costs, financial expenses, net and tax on income, each of which are managed on a group basis. For the year ended December 31, 2018, we derived $90.8 million of revenues from our Proprietary Products segment, or 79% of total revenues, and $23.7 million of revenues from our Distribution segment, or 21% of total revenues. For the year ended December 31, 2017, we derived $79.5 million of revenues from our Proprietary Products segment, or 77% of total revenues, and $ 23.3 million of revenues from our Distribution segment, or 23% of total revenues. For the year ended December 31, 2016, we derived $56.0 million of revenues from our Proprietary Products segment, or 72% of total revenues, and $21.5 million of revenues from our Distribution segment, or 28% of total revenues.

Factors Affecting Our Results of Operations

Demand for our Products

Over the past few years, we have seen an increase in demand for products in our Proprietary Products segment. Our Glassia supplies to Takeda significantly increased throughout the term of our strategic partnership, and based on our agreement with Takeda, we expect Glassia supplies to continue to increase through 2020. In addition, during 2018 we launched KEDRAB in the United States. As a result, we expect that our revenues will grow in a range of approximately 9% to 14% in 2019, allowing us to achieve our revenue goal of $125 to $130 million by 2019 through increased sales of our existing products in the Proprietary Products segment, mainly driven from sales of Glassia and KEDRAB in the United States. As discussed below, after 2020, Takeda has no obligation to purchase a minimum amount of Glassia, and we expect that the resulting decrease in revenues will be partially offset by income from royalty payments from Takeda on sales of Glassia and continued increased sales of Glassia in rest of the world countries through local distributors and sales of KEDRAB in the United States and other countries.

The AAT augmentation market for AATD in the United States, which is the primary market for Glassia, has grown by more than 6-8% annually in the last few years, and we expect that the overall market for Glassia will continue to increase due to new patient identification. In the United States and Europe, we believe that AATD is currently significantly under-identified and under-treated, as we estimate that only approximately 6% and 2.5% of all potential cases of AATD are treated in the United States and Europe, respectively, with an aggregate of up to an estimated 180,000-190,000 patients suffering from AATD, of which less than 10% have been diagnosed. We expect that our market opportunity for our AAT products, including Glassia and Inhaled AAT for AATD (if approved), will continue to grow as awareness of AATD expands due to factors such as marketing activities, inexpensive and effective diagnosis tools, and improved training. In addition, various awareness and patient identification programs initiated by companies producing AATD treatments are expected to increase demand for Glassia and, once approved, Inhaled AAT for AATD.

Sales of our Distribution segment products are made through public tenders of Israeli hospitals and health maintenance organizations on an annual basis. The prices we can offer, as well as the availability of products, are key factors in meeting the local demand of the Israeli market. Our Distribution segment experienced a moderate growth in sales in 2018 compared to 2017, despite the growing competition. The Distribution segment may continue to grow if we will be able to increase our product portfolio or win more tenders.

Strategic Partnerships

In July 2010, we received FDA approval for the marketing of Glassia in the United States. Following this approval, we entered into a 30 year strategic arrangement with Takeda (originally executed with Baxter, which subsequently assigned the agreement to Baxalta, which was subsequently acquired by Shire, which was recently acquired by Takeda), for the marketing and distribution of Glassia in the United States, Canada, Australia and New Zealand and for the licensing of our technology, granting Takeda rights to manufacture Glassia for sales in these territories. We began recognizing revenues from sales of Glassia in the United States under this strategic arrangement with Takeda in September 2010. From the inception of the strategic arrangement through December 31, 2018, we have received $39.5 million from Takeda for distribution rights, a portion of which has been accrued as deferred revenue, and for achieving milestones set forth in the distribution and licensing agreements. We have recognized cumulative revenues until December 31, 2018 from Takeda in the amount of $312 million. We currently generate revenues from sales of Glassia to Takeda, and incur cost of revenues to produce it. In accordance with the latest amendment to the manufacturing and distribution agreement, which became effective as of October 5, 2016, Takeda may begin producing Glassia in its own manufacturing facility as early as 2021, and only pay us royalties. As Takeda transitions to producing Glassia in its own facilities, we will incur a substantial reduction in revenues (as well as costs of goods sold), driven by the reduction in Glassia manufacturing. Such decrease in revenues is expected to be partially offset by income from royalty payments from Takeda on sales of Glassia in the United States and continued increased sales of Glassia in the rest of the world countries through local distributors and by income from sales of KEDRAB in the United States. See “Item 3. Key Information — D. Risk Factors — In our Proprietary Products segment, we currently rely on one of our strategic partners that accounts for a significant portion of our total sales and our distribution plan for our principal product candidate relies on another strategic partner, and any disruption to our relationships with these distributors would have an adverse effect on our results of operations and profitability.”

In addition, in July 2011, we signed a strategic agreement with Kedrion to cooperate in the clinical development and exclusive marketing and sales in the United States of KEDRAB, our hyper-immune anti-rabies prophlaxis treatment, which was launched in the United States in April 2018. We have recognized cumulative revenues until December 31, 2018 from Kedrion in the amount of approximately $12 million. Kedrion markets its products in Europe, the United States and in approximately 40 other countries worldwide.

Product Development Costs

Since our company was founded, we have focused on developing a broad portfolio of plasma-derived protein therapeutics for a variety of indications. The development of plasma-derived protein therapeutics is characterized by significant up-front product development costs, including, for example, costs for conducting pre-clinical and clinical trials to obtain regulatory approvals, regulatory expenses, costs for materials for development, external consulting and services fees and opportunity costs for reallocating our production facility to produce clinical trial materials and conforming our production processes for regulatory purposes. In order 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 post marketing required clinical trials for Glassia in the United States and 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 — Takeda (Glassia)” and “Business — Strategic Partnerships - Kedrion (KEDRAB).”

Product development costs may fluctuate from period to period, as our product candidates pass through various stages of development. For example, for the years ended December 31, 2018 and 2017, we incurred moderate research and development expenses related to clinical trials related to Inhaled AAT for AATD in Europe and the United States, AAT for the treatment of newly diagnosed Type-1 diabetes and lung transplantation rejection and GvHD. 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 regards to our product pipeline. See “Item 4. Information on the Company — Our Product Pipeline and Development Program.”

Product Competition

The worldwide market for pharmaceuticals in general and biopharmaceutical and plasma products in particular has undergone a process of mergers and acquisitions among companies active in such markets. This trend has led to a reduction in the number of competitors in the market, and the strengthening of the remaining competitors, mainly for specific immunoglobulin products.

While there are additional producers of AAT products approved in the United States and Europe, including Takeda, we have not seen significant changes in these producers' activities in the market. Additionally, our strategic alliance with Takeda has strengthened Glassia's competitive positioning in the market. See "Item 3. Key Information — D. Risk Factors — In our Proprietary Products segment, we currently rely on one of our strategic partners that accounts for a significant portion of our total sales and our distribution plan for our principal product candidate relies on another strategic partner, and any disruption to our relationships with these distributors would have an adverse effect on our results of operations and profitability."

Costs of Raw Materials

In our Proprietary Products segment, a significant portion of our manufacturing costs are for raw materials consisting of plasma or fraction IV of plasma. The consolidation among plasma companies has led to a decrease in the number of independent plasma collection centers in the world.

In order to ensure the availability of plasma and fraction IV, we have secured supply of plasma and fraction IV from multiple suppliers, including from Takeda for the manufacturing of Glassia and Kedrion for the manufacturing of KEDRAB.

In our Distribution segment, our costs are for the purchase of products for sale from our suppliers. Our annual purchases are forecasted each year with each supplier, but individual product purchases during the year are made on a purchase order basis. For these instances, we tend not to have minimum purchase obligations, and as such, are able to respond accordingly to pricing fluctuations that occur year to year. Historically, we have not seen significant price fluctuations from our two largest suppliers. Unless absent of material changes in the market, such as a significant increase in the price of plasma or plasma-derivatives shall occur, we do not expect a significant increase in the cost of purchasing products.

Key Components of Our Results of Operations

Revenues

In our Proprietary Products segment, we generate revenues from the sale of products to strategic partners and distributors, as well as from the licensing of our technology. We derived a significant portion of our total revenues from sales of Glassia to Takeda. Sales to Takeda accounted for approximately 55%, 59% and 52% of our total revenues in the years ended December 31, 2018, 2017 and 2016, respectively. Revenue from all sales of Glassia comprised approximately 60%, 64% and 56% of our total revenues for the years ended December 31, 2018, 2017 and 2016, respectively. We expect revenues attributable to the sale of Glassia to Takeda will grow in the next two years, in line with the expected Glassia orders by Takeda pursuant to the fifth amendment to the Manufacturing, Supply and Distribution Agreement, until Takeda begins production of Glassia, at which time our sales to Takeda will be reduced and be replaced by royalties from Takeda. Following the launch of KEDRAB in the United States in April 2018, sales of KEDRAB to Kedrion during the year ending December 31, 2018 accounted for approximately 10% of our total revenues.

Revenues from our Proprietary Products segments also include a recognized portion of prior upfront and milestone payments from strategic partners.

Revenues are presented net of any discounts and/or marketing contribution payments extended to our partners and distributors.

In our Distribution segment, we generate revenues from the sale in Israel of imported products produced by third parties. During the three year period ended December 31, 2018, sales of IVIG decreased due to growing competition. Sales of IVIG accounted for approximately 12%, 12% and 17% of our total revenues for the years ended December

31, 2018, 2017 and 2016, respectively.

In the future, as we further commercialize our products, we expect to derive a greater percentage of our revenues from our Proprietary Products segment, mainly as a result of continued growth in sales of our existing products and the potential launch, if approved, of new AAT products and new indications for existing products currently in different development phases.

Cost of Revenues

Cost of revenues in our Proprietary Products segment includes expenses for the manufacturing of products such as raw materials, payroll, utilities, laboratory costs and depreciation. Cost of revenues also includes provisions for write-downs of inventories and inventory write offs. Costs of revenues in our Distribution segment consists of costs of products acquired, packaging and labeling for sales by us in Israel.

In addition to the successful strategic partnerships with Takeda and Kedrion and successful penetration to the U.S. market, we have focused during the years ended December 31, 2018, 2017 and 2016 on increasing our production outputs and improving profitability. In addition, implementing significant technology improvements and streamlining our manufacturing process resulted in significantly increased manufacturing capacity at our facility. The strategic partnership with Takeda enabled us to achieve economies of scale and lower our per-unit costs, and we believe that the increase in production capacity will lead to a further increase in profitability. We have been implementing production improvements for Glassia that we expect will lead to improved margins and higher productivity in anticipation of increased demand for our existing products as well as for additional applications for AAT. Any changes in our Glassia and KEDRAB production processes must be approved by all relevant regulatory bodies, including the FDA.

Gross Profit

Gross profit is the difference between total revenues and the cost of revenues. Gross profit is mainly affected by volume of sales and launching new products, cost of raw materials and plant maintenance and overhead. We have seen an increase in gross profitability in recent years as a result of the increase in our sales and the corresponding reduction in per unit costs attributable to greater production output.

Our gross margins are generally higher in our Proprietary Products segment (42%, 35% and 33% for the years ended December 31, 2018, 2017 and 2016, respectively) than in our Distribution segment (15%, 17%, 15% for the years ended December 31, 2018, 2017, and 2016, respectively).

We expect that our overall gross margins will increase to the extent that our sales from Proprietary Products segment increase as a percentage of our total sales, and we expect our gross margins in the Proprietary Products segment to increase further to the extent that our sales of Glassia (or other AAT products) and KEDRAB increase as these products have higher gross margins than our immunoglobulin proprietary products sold in Rest of the World (“ROW”) countries.

In our Distribution segment we will seek to increase our gross margins through the potential addition of new, more profitable products, to our portfolio, thereby improving product mix.

Research and Development Expenses

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 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.

We expect our research and development expenses to increase in 2019 to reflect our plan to fund certain additional clinical trials for AAT for certain additional indications including Inhaled AAT for AATD, which is pending an FDA approval of our IND. However, actual spending could differ if our plans change or if we potentially reduce our anticipated funding on research for existing products or partner with other parties to fund development of current product candidates.

Selling and Marketing Expenses

Selling and marketing expenses principally consist of expenditures incurred for sales incentive, advertising, marketing or promotional activities, shipping and handling costs, product liability insurance and business development activities, as well as marketing authorization fees to regulatory agencies. Due to our strategic partnerships in our Proprietary Products segment, we expect these costs to remain at a similar level other than ongoing effort to increase sales of existing products. However, we may incur higher expenses in the future, as we have not entered into strategic partnerships for all of our pipeline products, which we may decide to sell using our own, to be established, direct sales force. We market our products in our Distribution segment to health maintenance organizations and hospitals in Israel.

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 costs, legal and audit fees as well as employee welfare costs. We expect general and administrative expenses to remain stable.

Financial Income

Financial income is comprised of interest income on amounts invested in bank deposits and short-term investments and the portion of changes in fair value of financial instruments at fair value through other comprehensive income.

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

Income (expense) in respect of currency exchange differences and derivatives instruments are comprised of changes on balances 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 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 capital leases.

Taxes on Income

We have not been required to pay income taxes since 1997 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. In 2018, we initially recognized deferred tax asset for a portion of our carryforward losses.

One of our Israeli facilities has Approved Enterprise status granted by the Israel Investment Center under 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 will apply 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 have 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 is also eligible for tax benefits as a Privileged Enterprise, which will 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 are scheduled to expire at the end of 2020 and 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 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 carryforwards, 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.

As of December 31, 2018, we have net operating loss carryforwards of approximately $65.2 million. The net operating loss carryforwards have no expiration date. Following the full utilization of our net operating loss carryforwards, we expect that our effective income tax rate in Israel will reflect the benefits discussed above.

Results of Operations

The following table sets forth certain statement of operations data:

	Year Ended December 31,		
	2018	2017	2016
	(U.S. Dollars in thousands)		
Revenues from Proprietary Products segment	$90,784	$79,559	$55,958
Revenues from Distribution segment	23,685	23,266	21,536
Total revenues	114,469	102,825	77,494
Cost of revenues from Proprietary Products segment	52,796	51,335	37,723
Cost of revenues from Distribution segment	20,201	19,402	18,411
Total cost of revenues	72,997	70,737	56,134
Gross profit	41,472	32,088	21,360
Research and development expenses	9,747	11,973	16,245
Selling and marketing expenses	3,630	4,398	3,243
General and administrative expenses	8,525	8,273	7,353
Other expense	311	-	-
Operating income (loss)	19,259	7,444	(5,481)
Financial income	820	500	469
Income (expense) in respect of currency exchange differences and derivatives instruments	602	(612)	127
Financial expense	(340)	(162)	(126)
Income (loss) before taxes on income	20,341	7,170	(5,011)
Taxes on income	(1,955)	269	1,722
Net income (loss)	22,296	6,901	$(6,733)

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Year Ended December 31, 2018 Compared to Year Ended December 31, 2017

Segment Results

			Change 2018 vs. 2017	
	2018	2017	Amount	Percent
	(U.S. Dollars in thousands)			
Revenues:				
Proprietary Products	$90,784	$79,559	$11,225	14 %
Distribution	23,685	23,266	419	2 %
Total	$114,469	$102,825	$11,644	11 %
Cost of Revenues:				
Proprietary Products	$52,796	$51,335	$1,461	3 %
Distribution	20,201	19,402	799	4 %
Total	$72,997	$70,737	$2,260	3 %
Gross Profit:				
Proprietary Products	$37,988	$28,224	$9,764	35 %
Distribution	3,484	3,864	(380)	(10)%
Total	$41,472	$32,088	$9,384	29 %

Revenues

In the year ended December 31, 2018, we generated $114.5 million of total revenues, compared to $102.8 million in the year ended December 31, 2017, an increase of $11.7 million, or approximately 11%. This increase was primarily due to a $11.2 million increase in our Proprietary Products segment revenues, mainly due to the launch of KEDRAB in United States during 2018, and a $0.5 million increase in our Distribution segment, mainly attributable to increased sales of new products and a different product mix.

Cost of Revenues

In the year ended December 31, 2018, we incurred $73.0 million of cost of revenues, compared to $70.7 million in the year ended December 31, 2017, an increase of $2.3 million, or approximately 3%. The cost of revenues in our Proprietary Products segment increased by $1.5 million, primarily due to an increase in volume of sales. The cost of revenues in our Distribution segment increased by $0.8 million, primarily due to an increase in volume of sales.

Costs of revenues in the year ended December 31, 2018 included a $1.8 million write-off of indirect manufacturing costs and $0.8 million of process materials scraps as a result of a labor strike that caused lower than standard production level during the third quarter of 2018.

Gross profit

Gross profit in our Proprietary Products segment increased by $9.8 million in 2018, primarily due to the launch of KEDRAB in the United States in April 2018, improved manufacturing efficiencies and our ability to increase sale prices in ROW markets. Gross profit in our Distribution segment decreased by $0.4 million in 2018, primarily due to a different mix of sales with lower gross margin. As a percentage of total revenues, gross margin increased to 36.2% for the year ended December 31, 2018 from 31.2% for the year ended December 31, 2017. Gross margin for the Proprietary Products segment, as a percentage of revenues from that segment, was 41.8% and 35.5% for the years ended December 31, 2018 and 2017, respectively. Gross margin for the Distribution segment, as a percentage of revenues from that segment, was 14.7% and 16.6% for the years ended December 31, 2018 and 2017, respectively. The increase in gross profit margin was primarily driven by an increase in the Proprietary Products segment revenues

and high profitability of KEDRAB.

Research and Development Expenses

In the year ended December 31, 2018, we incurred $9.7 million of research and development expenses, compared to $12 million in the year ended December 31, 2017, a decrease of $2.3 million, or approximately 19%. This decrease was primarily due to a $1.2 million decrease in clinical trial expenses, mainly attributed to a decrease in expenses in connection with the Inhaled AAT clinical trial and its relevant consultants as a result of its deferral to 2019, partially offset by an increase in labor costs. Research and development expenses accounted for approximately 8.5% and 11.6% of total revenues for the years ended December 31, 2018 and 2017, respectively.

Set forth below are the research and development expenses associated with our major development programs in the years ended December 31, 2018 and 2017:

	Year ended December 31,	
	2018	2017
	(U.S. Dollars in thousands)	
Inhaled AAT	$356	$949
AAT for newly diagnosed Type-1 Diabetes	48	475
AAT IV for lung transplantation rejection	194	586
AAT IV for treatment of GvHD	356	148
Anti Rabies	208	340
Recombinant	223	102
Unallocated salary	5,823	6,413
Unallocated facility cost allocated to research and development	1,990	2,325
Unallocated other expenses	549	635
Total research and development expenses	$9,747	$11,973

Research and development expenses for Inhaled AAT for AATD decreased by $0.6 million in 2018 due to continued discussions with the FDA regarding its concerns that delayed the execution of the planned clinical trial. Research and development expenses for Type-1 Diabetes decreased by $0.4 in 2018 due to the completion of the clinical trial in 2017. Research and development expenses for Anti Rabies decreased by $0.1 million in 2018 due to low requirement rate for the FDA's post marketing commitment for pediatric study. Research and development expenses for GvHD increased by $0.2 million due to the initiation of a proof-of-concept trial for the treatment of acute GvHD. Research and development expenses for recombinant human Alpha 1 Antitrypsin increased by $0.1 million in 2018 due to a development plan initiated in 2018. Unallocated expenses are expenses that are not managed by project and are allocated between various tasks that are not always related to a major project. In the years ended December 31, 2018 and 2017, we incurred $5.8 million and $6.4 million, respectively, of unallocated salary expenses which represent all research and development salary expenses, $2.0 million and $2.3 million, respectively, of facility costs allocated to improvements in processes and $0.5 million and $0.6 million, respectively, of unallocated other expenses.

Our current intentions as to the short-term development timeline for our major development programs are described in "Business — Our Product Pipeline and Development Program," and we also have long-term development goals. However, 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 — Risk 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

In the year ended December 31, 2018, we incurred $3.6 million of selling and marketing expenses, compared to $4.4 million in the year ended December 31, 2017, a decrease of $0.8 million, or approximately 17%. This decrease was primarily due to a $0.7 million decrease in regulatory fees and decrease of $0.2 million of marketing support to distributors. Selling and marketing expenses accounted for approximately 3.2% and 4.3% of total revenues for the years ended December 31, 2018 and 2017, respectively.

General and Administrative Expenses

In the year ended December 31, 2018, we incurred $8.5 million of general and administrative expenses, compared to $8.3 million in the year ended December 31, 2017, a moderate increase of $0.2 million, or approximately 3%. This increase was primarily due to an increase of $0.2 million in payments to external consultants and share-based payments expense. General and administrative expenses accounted for approximately 7.4% and 8.0% of total revenues for the years ended December 31, 2018 and 2017, respectively.

Other expenses

In the year ended December 31, 2018, we incurred $0.3 million of other expenses, primarily due to an ongoing technology transfer project preformed with an external service provider that is planned to be completed during 2020.

Financial Income

In the years ended December 31, 2018 and December 31, 2017, we generated $0.8 million and $0.5 million of financial income, respectively, from our short term investment portfolio and bank deposits.

Expense in respect of currency exchange differences and derivatives instruments

In the year ended December 31, 2018, we generated $0.6 million of income in respect of currency exchange differences on balances in other currencies versus the U.S. dollar and derivatives impact compared to expense of $0.6 million in the year ended December 31, 2017.

Financial Expenses

In the year ended December 31, 2018, we incurred $0.3 million of financial expenses, compared to $0.2 million in the year ended December 31, 2017.

Taxes on Income

In the year ended December 31, 2018, we recognized a deferred tax asset representing a portion of carryforward losses that we estimate that we will realize in the coming years, resulting in tax income of $2.0 million for such period. In the year the ended December 31, 2017, we had $0.3 million taxes on income mainly due to surplus expenses.

Year Ended December 31, 2017 Compared to Year Ended December 31, 2016

Segment Results

			Change 2017 vs. 2016		
	2017	2016	Amount	Percent	
	(U.S. Dollars in thousands)				
Revenues:					
Proprietary Products	$79,559	$55,958	$23,601	42.2	%
Distribution	23,266	21,536	1,730	8	%
Total	$102,825	$77,494	$25,331	32.7	%
Cost of Revenues:					
Proprietary Products	$51,335	$37,723	$13,612	36	%
Distribution	19,402	18,411	991	5.4	%
Total	$70,737	$56,134	$14,603	26	%
Gross Profit:					
Proprietary Products	$28,224	$18,235	$9,989	54.8	%
Distribution	3,864	3,125	739	23.7	%
Total	$32,088	$21,360	$10,728	50.2	%

Revenues

In the year ended December 31, 2017, we generated $102.8 million of total revenues, compared to$77.5 million in the year ended December 31, 2016, an increase of $25.3 million, or approximately 33%. This increase was primarily due to a 23.6 million increase in our Proprietary Products segment revenues, mainly due to an increase in sales of Glassia in United States, and a $1.7 million increase in our Distribution segment, mainly attributable to increased sales of new products and a different mix of sales.

Cost of Revenues

In the year ended December 31, 2017, we incurred $70.7 million of cost of revenues, compared to $56.1 million in the year ended December 31, 2016, an increase of $14.6 million, or approximately 26%.The cost of revenues in our Proprietary Products segment increased by $13.6 million mainly due to an increase in volume of sales. The cost of revenues in our Distribution segment increased by $1 million, primarily due to an increase in volume of sales.

Gross profit in our Proprietary Products segment increased by $10 million in 2017, primarily due to an increase in sales of Glassia in United States. Gross profit in our Distribution segment increased by $0.7 million in 2017, primarily due to different mix of sales with higher gross margin. As a percentage of total revenues, gross margin increased to 31.2% for the year ended December 31, 2017 from 27.6% for the year ended December 31, 2016. Gross margin for the Proprietary Products segment, as a percentage of revenues from that segment, was 35.5% and 32.6% for the years ended December 31, 2017 and 2016, respectively. Gross margin for the Distribution segment, as a percentage of revenues from that segment, was 16.6% and 14.5% for the years ended December 31, 2017 and 2016. The increase in gross profit margin was primarily driven by an increase in the Proprietary Products segment revenues.

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Research and Development Expenses

In the year ended December 31, 2017, we incurred $12 million of research and development expenses, compared to $16.2 million in the year ended December 31, 2016, a decrease of $4.2 million, or approximately 26%. This decrease was primarily due to a $4.5 million decrease in clinical trial expenses, mainly attributed to a decrease in expenses in connection with Inhaled AAT, Type-1 Diabetes and Anti Rabies clinical trials as a result of their deferral to 2018, partially offset by an increase in labor costs. Research and development expenses accounted for approximately 11.6% and 21.0% of total revenues for the years ended December 31, 2017 and 2016, respectively.

Set forth below are the research and development expenses associated with our major development programs in the years ended December 31, 2017 and 2016:

	Year ended December 31,	
	2017	2016
	(U.S. Dollars in thousands)	
Inhaled AAT	$949	$2,695
AAT for newly diagnosed Type-1 Diabetes	475	2,320
AAT IV for lung transplantation rejection and for GvHD	734	194
Anti Rabies	340	1,772
Unallocated salary	6,413	5,237
Unallocated facility cost allocated to research and development	2,325	3,244
Unallocated other expenses	737	783
Total research and development expenses	$11,973	$16,245

Research and development expenses for Inhaled AAT for AATD decreased by $1.7 million in 2017 due to the completion of the clinical trial in 2016 and the withdrawal of the EMA application for Inhaled Alpha1-Antitrypsin in 2017. Research and development expenses for Type-1 Diabetes decreased by $1.8 in 2017 due to the completion of the clinical trial. Research and development expenses for Anti Rabies decreased by $1.4 million in 2017 as we received FDA approval of KEDRAB in 2017 for Post-Exposure Prophylaxis Against Rabies Infection. Unallocated expenses are expenses that are not managed by project and are allocated between various tasks that are not always related to a major project. In the years ended December 31, 2017 and 2016, we incurred $6.4 million and $5.2 million, respectively, of unallocated salary expenses, $2.3 million and $3.2 million, respectively, of facility costs allocated to improvements in processes and $0.7 million and $0.8 million, respectively, of unallocated other expenses.

Selling and Marketing Expenses

In the year ended December 31, 2017, we incurred $4.4 million of selling and marketing expenses, compared to $3.2 million in the year ended December 31, 2016, an increase of $1.2 million, or approximately 37.5%. This increase was primarily due to a $0.2 million increase in marketing support to distributors and a $0.4 million increase in regulatory fees. Selling and marketing expenses accounted for approximately 4.3% and 4.2% of total revenues for the years ended December 31, 2017 and 2016, respectively.

General and Administrative Expenses

In the year ended December 31, 2017, we incurred $8.3 million of general and administrative expenses, compared to $7.4 million in the year ended December 31, 2016, an increase of $0.9 million, or approximately 12.1%. This increase was primarily due to an increase of $0.7 million in labor costs and employee related expenses. General and administrative expenses accounted for approximately 8.0% and 9.5% of total revenues for the years ended December 31, 2017 and 2016, respectively.

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Financial Income

In each of the years ended December 31, 2017 and December 31, 2016 we generated $0.5 million of financial income from our short term investment portfolio.

Expense in respect of currency exchange differences and derivatives instruments

In the year ended December 31, 2017, we incurred $0.6 million of expenses in respect of currency exchange differences on balances in other currencies versus the U.S. dollar compared to income of $0.1 million in the year ended December 31, 2016.

Financial Expenses

In the year ended December 31, 2017, we incurred $0.2 million of financial expenses, compared to $0.1 million in the year ended December 31, 2016.

Taxes on Income

In the year ended December 31, 2017, we had $0.3 million taxes on income mainly due to surplus expenses. In the year the ended December 31, 2016, we had $1.7 million taxes on income mainly due to a settlement agreement with the Israel Tax Authority for the tax years 2004-2006, pursuant to which we paid $1.3 million.

Quarterly Results of Operations

The following tables set forth unaudited quarterly consolidated statements of operations data for the four quarters of fiscal years 2018 and 2017. We have prepared the statement of operations data for each of these quarters on the same basis as the audited consolidated financial statements included elsewhere in this Annual Report and, in the opinion of management, each statement of operations includes all adjustments, consisting solely of normal recurring adjustments, necessary for the fair statement of the results of operations for these periods. This information should be read in conjunction with the audited consolidated financial statements and related notes included elsewhere in this Annual Report. These quarterly operating results are not necessarily indicative of our operating results for any future period.

	Three Months Ended							
	December 31, 2018	September 30, 2018	June 30, 2018	March 31, 2018	December 31, 2017	September 30, 2017	June 30, 2017	March 31, 2017
	(U.S. Dollars in thousands)							
Revenues from Proprietary Products	$43,138	$ 9,454	$25,978	$12,214	$ 28,991	$ 17,058	$26,874	$6,636
Revenues from Distribution	5,073	5,521	7,864	5,227	6,719	5,860	5,675	5,012
Total revenues	48,211	14,975	33,842	17,441	35,710	22,918	32,549	11,648
Cost of revenues from Proprietary Products	22,290	7,869	16,458	6,179	18,608	11,509	16,053	5,165
Cost of revenues from Distribution	4,665	4,587	6,703	4,246	5,472	4,961	4,784	4,185
Total cost of revenues	26,955	12,456	23,161	10,425	24,080	16,470	20,837	9,350
Gross profit	21,256	2,519	10,681	7,016	11,630	6,448	11,712	2,298
Research and development expenses	2,573	2,323	2,097	2,754	1,917	3,418	3,487	3,151
	906	818	936	970	1,265	1,021	1,084	1,028

Selling and marketing expenses								
General and administrative expenses	2,393	1,902	2,166	2,064	2,003	2,323	2,117	1,830
Other expense (income)	-	-	311	-	-	-	-	-
Operating income (loss)	15,384	(2,524)	5,171	1,228	6,445	(314)	5,024	(3,711)
Financial income	192	214	185	229	234	92	96	78
Income (expense) in respect of currency exchange differences and derivatives, net	268	3	375	(44)	(133)	-	(245)	(234)
Financial expense	(43)	(84)	(56)	(157)	(112)	(14)	(13)	(23)
Income (loss) before taxes on income	15,801	(2,391)	5,675	1,256	6,434	(236)	4,862	(3,890)
Taxes on income	(1,944)	-	(11)	-	182	-	-	87
Net income (loss)	$17,745	$(2,391)	$5,686	$1,256	$6,252	$(236)	$4,862	$(3,977)

Liquidity and Capital Resources

Our primary uses of cash are to fund working capital requirements, research and development expenses and capital expenditures. 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 Tel Aviv Stock Exchange, our 2013 initial public offering in the United States and listing on Nasdaq and our 2017 underwritten public offering), and the issuance of convertible debentures and warrants to purchase our ordinary shares. The balance of cash and cash equivalents and short-term investments as of December 31, 2018, 2017 and 2016 totaled $50.6 million, $43.0 million and $28.6 million, respectively. We plan to fund our future operations through continued sales and distribution of our proprietary and distribution products, commercialization and or out-licensing of our pipeline product candidates, and raising additional capital through the issuance of equity or debt.

We have certain strategic partnership and distribution agreements under which we receive payments for the achievement of certain milestones. Since inception and through December 31, 2018, we received an aggregate of $48.5 million in payments under these agreements, and there are $5.5 million in payments under these agreements that we could potentially receive if we achieve additional milestones as set forth in such agreements. See “Item 4. Information on the Company— Strategic Partnerships — Takeda (Glassia).”

Our capital expenditures for the years ended December 31, 2018, 2017 and 2016 were $2.9 million, $4.1 million and $2.6 million, respectively. Our capital expenditures currently relate primarily to the maintenance and improvements of our facilities. We expect our capital expenditures to remain substantially similar in the near term as such capital expenditures are planned to be attributable mainly to the maintenance and improvements of our facilities.

We believe our current cash and cash equivalents and short-term investments will be sufficient to satisfy our liquidity requirements for the next 12 months.

Cash Flows from Operating Activities

Net cash provided by operating activities was $ 10.5 million for the year ended December 31, 2018. This net cash provided by operating activities reflects a net income of $22.3 million and non-cash expenses of $1.7 million and an increase in inventory of $8.2 million that we expect to sell in 2019.

Net cash provided by operating activities was $3.6 million for the year ended December 31, 2017. This net cash provided by operating activities reflects a net income of $6.9 million and non-cash expenses of $4.6 million and an increase in trade receivables of $9.9 million that were collected at the beginning of 2018.

Net cash provided by operating activities was $1.9 million for the year ended December 31, 2016. This net cash provided by operating activities reflects a net loss of $6.7 million and non-cash expenses of $5.7 million and a decrease in trade receivables of $3.5 million that were collected during 2016.

Cash Flows from Investing Activities

Net cash used in investing activities was $5.2 million for the year ended December 31, 2018. This net cash used in investing activities reflects $2.3 million net cash invested in short-term investments and investment in property, plant and equipment of $2.9 million.

Net cash used in investing activities was $15.6 million for the year ended December 31, 2017. This net cash used in investing activities reflects $11.5 million net cash invested in short-term investments and investment in property, plant and equipment of $4.2 million.

Net cash provided by investing activities was $1.6 million for the year ended December 31, 2016. This net cash provided by investing activities reflects $4.2 million net cash proceeds from sale of short-term investments, partially offset by investment in property, plant and equipment of $2.6 million.

Cash Flows from Financing Activities

Net cash used in financing activities was $0.6 million for the year ended 2018. This net cash used in financing activities reflects $0.6 million repayments of long-term loans.

Net cash provided by financing activities was $15.3 million for the year ended 2017. This net cash provided by financing activities reflects $15.6 million net proceeds from the issuance of shares offset by a $0.5 million repayment of long-term loans.

Net cash provided by financing activities was $1.5 million for the year ended 2016. This net cash provided by financing activities reflects a $1.5 million net receipt of long term loans. We have pledged specific assets which are the subject of those loans.

Contractual Obligations and Commitments

The following is a summary of our contractual obligations and commitments as of December 31, 2018 (in thousands):

	Total	Less than 1 Year	1 – 3 Years	4-5 Years	More than 5 Years
	(U.S. Dollars in thousands)				
Purchase commitments	42,268	-	-	-	-
Long-term debt obligations (1)	1,331	595	704	32	-
Operating lease obligations	5,434	983	1,411	1,807	1,233
Total	49,033	1,578	2,115	1,839	1,233

(1) Includes interest payments on our long term loans which bear annually fixed interest rate in the range of 3.15%-3.55%.

Purchase commitments are obligations under purchase agreements or purchase orders not yet fulfilled that are non-cancelable. Operating leases consist of contractual obligations from offices and vehicles leases agreements.

We are also obligated to make certain severance or pension payments to our Israeli employees upon their retirement under Israeli law. Due to the uncertainty of the timing of future cash flows associated with these payments (see Note 2q and Note 16 in our consolidated financial statements included in this Annual Report), we are unable to make reasonably reliable estimates for the period of cash settlement, if any, with respect to such obligations.

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Seasonality

We have experienced in the past, and expect to continue to experience, certain fluctuations in our quarterly revenues. Historically, our revenues have been strongest in our fourth quarter as compared to the rest of the quarters.

Off-Balance Sheet Arrangements

As of December 31, 2018, we have no off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to investors.

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. Significant 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.

While our significant accounting policies are more fully described in Note 2 to our consolidated financial statements appearing elsewhere in this Annual Report, we believe that the following accounting policies are the most critical for fully understanding and evaluating our financial condition and results of operations.

Revenue Recognition

Revenues are recognized in profit or loss when the revenues can be measured reliably, it is probable that the economic benefits associated with the transaction will flow to us and the costs incurred or to be incurred in respect of the transaction can be measured reliably. 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. The revenue recognition occurs at a point in time when control of the asset is transferred to the customer, generally on delivery of the goods. Customer payment terms are as acceptable in the industry. Some contracts with customers include variable consideration, such as a right of return, trade discounts or volume rebates. We recognize revenue from sale of goods measured at the fair value of the consideration received or receivable, net of returns and allowances, trade discounts and volume rebates and certain marketing contribution provided to our distributors. If revenue cannot be reliably measured, we defer revenue recognition until the uncertainty is resolved.

Agreements with strategic partners that include upfront and milestone payments contain a performance obligation that is satisfied over time given that the customer simultaneously receives and consumes the benefits provided by us. We recognize revenue for upfront payments over time rather than at a point of time. We identified the existence of a significant financing component resulting from an upfront payment and recorded revenue against finance expense in the financial statements for the year ended December 31, 2018.

We recognize revenues from the distribution of drugs in Israel manufactured by third-parties for clinical uses. If we were to operate or act as an agent or broker without being exposed to the risks and rewards associated with the transaction, our revenues would be presented on a net basis. However, we operate as a principal supplier and not as an agent or broker, and therefore, are exposed to the risks and rewards associated with the transaction. As such, our revenues are presented on a gross basis.

Clinical Trial Accruals and Related Expenses

We accrue and expense costs for clinical trial activities performed by third parties (or CROs), based upon estimates made as of the reporting date of the work completed over the life of the respective study in accordance with agreements established with the CRO. We determine the estimates of clinical activities incurred at the end of each reporting period through discussion with internal personnel and outside service providers as to the progress or stage of completion of trials or services, as of the end of each reporting period, pursuant to contracts with numerous clinical trial centers and CROs and the agreed upon fee to be paid for such services.

To date, we have not experienced significant changes in our estimates of clinical trial accruals after a reporting period. However, due to the nature of estimates, we cannot assure you that we will not make changes to our estimates in the future as we become aware of additional information about the status or conduct of our clinical trials.

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 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.

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.

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We had no impairment of non-financial assets in 2018.

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 shares).

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 shares.

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, 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 on the TASE. The price of our ordinary shares on the TASE 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, except for awards where vesting is conditional upon a market condition, which are treated as vesting irrespective of whether the market condition is satisfied, provided that all other vesting conditions (service and/or performance) are satisfied.

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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. See Note 2q and Note 16 in 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.

Accounting for Income Taxes

At the end of each reporting period, we are required to estimate our income taxes. There are transactions and calculations for which the ultimate tax determination is uncertain during the ordinary course of business, determined according to complex tax laws and regulations. Where the effect of these laws and regulations is unclear, we use estimates in determining the liability for the tax to be paid on our past profits, which we recognize in our financial statements. We believe the estimates, assumptions and judgments are reasonable, but this can involve complex issues which may take a number of years to resolve. Where the final tax outcome of these matters is different from the amounts that were initially recorded, such differences will impact the income tax and deferred income tax provisions in the period in which such determination is made. In addition, at the end of each reporting period, we estimate our ability to utilize our carryforward losses and accordingly account for the relevant amount of deferred taxes. When calculating the deferred tax asset, we estimate the effective tax rate to be applied for the years in which we expect the carryforward loss to be utilized, considering the impact of the Israeli Law for the Encouragement of Capital Investments, 1959 (as amended) and rulings that we received from the Israel Tax Authority.

Short-term investments

Our short-term bank investments include deposits that have a maturity of more than three months from the deposit date but less than one year and financial assets measured at fair value through other comprehensive income that include debt securities. Debt financial instruments are subsequently measured at fair value through profit or loss (“FVPL”), amortized cost or fair value through other comprehensive income (“FVOCI”). The classification is based on two criteria: our business model for managing the assets; and whether the instruments’ contractual cash flows represent solely payments of principal and interest on the principal amount outstanding (“SPPI”).

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The classification and measurement of our debt financial assets are as follows:

- Debt instruments measured at amortized cost for financial assets that are held within a business model with the objective to hold the financial assets in order to collect contractual cash flows that meet the SPPI criteria. This category includes our trade and other receivables.

- Debt instruments measured at FVOCI, with gains or losses recycled to profit or loss on the recognition. Financial assets in this category are our quoted debt instruments that meet the SPPI criteria and are held within a business model both to collect cash flows and to sell. Interest earned whilst holding available for sale financial investments is reported as interest income using the effective interest rate method.

Our policy is to record an allowance for expected credit loss ("ECL") for all debt financial assets not measured at FVPL. ECLs are based on the difference between the contractual cash flows due in accordance with the contract and the cash flows that we actually expect to receive. For other debt financial assets (i.e., debt securities measured at FVOCI), the ECL is based on the 12-month ECL. The 12-month ECL is the portion of lifetime ECLs that results from default events on a financial instrument that are possible within 12 months after the reporting date. As of December 31, 2018, we have not recorded an ECL allowance.

Item 6. Directors, Senior Management and Employees

Executive Officers and Directors

The following table sets forth certain information relating to our executive officers and directors as of February 27, 2019.

Name	Age	Position
Executive Officers:		
Amir London	50	Chief Executive Officer
Chaime Orlev	48	Chief Financial Officer
Michal Ayalon, PhD	52	Vice President, Research and Development and IP
Yael Brenner	55	Vice President, Quality
Eitan Kyiet	50	Vice President, Business and Development
Eran Nir	46	Vice President, Operations
Orit Pinchuk	54	Vice President, Regulatory Affairs and PVG
Ariella Raban	43	Vice President, Human Resources
Dr. Michal Stein	45	Vice President, Medical Director for Immunology
Dr. Naveh Tov	54	Vice President, Clinical Development and Medical Director for Pulmonary Diseases
Directors:		
Leon Recanati*	70	Chairman, Chairman of Compensation Committee
David Tsur	68	Director, Active Deputy Chairman
Dr. Michael Berelowitz*	74	Director
Avraham Berger*	67	Director, Chairman of Audit Committee
Asaf Frumerman*	34	Director
Jonathan Hahn	36	Director
Prof. Itzhak Krinsky, Ph.D*	67	Director
Efrat Makov*	50	Director
Shmuel (Milky) Rubinstein*	79	Director

* Independent director under the Nasdaq listing requirements.

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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 since December 2013. Mr. London brings with him over 20 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, a leading Israeli-based $350 million healthcare distribution company, and the General Manager of Cure Medical, from 2006 to 2009, 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. Prior to that, Mr. Orlev had served in senior finance roles for nearly 20 years, with approximately 12 years spent in the life sciences industry. Most recently, 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, orphan disease-focused 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 focused on treating rare and serious chronic diseases. In this role, Mr. Orlev helped lead the company’s 2015 over $100 million initial public offering and listing on Nasdaq, and participated in the negotiations and closing of the licensing agreement for the company’s lead product to F. Hoffmann-La Roche. Previously, Mr. Orlev was Chief Financial Officer at Oramed Pharmaceuticals Inc. (Nasdaq: ORMP), which has developed an innovative technology to transform injectable treatments into oral therapies. In this role, he led multiple capital raises. Mr. Orlev is a certified public accountant in Israel, holds an MBA degree from the Leon 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.

Dr. Michal Ayalon has served as our Vice President, Research and Development and IP since February 2019. Prior to joining us, from 2018 to 2019, Dr. Ayalon served as Head of R&D at 89bio Ltd., where Dr. Ayalon led the overall development strategy of the company and managed all R&D functions, including medical, clinical, pre-clinical, CMC, regulatory, and project management. Prior to that, from 2016 to 2018, Dr. Ayalon served as Project Champion at Teva Pharmaceutical Industries Ltd., , where she led novel biologics and biosimilar projects in oncology, respiratory and metabolic disease. In 2015, Dr. Ayalon served as Vice President of Research & Development at Galmed Pharmaceuticals Ltd., where she led the pre-clinical as well as CMC activities and managed the clinical operation group. Prior to that, Dr. Ayalon worked for Immune Pharmaceuticals, Inc. (from 2012 to 2015), BioLineRx and Compugen Ltd. Dr. Ayalon received her B.Sc., M.Sc. and Ph.D. from Tel-Aviv University, Faculty of Life Sciences. Dr. Ayalon completed her postdoctoral research at Weizmann Institute of Science in the Department of Molecular Biology of the Cell. Dr. Ayalon is the author of multiple patents and publications.

Yael Brenner has served as our Vice President, Quality since March 2015. Ms. Brenner has more than 20 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 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 in addition is a Certified Quality Engineer (CQE) from the American and Israeli Societies for Quality.

Eitan Kyiet has served as our Vice President, Business Development since October 2018. Prior to joining us, Mr. Kyiet served as Chief Operating Officer of PolyPid, a clinical stage emerging biopharmaceutical company. Earlier in his career, Mr. Kyiet served as a Director, Worldwide Supply Chain, at Biosense Webster (a Johnson & Johnson company), a leader in the diagnosis and treatment of heart arrhythmias. Prior to that, Mr. Kyiet served as Director,

Global Strategic Operations and Alliances, at Lumenis, Ltd., a leading medical equipment and laser device manufacturer. Mr. Kyiet began his career practicing corporate law, both as an associate and as a Partner at Amit, Pollak, Matalon & Co. Mr. Kyiet holds an LLB degree from Haifa University, Faculty of Law and an Executive M.B.A. degree from the Haifa Graduate Business School.

Eran Nir has served as our Vice President, Operations since November 1, 2016. Mr. Nir has over 14 years of operations management experience in the pharmaceutical and medical industries. Mr. Nir's recent roles include management of TEVA's Pharmaceutical 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 extensive 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 world-class operational excellence systems. Mr. Nir holds a B.Sc. degree in Industrial and Management Engineering and a MBA degree in Business Management, both from Ben-Gurion University.

Orit Pinchuk has served as our Vice President, Regulatory Affairs and PVG since October 2014. Ms. Pinchuk has experience of more than 20 years in the pharmaceutical industry, fulfilling key positions that cover, among others, disciplines of Regulatory Affairs and Compliance. Prior to joining Kamada, Ms. Pinchuk was at Teva Pharmaceuticals Industries, from 1993 to 2014, 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 extensive experience with FDA, EMA and Canada 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.

Ariella Raban has served as our Vice President, Human Resources since May 2018. Ms. Raban joined us in March 2014 and served as Human Resources Manager at our manufacturing facility in Beit Kama. Ms. Raban has more than a decade of expertise in different positions in the field of human resources in the pharmaceutical industry. Prior to joining us, Ms. Raban served as a Human Resources Manager at Teva Pharmaceuticals Industries Ltd. Ms. Raban holds a B.A. degree in Humanities Social Science from Ben-Gurion University.

Dr. Michal Stein has served as our Vice President, Medical Director for Immunology, since June 2017. Prior to that, from 2013 to 2017 Dr. Stein served as Medical Director at Sanofi-Aventis Israel Ltd. In this position, Dr. Stein led the medical affairs and pharmacovigilance departments, overseeing all aspects of product life-cycle management and compliance with pharmacovigilance regulations. From 2009 through 2013, Dr. Stein held multiple positions of increasing responsibility at Merck Sharp & Dohme, including Pharmacovigilance Country Lead, Medical & Scientific Liaisons Team Leader and Medical Affairs Manager, with expertise in vaccines, women's health and HIV. From 2005 through 2009, Dr. Stein served as Medical Affairs Manager, with expertise in oncology, at Roche Pharmaceuticals. Prior to that, from 2001 through 2005, Dr. Stein was a practicing physician in Israel, first at Rabin Medical Center, Belinson Campus, and then at Schneider Children's Medical Center. Dr. Stein holds an MD degree from Sackler school of Medicine, Tel Aviv University.

Dr. Naveh Tov has served as our Vice President, Clinical Development and Medical Director for Pulmonary Diseases, since July 2016. Prior to joining us, Dr. Tov has served as our Medical Director in a part- time consultancy role, from 2007. Dr. Tov served in both active hospital academic and clinical positions at Bnei Zion Medical Center, Haifa, Israel from 1994 through 2016. Dr. Tov specializes in Internal, Pulmonary and Sleep Medicine and served as Head of the Pulmonary Unit and as Deputy of Internal Ward C at Bnei Zion Medical Center, for 14 years from 2002 through 2016. During these years, Dr. Tov served in academia and held appointments at the Ruth and Bruce Rappaport Faculty of Medicine of The Technion – Israel Institute of Technology. Dr. Tov is a member of the American Thoracic Society and the European Respiratory Society. Dr. Tov holds an M.D. and a Ph.D. from the Ruth and Bruce Rappaport Faculty of Medicine of The Technion – Israel Institute of Technology.

Directors

Leon Recanati has served on our board of directors since May 2005 and has served as Chairman since March 2013. Mr. Recanati currently serves as a board member 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., GlenRock Medical, Gov Financial Holdings Ltd. ("Gov"), Govli Limited, Microbes Inc., RelTech Holdings

Ltd., Legov Ltd., Insight Capital Ltd., and Shavit Capital Funds. Mr. Recanati currently serves as Chairman and Chief Executive Officer of GlenRock. Previously, Mr. Recanati was Chief Executive Officer and/or Chairman of IDB Holding Corporation; 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 MBA 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 as Active Deputy Chairman of our board of directors since July 2015. Prior to that, Mr. Tsur served as our Chief Executive Officer and a director since our inception. Prior to co-founding Kamada in 1990, Mr. Tsur served as Chief Executive Officer of Arad Systems and RAD Chemicals Inc. Since January 2018, Mr. Tsur serves as a Chairman of the Board of Directors in 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 BA degree in Economics and International Relations and an MBA degree in Business Management, both from the Hebrew University of Jerusalem.

Dr. Michael Berelowitz has served on our board of directors since August 2015. Dr. Berelowitz brings over 40 years of clinical development and academic research experience, including 15 years of pharmaceutical development experience with Pfizer, Inc. From 2011 through 2015, Dr. Berelowitz served as a member of the board of directors of Endocrine Fellows Foundation. Dr. Berelowitz currently serves as the chair of the corporate governance and nominations committee and as a member of the audit committee of Recro Pharma, Inc. Dr. Berelowitz also currently serves as a member of the compensation committee of Oramed Pharmaceuticals Inc., where he has served on the board since May 2010. Since February 2017, Dr. Berelowitz has served as a member of the audit committee of Cellect Biotechnology Ltd. While at Pfizer, Dr. Berelowitz was Senior Vice President and Head of Clinical Development and Medical Affairs in the Specialty Care Business Unit. Dr. Berelowitz held various other roles at Pfizer, beginning as a Medical Director in the Diabetes Clinical Research team and then assuming positions of increasing responsibility. Prior to that, Dr. Berelowitz spent a number of years in academia and has held appointments at the University of Chicago, University of Cincinnati College of Medicine, SUNY at StonyBrook and, most recently, Mount Sinai School of Medicine. Dr. Berelowitz holds a MBChB degree from University of Cape Town- School of Medicine.

Avraham Berger has served on our board of directors since August 2016. Mr. Berger was initially elected as an external director (within the meaning of the Israeli Companies Law, 1999 (the “Companies Law”)) and served in such capacity until January 30, 2017, since which time he has served as an ordinary (non-external) director. Until 2014, Mr. Berger served as a senior partner and chief executive officer of PwC Israel, for more than 20 years. Mr. Berger joined PwC Israel in 1976 and led it from 1991. Mr. Berger has vast experience in mergers and acquisitions and complex public offerings, both in Israel and abroad. Mr. Berger lectures at professional forums and has published several articles in the professional press. Mr. Berger also serves as Chairman of the board of directors of TopAudio Ltd. and serves as director on the board of Weizmann Institute of Science. Mr. Berger holds a BA degree in Accounting and Economics awarded from Tel Aviv University and is a certified public accountant in Israel.

Asaf Frumerman has served on our board of directors since December 2017. Mr. Frumerman is a partner at Brosh Capital Partners L.P. Prior to that, Mr. Frumerman served as an analyst at The Dragon Variation Fund, and as an accountant at A. Frumerman & Co., from 2011 to 2013. From 2010 to 2011, Mr. Frumerman served as a counsel at Ernst & Young (Israel) Ltd. Mr. Frumerman holds a BA degree in Accounting and LLB degree from the College of Management.

Jonathan Hahn has served on our board of directors since March 2010. Mr. Hahn serves as the President and a director of Tuteur where he has been since 2013. Prior to that, Mr. Hahn served as Strategic Planning Manager at Tuteur and held a business development position at Forest Laboratories, Inc., based in New York. Mr. Hahn holds a BA degree from San Andrés University and an MBA degree from New York University — Stern School of Business, with specializations in Finance and Entrepreneurship.

Prof. (Emeritus) Itzhak Krinsky, Ph.D, has served on our board of directors since December 2017. Prof. Krinsky has broad-based expertise in the pharmaceutical industry, years of experience in investment banking, and a distinguished academic career in finance and business economics. Prof. Krinsky developed extensive knowledge of the pharmaceutical industry during his 12 years of working at Teva Pharmaceutical Industries Ltd., from which he retired a few years ago. During his tenure at Teva, Prof. Krinsky served as Executive Vice President, Corporate Business Development, a member of the Teva Executive Committee, Chairman of Teva Japan, Chairman of Teva South Korea, and Head of Business Development Asia Pacific. Prior to joining Teva, Prof. Krinsky held various senior positions at investment banks in New York City, including with Bankers Trust, Deutsche Bank, and the Silverfern Group, Inc. Before his career on Wall Street, Prof. Krinsky was a Professor of Finance and Business Economics at the Michael G. DeGroote School of Business, McMaster University, Ontario, Canada. Prof. Krinsky has published more than 80 articles in leading peer reviewed academic journals. Prof. Krinsky currently serves as a director in several private and public companies, including Globrands Ltd. since July 2018; Wavelength Pharmaceuticals since October 2017; Achellos Therapeutics and Exodos Life Sciences Limited Partnership, both since April 2017; Noramco Inc. since September 2018; and PolyPid Ltd. since December 2018. In 2014, Prof. Krinsky was named by SCRIP as one of the top 100 Global Leaders in the Pharmaceutical Industry. Prof. Krinsky received BA and MA degrees in Economics from Tel Aviv University, Israel and a Ph.D. in Economics from McMaster University in Canada.

Efrat Makov has served on our board of directors since December 2018. Ms. Makov serves as a director of BioLight Life Sciences Ltd. (TASE: BOLT) (formerly Bio Light Israeli Life Sciences Investments Ltd.), an emerging global ophthalmic company, since April 2011. Ms. Makov also serves as a director of Anchiano Therapeutics Ltd. (TASE: ANCN) (formerly BioCanCell Ltd.), a clinical-stage biopharmaceutical company. Ms. Makov served as the Chief Financial Officer of Alvarion Ltd. (formerly Nasdaq; TASE: ALVR), a global provider of autonomous Wi-Fi networks, from April 2007 to December 2010. Ms. Makov served as the Chief Financial Officer of Aladdin Knowledge Systems Ltd. (formerly Nasdaq; TASE: ALDN) (n/k/a Safenet, Inc.), an information security leader specializing in authentication, software DRM and content security, from September 2005 to January 2007, where she was responsible for the finance, operations, information systems and human resources functions. Prior to that, Ms. Makov served in management positions at two Israeli-based public companies, including as Vice President of Finance at Check Point Software Technologies Ltd. (Nasdaq: CHKP), a worldwide leader in IT security, from September 2002 to August 2005. Ms. Makov served as Director of Finance for NUR Macroprinters Ltd. (formerly Nasdaq: NURM) (n/k/a Ellomay Capital), from August 2000 to August 2002. Prior to that, Ms. Makov spent seven years in public accounting with Arthur Andersen LLP in its New York, London and Tel Aviv offices. Ms. Makov holds a B.A. degree in Accounting and Economics from Tel Aviv University and is a certified public accountant in Israel and the United States.

Shmuel (Milky) Rubinstein has served on our board of directors since December 2017. Mr. Rubinstein has served as an external director of Clal Biotechnology Industries Ltd. since 2011. In addition, Mr. Rubinstein currently serves on the board of the directors of several companies, including Exalenz Breathtaking Solutions Ltd., since 2008, Medison Biotech Ltd., since 2011, Trima Pharma Ltd., since 2015, the National Authority for Yiddish Culture since 2014, and Ichilov Health Corporation since September 2017. Mr. Rubinstein serves as a member of the advisory board of Sol-Gel Ltd., since 2016. Mr. Rubinstein served as the Chairman of the board of directors of Tiltan Pharma Ltd. from 2015 until June 2017. Mr. Rubinstein served as the Chief Executive Officer and General Manager of Taro Pharmaceuticals Industries Ltd. (NYSE:TARO) from 1990 to 2010. Mr. Rubinstein also acts as a consultant to several companies, including startup companies and for BDO. In 2003, Mr. Rubinstein received the Industry Award from the Manufacturers Association of Israel. Mr. Rubinstein is a graduate of the International Marketing Course of the Wharton School of Business, Philadelphia, the United States.

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.”

Board of Directors

Under our articles of association, the number of directors on our board of directors must be no less than five and no more than 11. Our board of directors currently consists of nine directors, seven of whom 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.

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 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.

A general meeting of our shareholders may remove a director 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.

Alternate Directors

As permitted under the Companies Law, our articles of association provide that any director may, subject to the board of directors' approval, by written notice to us, appoint another person who is qualified to serve as a director to serve as an alternate director. Under the Companies Law, a person who is not qualified to be appointed as a director, a person who is already serving as a director or a person who is already serving as an alternate director may not be appointed as an alternate director. Nevertheless, a director may be appointed as an alternate director for a member of a committee of the board of directors so long as he or she is not already serving as a member of such committee. Similarly, an independent director within the meaning of the Companies Law may not appoint an alternate director unless such alternate director is eligible to be an independent director within the meaning of the Companies Law. An alternate director may be appointed for one meeting of the board of directors or until notice is given of the cancellation of the appointment.

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.

However, according to a recent amendment 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 (i) the requirement to appoint external directors and that one external director serve on each committee of the board of directors authorized to exercise any of the powers of the board of directors; (ii) certain limitations on the employment or service of an external director or his or her spouse, children or other relatives, following the cessation of the service as an outside director, by or for the company, its controlling shareholder or an entity controlled by the controlling shareholder; (iii) the composition, meetings and quorum of the audit committee; and (iv) the composition and meetings of the compensation committee. 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. According to the exemption, an external director serving at the time a company elects to adopt the exemption may continue to serve as an "ordinary" (non-external) director until the earlier of (i) the end of his/her term and (ii) the second annual general meeting after the adoption of the exemption (and thereafter may be re-elected for multiple terms), despite the two year "cooling off period during which former external directors are generally prohibited from serving in any capacity for an Israeli company following external director service.

On January 30, 2017, following analysis of our qualification to rely on the exemption, our board of directors determined to adopt the exemption. If in the future we were to have a controlling shareholder, we would again be required to comply with the requirements relating to external directors and the composition of the audit committee and compensation committee under Israeli law.

Audit Committee

We have an audit committee consisting of Mr. Avraham Berger, Ms. Efrat Makov and Mr. Shmuel (Milky) Rubinstein. Mr. Avraham Berger serves as the chairman of the audit committee.

According to the recent amendment to regulations promulgated under the Companies Law described above, an Israeli 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 (within the meaning of the Companies Law), such as ourselves, 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 Companies Law with respect to (among other things) the composition, quorum and majority requirements at meetings of the audit committee. On January 30, 2017, following analysis of our qualification to rely on the exemption, our Board of Directors determined to adopt the exemption.

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 Avraham Berger 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 Mr. Leon Recanati, Mr. Avraham Berger, Mr. Asaf Frumerman and Prof. Itzhak Krinsky, Mr. Recanati serves as the chairman of the compensation committee.

According to the recent amendment to regulations promulgated under the Companies Law described above, an Israeli 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 the Companies Law with respect to (among other things) the composition and meetings of the compensation committee. On January 30, 2017, following analysis of our qualification to rely on the exemption, our Board of Directors determined to adopt the exemption.

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.

We rely on the "foreign private issuer exemption" with respect to the Nasdaq requirement to have a formal charter for the compensation committee.

Research and Development Committee

Our board of directors recently established a research and development committee, which currently consists of Mr. Michael Berelowitz, Mr. Shmuel (Milky) Rubinstein and Mr. David Tsur. Mr. Berelowitz serves as the chairman of the research and development committee. The research and development committee assists the board of directors with oversight of our research and development strategy, the pipeline, the research and development function and other tasks as specifically decided by the board of directors.

Strategy Committee

Our strategy committee currently consists of Mr. Jonathan Hahn and Prof. Itzhak Krinsky, who serve as joint chairmen, Mr. David Tsur, Ms. Efrat Makov and Dr. Michael Berelowitz. Our strategy committee is responsible for directing our management in carrying out its various responsibilities related to our company's long-term strategy, financial initiatives and strategic transactions.

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. Linur Dloomy of Brightman Almagor Zohar & Co. (a member firm of Deloitte Touche Tohmatsu) 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 considered 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. 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:

- 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.

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 was approved by our shareholders on August 30, 2016 and was amended by our shareholders on November 30, 2017 and December 20, 2018. Our compensation Policy applies to the following office holders: the chief executive officer, members of our executive management, each person fulfilling such positions even if his or her title is different, and directors. The compensation policy has been drafted and approved in accordance with the requirements of the Companies Law and determines (among other things) the amount of the

compensation of our office holders, its components, the maximum values for the various components of compensation, and the method for determining compensation.

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Compensation of Directors

We pay our directors (other than Asaf Frumerman) 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 all of our directors (other than Asaf Frumerman) an annual fee of NIS 84,850 (approximately $22,639), as well as a fee of NIS 3,270 (approximately $872) for each board or committee meeting attended in person, NIS 1,962 (approximately $523) for each board or committee meeting attended via telephone or videoconference and NIS 1,635 (approximately $436) for participation by written consent.

We pay Mr. Tsur, in consideration for his services as Active Deputy Chairman on a half-time basis, in which capacity he has served since July 1, 2015, a monthly gross salary of NIS 45,000 (approximately $12,006), in addition to the annual fee and per-meeting fees described above. Mr. Tsur is entitled to annual leave in accordance with Israeli law. Either Mr. Tsur or we may terminate Mr. Tsur's engagement as Active Deputy Chairman upon six months prior written notice (payment in lieu of such notice period is permitted at our discretion). In the event of termination of Mr. Tsur's engagement as Active Deputy Chairman by us other than for cause, Mr. Tsur shall be entitled to six gross monthly salaries, as well as additional deposits into his manager's insurance policy.

From time to time, we grant options to directors. Most recently, in accordance with our shareholders' approval, on December 20, 2018, we granted : (i) to each of our directors serving in such capacity prior to the 2018 annual general meeting and who were re-elected to serve as directors at the meeting (other than Mr. Asaf Frumerman), (1) options to purchase 5,000 ordinary shares, exercisable on a cashless basis based on an exercise price of NIS 18.93 (approximately $5.04) per share; and (2) options to purchase 10,000 ordinary shares, exercisable on a cashless basis based on an exercise price of NIS 22.54 (approximately $6) per share (where, in each case, the exercise price is equal to the higher of (a) the average closing price of our ordinary shares on the TASE during the 30 trading days prior to the applicable date of the approval of the respective option grant by our board of directors plus 5% and (b) the closing price of our ordinary shares on the TASE on the applicable date of the approval of the respective option grant by our board of directors); and (ii) to Ms. Efrat Makov, who stood for election as a director for the first time at the 2018 annual general meeting, options to purchase 5,000 ordinary shares, exercisable on a cashless basis based on an exercise price of NIS 20.14 (approximately $5.36) per share (which is equal to the higher of (a) the average closing price of our ordinary shares on the TASE during the 30 trading days prior to the date of the approval of the option grant by our shareholders at the meeting plus 5% and (b) the closing price of our ordinary shares on the TASE on the date of the approval of the option grant by our shareholders at the meeting). The foregoing options will vest over a period of four years in 13 installments: 25% of the options will vest on the first anniversary of the grant date and 6.25% of the remaining options will vest at the end of each quarter thereafter. The options will be exercisable for 6.5 years following the date of grant and all unexercised options will expire immediately thereafter. The options were granted under the 2011 Israeli Share Option Plan. The foregoing terms are in accordance with our compensation policy, as amended by our shareholders at the general meeting held on December 20, 2018.

Except with respect to Mr. David Tsur, our Active Deputy Chairman, as described above, 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.

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 Executive Officers

The aggregate compensation incurred by us in relation to our executive officers and our Active Deputy Chairman of the Board of Directors, including share-based compensation, for the year ended December 31, 2018, was approximately $3.1 million. This amount includes approximately $256,000 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.

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, Clinical Development and Medical Director for Pulmonary Diseases, Vice President, Research and Development and IP and Vice President, Regulatory Affairs and PVG, as of December 31, 2018.

Name and Position	Salary	Bonus[1]	Value of Options Granted[2]	Other[3]	Total
	(in thousands)				
Amir London Chief Executive Officer	$327,408	$139,527	$ 56,614	$25,819	$549,368
Dr. Naveh Tov Vice President, Clinical Development and Medical Director for Pulmonary Diseases	$231,767	$39,288	$ 29,769	$15,173	$315,997
Chaime Orlev Chief Financial Officer	$217,441	$38,554	$ 32,238	$17,469	$305,702

Dr. Liliana Bar[4]					
Former Vice President, Research and Development and IP	$214,112	$64,534	$ 1,117	$17,191	$296,954
Eran Nir					
Vice President Operations	$198,987	$35,616	$ 32,701	$20,908	$288,212

(1) The annual bonus is subject to the fulfillment of certain targets determined for each year by the compensation committee and board of directors.

(2) The value of options is the expense recorded in our financial statements for the period ended December 31, 2018 with respect to all options granted to such executive officer.

(3) Cost of use of company car.

(4) Dr. Bar ceased to serve as our Vice President, Research and Development and IP in January 2019.

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) 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.

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.

Under the Companies Law, 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.

Agreements with Five Most Highly Compensated Senior 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 "— 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. Except for David Tsur, our Active Deputy Chairman, 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 (for our chief executive officer) and by our chief executive officer (for the other office holders). In addition, all such executive officers are entitled to a company car, as well as sick pay, convalescence pay, manager's insurance and a study fund ("keren hishtalmut"), all in accordance with Israeli law, and annual leave.

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, the Board of Directors and our 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.

Dr. Naveh Tov, Vice President, Clinical Development and Medical Director for Pulmonary Diseases. Effective as of July 2016, we entered into an employment agreement with Dr. Naveh Tov with respect to his employment as our Vice President, Clinical Development and Medical Director for Pulmonary Diseases. 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.

Dr. Liliana Bar, Former Vice President, Research and Development and IP. Effective as of June 17, 2012, we entered into an employment agreement with Dr. Liliana Bar with respect to her employment as our Vice President, Research and Development and IP. Either party was entitled to terminate the agreement at any time upon two months' prior written notice to the other party, and we were entitled to terminate the agreement immediately for cause in accordance with Israeli law. In January 2019, Dr. Bar ceased to serve in such position and her employment with our company terminated.

Eran Nir, Vice President Operations. Effective as of November 1, 2016, we entered into an employment agreement with Mr. Eran Nir with respect to his employment as our Vice President, Operations. 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.

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 are also entitled to special bonuses upon the achievement of certain company milestones.

Employees

As of December 31, 2018, we employed 408 employees, according to the following division: 202 in Operations, 104 in Quality, 20 in Research and Development, 17 in Regulation, 19 in Business Development, 8 in Medical & Clinical, 14 in Human Resources & Administration and 24 in Finance (our Procurement Department merged into the Finance department). As of December 31, 2017, we employed 413 employees, according to the following division: 199 in Operations, 104 in Quality, 21 in Research and Development, 20 in Regulation, 16 in Business Development, 12 in Medical & Clinical, 16 in Human Resources & Administration and 25 in Finance (our Procurement Department merged into the Finance department). As of December 31, 2016, we employed 377 employees, according to the following division: 193 in Operations (including Procurement Department), 92 in Quality, 19 in Research and Development, 19 in Regulation, 17 in Business Development, 8 in Medical, 14 in Human Resources and 15 in Finance.

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 July 2018, during the course of our negotiations with the Histadrut and the employees' committee on the extension of the collective bargaining agreement beyond the December 2017 expiration, the employee's committee commenced a labor strike, which continued for approximately one month. In November 2018, we signed a new collective bargaining agreement with the employees' committee and the Histadrut, which will expire in December 2021. Approximately 59% of our employees, all of whom are located at our Beit Kama facility, currently work under the collective bargaining agreement signed in November 2018. The collective bargaining agreement governs certain aspects of our employee-employer relations, such as: firing procedures, annual salary raise, eligibility for certain compensation terms and welfare.

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 Israel Ministry of Economy and Industry (formerly named the Ministry of Industry, Trade and Labor) 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.

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 40,295,078 ordinary shares outstanding as of February 26, 2019 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 options exercisable into ordinary shares within 60 days of the date of this Annual Report 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. They are not, however, deemed to be outstanding and beneficially owned for the purpose of computing the percentage ownership of any other shareholder.

Name	Number	Percentage	
Amir London (1)	206,375	*	
Chaime Orlev (2)	11,805	*	
Michal Ayalon	-	-	
Yael Brenner (3)	40,526	*	
Eitan Kyiet (4)	5,000	*	
Eran Nir (5)	20,597	*	
Orit Pinchuk (6)	43,025	*	
Ariella Raban (7)	18,189	*	
Dr. Michal Stein (8)	12,588	*	
Dr. Naveh Tov (9)	30,350	*	
Leon Recanati (10)	4,025,936	9.98	%
David Tsur (11)	1,079,100	2.66	%
Dr. Michael Berelowitz (12)	4,688	*	
Avraham Berger (13)	4,688	*	
Asaf Frumerman(14)	-	-	
Jonathan Hahn (15)	3,095,188	7.68	%
Prof. Itzhak Krinsky, Ph.D (16)	5,250	*	
Efrat Makov	-	-	
Shmuel (Milky) Rubinstein (17)	4,383	*	
Directors and Executive Officers as a group (19 persons)	8,650,186	21.09	%

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* Less than 1% of our ordinary shares.

(1) Includes 4,875 ordinary shares, 37,125 restricted shares and options to purchase 164,375 ordinary shares exercisable within 60 days of the date of this Annual Report, at a weighted average exercise price of NIS 25.00 (or $6.67) per share, which expire between May 15, 2020 and June 20, 2025. Does not include unvested options to purchase 109,125 ordinary shares that are not exercisable within 60 days of this Annual Report.

(2) Represents 11,805 restricted shares. Does not include unvested options to purchase 19,794 ordinary shares that are not exercisable within 60 days of this Annual Report.

(3) Includes 1,959 ordinary shares, 6,441 restricted shares and options to purchase 32,126 ordinary shares exercisable within 60 days of the date of this Annual Report, at a weighted average exercise price of NIS 18.49 (or $4.93) per share, which expire between October 27, 2021 and December 27, 2024. Does not include unvested options to purchase 18,075 ordinary shares that are not exercisable within 60 days of this Annual Report.

(4) Represents 5,000 restricted shares.

(5) Represents 2,915 ordinary shares, 7,651 restricted shares and options to purchase 10,031 ordinary shares exercisable within 60 days of the date of this Annual Report, at an exercise price of NIS 21.74 (or $5.80) per share, which expire between May 24, 2023 and December 27, 2024. Does not include unvested options to purchase

21,669 ordinary shares that are not exercisable within 60 days of this Annual Report.

(6) Includes 1,959 ordinary shares, 6,441 restricted shares and options to purchase 34,625 ordinary shares exercisable within 60 days of the date of this Annual Report, at an exercise price of NIS 39.36 (or $10.50) per share, which expire between July 13, 2020 and December 27, 2024. Does not include unvested options to purchase 18,076 ordinary shares that are not exercisable within 60 days of this Annual Report.

(7) Includes 313 ordinary shares, 5,687 restricted shares and options to purchase 12,189 ordinary shares exercisable within 60 days of the date of this Annual Report, at an exercise price of NIS 47.18 (or $13.61) per share, which expire between October 27, 2021 and December 27, 2024. Does not include unvested options to purchase 17,812 ordinary shares that are not exercisable within 60 days of this Annual Report

(8) Includes 1,302 ordinary shares, 6,598 restricted shares and options to purchase 4,688 ordinary shares exercisable within 60 days of the date of this Annual Report, at an exercise price of NIS 20.94 (or $5.59) per share, which expire between May 14, 2020 and December 27, 2024. Does not include unvested options to purchase 19,012 ordinary shares that are not exercisable within 60 days of this Annual Report.

(9) Includes 3,176 ordinary shares, 7,391 restricted shares and options to purchase 19,783 ordinary shares exercisable within 60 days of the date of this Annual Report, at an exercise price of NIS 27.19 (or $7.26) per share, which expire between May 15, 2020 and December 27, 2024. Does not include unvested options to purchase 19,919 ordinary shares that are not exercisable within 60 days of this Annual Report.

(10) Mr. Recanati holds 677,479 ordinary shares directly and 3,295,644 ordinary shares indirectly through Gov. Gov is wholly-owned by Mr. Recanati, the Chairman of our board of directors, who exercises sole voting and investment power over the shares held by Gov. In addition, includes options to purchase 52,813 ordinary shares exercisable within 60 days of the date of this Annual Report, at an exercise price of NIS 47.35 (or $12.63) per share, which expire between May 14, 2020 and June 20, 2025. Does not include unvested options to purchase 22,188 ordinary shares that are not exercisable within 60 days of this Annual Report.

(11) Mr. David Tsur directly holds 771,287 ordinary shares and options to purchase 307,813 ordinary shares exercisable within 60 days of the date of this Annual Report, at a weighted average exercise price of NIS 48.38 (or $12.91) per share, which expire between November 30, 2019 and June 20, 2025. Does not include unvested options to purchase 22,188 ordinary shares that are not exercisable within 60 days of this Annual Report.

(12) Subject to options to purchase 4,688 ordinary shares exercisable within 60 days of the date of this Annual Report, at a weighted average exercise price of NIS 17.46 (or $4.66) per share, which expire between March 2, 2023 and June 20, 2025. Does not include unvested options to purchase 20,313 ordinary shares that are not exercisable within 60 days of this Annual Report.

(13) Subject to options to purchase 4,688 ordinary shares exercisable within 60 days of the date of this Annual Report, at a weighted average exercise price of NIS 17.46 (or $4.66) per share, which expire between March 2, 2023 and June 20, 2025. Does not include unvested options to purchase 20,313 ordinary shares that are not exercisable within 60 days of this Annual Report.

(14) We were informed by Mr. Frumerman that he is a partner at Brosh Capital Partners L.P. For information regarding the holdings of the Brosh Capital Partners group, see “Item 7. Major Shareholders and Related Party Transactions — Major Shareholders.”

(15) Mr. Jonathan Hahn directly holds 313,841 ordinary shares and options to purchase 29,686 ordinary shares exercisable within 60 days of this Annual Report, at an exercise price of NIS 44.28 (or $11.81) per share, which expire between May 14, 2020 and June 20, 2025. In addition, we were informed that Mr. Hahn holds 25% of the shares of Sinara Financing S.A. (“Sinara”), which holds 100% of the shares of Damar, which directly holds 2,751,661 ordinary shares. We were informed that additional 50% of the shares of Sinara are held by Mr. Hahn’s

siblings, who also directly hold an aggregate 576,649 ordinary shares. Does not include unvested options to purchase 20,316 ordinary shares that are not exercisable within 60 days of this Annual Report.

(16) Prof. Krinsky holds 5,250 ordinary shares directly. Does not include unvested options to purchase 15,000 ordinary shares that are not exercisable within 60 days of this Annual Report.

(17) Mr. Rubinstein holds 4,383 ordinary shares directly.

Equity Compensation Plans

In 2005, we adopted our 2005 Israeli Share Option Plan (the "2005 Plan"). We ceased to grant options under the 2005 Plan in 2010 and the 2005 Plan expired on July 5, 2015.

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"). Under the 2011 Plan, we are authorized to grant options and restricted shares 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, which is effective until July 23, 2021, is designed to reflect the provisions of the Israeli Tax Ordinance, which affords certain tax advantages to Israeli employees, officers and directors that are granted options 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.

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 each option granted under the 2011 Plan is equal to 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. The exercise price of options granted to directors and officers under the 2011 Plan is equal to the 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%. Options granted under the 2011 Plan are exercised by way of cashless exercise and accordingly, the grantee is not required to pay the exercise price when exercising the options and instead, receives upon exercise such number of ordinary shares with a total fair market value equal to the difference between the total fair market value of the ordinary shares underlying the exercised options and the total purchase price for such options.

The options granted under the 2011 Plan 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 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 all of the 90-day period is a 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 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.

Beginning in 2016, we have also granted restricted shares to our officers. The restricted shares awarded under the 2011 Plan generally vest over a period of four years in 13 installments: 25% of the restricted shares vest on the first anniversary of the grant date and 6.25% of the remaining restricted shares 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 assets, awards then outstanding under the 2011 Plan shall be assumed or substituted for shares or other securities of the surviving or acquiring entity as were distributed to our shareholders in connection and the transaction, subject to an appropriate adjustment to the exercise price (if applicable). 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 shares granted to our employees 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 shares 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, 2018, an aggregate of 500,886 ordinary shares were reserved for future issuance under the 2011 Plan (subject to certain adjustments specified in the 2011 Plan), and options to purchase 2,445,597 ordinary shares were outstanding under the 2011 Plan and 139,706 restricted shares were outstanding under the 2011 Plan. Any ordinary shares underlying options that expire prior to exercise or restricted shares that are forfeited under the 2011 Plan will become again available for issuance under the 2011 Plan.

Item 7. Major Shareholders and Related Party Transactions

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 40,295,078 ordinary shares outstanding as of February 26, 2019. 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 options exercisable into ordinary shares within 60 days of the date of this Annual Report 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. 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	
Leon Recanati(1)	4,025,617	9.98	%
Hahn Family(2)	3,671,837	9.11	%
Meitav Dash Investments Ltd. (3)	3,514,556	8.72	%
Brosh Capital Partners L.P.(4)	3,094,721	7.68	%
The Phoenix Holding Ltd.(5)	2,787,346	6.92	%

(1) Mr. Recanati holds 677,479 ordinary shares directly and 3,295,644 ordinary shares indirectly through Gov. Gov is wholly-owned by Mr. Recanati, the Chairman of our Board of Directors, who exercises sole voting and investment power over the shares held by Gov. In addition, includes options to purchase 52,494 ordinary shares exercisable within 60 days of the date of this Annual Report, at an exercise price of NIS 47.35 (or $12.63) per share, which expire between May 14, 2020 and June 20, 2025. Does not include unvested options to purchase 22,188 ordinary

shares that are not exercisable within 60 days of this Annual Report.

(2) According to Amendment No. 5 to Schedule 13G filed with the SEC on February 14, 2019, Damar, a company registered in Panama, directly holds 2,751,661 ordinary shares. According to the Statement, Damar is wholly-owned by Sinara Financing S.A., which is jointly owned by Mr. Jonathan Hahn, Ms. Tamar Hahn, Mr. Nicolas Hahn and the Fundacion Martinez. In addition, according to the Schedule 13G/A, Mr. Jonathan Hahn directly holds 313,841 ordinary shares, Ms. Tamar Hahn directly holds 288,324 ordinary shares and Mr. Nicolas Rodolfo Hahn directly holds 288,325 ordinary shares. Includes options to purchase 29,366 ordinary shares directly held by Mr. Jonathan Hahn that are exercisable within 60 days of the date of the table, at a weighted average exercise price of NIS 44.28 (or $11.81) per share, which expire between May 14, 2020 and May 30, 2024. Does not include unvested options to purchase 20,316 ordinary shares held by Mr. Jonathan Hahn that are not exercisable within 60 days of the date of the table.

(3) According to Amendment No.6 to Schedule 13G filed on February 7, 2019, the reported securities are beneficially owned by various direct or indirect majority or wholly-owned subsidiaries of Meitav Dash Investments Ltd.

(4) Based solely upon, and qualified in its entirety with reference to, Amendment No. 2 to Schedule 13D filed with the SEC on November 13, 2017. According to the Schedule 13D, (a) Brosh Capital Partners, L.P., a Cayman Islands limited partnership ("Brosh"), beneficially owns 2,411,175 ordinary shares; (b) Exodus Management Israel Ltd., an Israeli company, which serves as the general partner of Brosh ("Exodus GP") and as portfolio manager for a certain managed account (the "Exodus Managed Account"), may be deemed the beneficial owner of the (i) 2,411,175 ordinary shares directly owned by Brosh and (ii) 155,719 ordinary shares held in the Exodus Managed Account; (c) Mr. Amir Efrati, as the portfolio manager of each of Brosh and Exodus GP and because of certain Power of Attorney Agreements between him and each of Mr. Aharon Biram and Ms. Deutsch, may be deemed the beneficial owner of the (i) 2,411,175 ordinary shares owned by Brosh, (ii) 155,719 ordinary shares held in the Exodus Managed Account, (iii) 233,653 ordinary shares owned by Mr. Biram and (iv) 294,174 ordinary shares owned by Ms. Esther Deutsch; (d) Mr. Aharon Biram beneficially owns 233,653 ordinary shares; and (e) Ms. Esther Deutsch beneficially owns 294,174 ordinary shares.

(5) Based solely upon, and qualified in its entirety with reference to Amendment No. 5 to Schedule 13G filed with the SEC on February 14, 2019. According to the Statement, the shares are beneficially owned by various direct or indirect, majority or wholly-owned subsidiaries of the Phoenix Holding Ltd. The Phoenix Holding Ltd. is a controlled subsidiary of Delek Group Ltd. The majority of Delek Group Ltd.'s outstanding shares and voting rights are owned, directly and indirectly, by Itshak Sharon (Tshuva) through private companies wholly-owned by him, and the remainder is held by the public. Each of the reporting persons disclaims beneficial ownership of the reported shares in excess of their actual pecuniary interest therein.

To our knowledge, based on information provided to us by our transfer agent in the United States, as of February 27, 2019, we had one shareholder of record who was registered with an address in the United States, holding approximately 25.37 % 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, the only significant changes in the percentage ownership held by our major shareholders during the past three years have been the following: From January 1, 2016 to the date of this Annual Report, the ownership percentage of Hahn family decreased by 1.68% from 10.79% to 9.11%. Mr. Leon Recanati's ownership percentage decreased by 0.93% from 10.91% to 9.98% during such period. The Phoenix Holdings Group ownership percentage decreased by 0.91% from 7.83% to 6.92% during such period. The DS Apex group's ownership percentage increased by 1.45% from 7.83% to 8.72% during such period. The Brosh Capital Partners group's ownership percentage increased from less than 5% to 7.68% during such period.

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.

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Related Party Transactions

Tuteur S.A.C.I.F.I.A.

In August 2011, we entered into a distribution agreement with Tuteur that amends and restates a distribution agreement we entered into in November 2001. 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. Hahn's son, Mr. Jonathan Hahn, a director, is currently the President and a director of Tuteur. The amendment to the agreement was made as an arm's length transaction, in connection with the expected completion of Glassia's registration in Argentina and the commencement of its marketing in Argentina. On August 19, 2014, we entered into an amendment to the distribution agreement in order to add KamRho(D) as an additional product to be distributed by Tuteur and expanded the territories to include Bolivia. On January 21, 2019, we entered into an additional amendment to the distribution agreement in order to change the terms of payments by Tuteur, change the terms of shipment, appoint a sub-distributor in Paraguay and to extend a fixed discount for the Glassia, per vial, sale price in exchange for obtaining a bank guarantee from Tuteur to cover any future supply of products. Pursuant to the distribution agreement, as amended, Tuteur serves as the exclusive distributor of Glassia and KamRho(D), in Argentina, Paraguay and Bolivia. Tuteur is obligated under the agreement to commence marketing, sales and distribution of the products within each country covered by the agreement within two months after the grant of regulatory approval in each such country. Commencing the second year following the date that Tuteur commences sales of the product in Argentina, Tuteur will be obligated to purchase minimum amounts of products in the territories, in the total annual amount of not less than $1,006,800. In 2016, Tuteur was awarded a one-time success bonus in the amount of $100,000 based on achieving certain sales targets in 2015. In 2016, our board of directors approved the payment to Tuteur of a non-material amount to be used for the purpose of marketing activities aimed at locating new AATD patients and increasing the overall number of AATD patients treated with Glassia in Argentina. Such amount will be paid in several installments, according to Tuteur's actual expenses for such purpose, until the end of September 2019.

Tuteur shall cease to have exclusivity if it fails to comply with the minimum purchase requirement in each of the countries, on a country by country basis. Pursuant to the agreement, Tuteur is obligated to obtain the relevant regulatory approvals and reimbursement in each of the countries within 18 months of receiving the required registration documents from us. Glassia was approved by regulators in Argentina in July 2012. Glassia has not yet been submitted and approved by regulators in Paraguay or Bolivia. The parties have agreed to separately negotiate the allocation of any costs relating to clinical trials or studies required by relevant regulatory authorities in the applicable territory. We retain ownership of all relevant intellectual property.

The distribution agreement expires on December 31, 2019, provided that with respect to distribution in Bolivia, the agreement expires on the fifth anniversary of the date that Tuteur commences sales of a product in Bolivia. We are entitled to terminate the agreement upon 30 days' notice if a third party acquires more than 50% of the common stock or voting rights of Tuteur or Tuteur fails to receive the relevant regulatory approvals within the required time. Either party can terminate the agreement upon bankruptcy of the other party, a material breach of the agreement by the other party after a 30-day cure period and non-performance as a result of force majeure for more than two months. Our board of directors and audit committee approved the agreement and the amendments thereto and determined that each was not an "extraordinary transaction" within the meaning of the Companies Law.

Khairi S.A.

On June 4, 2016, we entered into a distribution agreement with Khairi S.A. ("Khairi") for the distribution by Khairi of Glassia and KamRho(D) in Uruguay. Distribution rights for Glassia and KamRho(D) in Uruguay were originally granted to Tuteur; however, as Tuteur is not incorporated in Uruguay, according to local regulatory requirements its ability to distribute pharmaceutical products in Uruguay is limited, while Khairi, which is located in the free trading zone in Uruguay, is not so limited. The distribution agreement with Khairi is an arm's length transaction, based on the terms of the distribution agreement previously signed with Tuteur. Mr. Leon Recanati (the Chairman of our board of

directors), Mr. Jonathan Hahn (a director) and his siblings and Mr. Reuven Behar (who served as a director from April 2013 until May 2016) are shareholders of Khairi. Mr. Reuven Behar serves as the chairman of the board of directors of Khairi. In 2016, Khari distributed our AAT product in Cuba in a non-material amount. In 2017, Khairi did not distribute any of our products. In 2018, we received regulatory approval to market our Glassia product in Uruguay through Khairi and first shipment was performed. Our audit committee and board of directors approved the engagement of Khairi in accordance with the Companies Law.

Fischer Behar Chen Well Orion & Co.

Since our initial public offering on the Tel Aviv Stock Exchange in 2005, we have retained the services of Fischer Behar Chen Well Orion & Co as our Israeli counsel. Mr. Reuven Behar, who served as a director from April 2013 until May 2016 is a partner at Fischer Behar Chen Well Orion & Co.

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.

Brosh Letter Agreement

On November 9, 2017, we entered into a letter agreement with Brosh Capital Partners, L.P. and certain of its affiliates (collectively, “Brosh”) regarding, among other things, amending the agenda for our 2017 annual general meeting of shareholders with respect to director nominees and board composition. At the 2017 annual general meeting, Mr. Asaf Frumerman, a nominee of Brosh, as well as industry experts, Prof. Itzhak Krinsky, Ph.D and Mr. Shmuel (Milky) Rubinstein, were added as members of our Board of Directors. The letter agreement terminated in accordance with its terms on November 9, 2018.

Item 8. Financial Information

Consolidated financial statements are set forth under Item 18.

Item 9. The Offer and Listing

Our ordinary shares are quoted on the Nasdaq Global Select Market and the TASE under the symbol “KMDA.”

Nasdaq Global Market

The following table sets forth, for the periods indicated since May 30, 2013, which was the date on which our ordinary shares began trading on the Nasdaq Global Select Market, the high and low sales prices of our ordinary shares as reported by the Nasdaq Global Select Market.

	Price Per Ordinary Share	
	High	Low
Annual:		
2018	$6.45	$4.35
2017	$8.61	$3.75
2016	$6.29	$3.26
2015	$5.15	$3.09
2014	$17.95	$3.02
Quarterly:		
Fourth Quarter 2018	$6.35	$4.63
Third Quarter 2018	$6.45	$4.80
Second Quarter 2018	$5.40	$4.35
First Quarter 2018	$5.75	$4.55
Fourth Quarter 2017	$5.25	$4.26
Third Quarter 2017	$6.05	$3.75
Second Quarter 2017	$8.61	$5.40
First Quarter 2017	$7.25	$5.50
Most Recent Six Months:		
February 2019	$6.43	$5.05
January 2019	$5.40	$5.05
December 2018	$5.40	$4.63
November 2018	$5.88	$5.05
October 2018	$6.35	$5.02
September 2018	$6.45	$5.68

On February 25, 2019, the last reported sale price of our ordinary shares on the Nasdaq Global Select Market was $6.10 per share.

Tel Aviv Stock Exchange

The following table sets forth, for the periods indicated, the reported high and low sales prices of our ordinary shares on the TASE in NIS and U.S. dollars at a rate of $1.00 = NIS 3.605, the exchange rate published by the Bank of Israel as February 25, 2019.

	NIS Price Per Ordinary Share		$ Price Per Ordinary Share	
	High	Low	High	Low
Annual:				
2018	23.20	15.05	6.44	4.17
2017	29.20	14.81	8.45	4.29
2016	23.25	13.10	6.32	3.56
2015	19.45	12.09	4.97	3.09
2014	62.00	11.60	15.85	2.97
Quarterly:				
Fourth Quarter 2018	23.20	17.32	6.44	4.80
Third Quarter 2018	22.50	18.75	6.24	5.20
Second Quarter 2018	18.98	15.05	5.26	4.17
First Quarter 2018	19.67	16.02	5.46	4.44
Fourth Quarter 2017	18.40	15.25	5.32	4.41
Third Quarter 2017	21.30	14.81	6.16	4.29
Second Quarter 2017	29.20	19.05	8.45	5.51
First Quarter 2017	27.10	20.89	7.84	6.04
Most Recent Six Months:				
February 2019	21.75	18.60	6.03	5.16
January 2019	19.77	18.60	5.48	5.16
December 2018	19.82	17.32	5.50	4.80
November 2018	20.85	20.10	5.78	5.58
October 2018	23.20	22.70	6.44	6.30
September 2018	22.50	22.13	6.24	6.14

On February 25, 2019, the last reported sale price of our ordinary shares on the TASE was NIS 21.55 per share, or $5.98 per share (based on the exchange rate reported by the Bank of Israel on such date, which was NIS 3.605 = $1.00).

Item 10. Additional Information

A. Share Capital

Not applicable.

B. Memorandum and Articles of Association

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.

Ordinary Shares

Voting

Holders of our ordinary shares have one vote per ordinary share on all matters submitted to a vote of shareholders at a shareholders' meeting. Shareholders may vote at shareholder meetings either in person, by proxy or, with respect to certain resolutions, by a voting instrument.

Israeli law does not allow public companies to adopt shareholder resolutions by means of written consent in lieu of a shareholder meeting.

Transfer of Shares

Fully paid ordinary shares are issued in registered form and may be freely transferred under our articles of association unless the transfer is restricted or prohibited by another instrument, Israeli law or the rules of a stock exchange on which the shares are traded.

Election of Directors

Our ordinary shares do not have cumulative voting rights for the election of directors. Rather, under our articles of association, directors (other than external directors, if any) are elected by the holders of a simple majority of our ordinary shares at a general shareholder meeting (excluding abstentions). See "Item 6. Directors, Senior Management and Employees — Board of Directors." As a result, the holders of our ordinary shares that represent more than 50% of the voting power represented at a shareholder meeting and voting thereon (excluding abstentions) have the power to elect any or all of our directors whose positions are being filled at that meeting (subject to the special approval requirements under the Israeli Companies Law for the election of external directors, if any). In addition, under our articles of association, 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 be filled by a vote of a simple majority of the directors then in office, and such appointment shall be valid until the next annual general meeting (or until such director ceases to serve in such capacity, if earlier).

Dividend and Liquidation Rights

Under Israeli law, we may declare and pay dividends only if, upon the determination of our board of directors, there is no reasonable concern that the distribution will prevent us from being able to meet the terms of our existing and foreseeable obligations as they become due. Under the Companies Law, the distribution amount is further limited to the greater of retained earnings or earnings generated over the two most recent years legally available for distribution according to our then last reviewed or audited financial statements, after subtracting earlier distributions if they have not yet been subtracted from the earnings, provided that the date of the financial statements is not more than six months prior to the date of distribution. In the event that we do not have retained earnings or earnings generated over the two most recent years legally available for distribution, we may seek the approval of the court in order to distribute a dividend. The court may approve our request if it is convinced that there is no reasonable concern that the payment of a dividend will prevent us from satisfying our existing and foreseeable obligations as they become due.

In the event of our liquidation, after satisfaction of liabilities to creditors, our assets will be distributed to the holders of ordinary shares in proportion to the nominal value of their shareholdings. Dividend and liquidation rights may be affected by the grant of preferential dividend or distribution rights to the holders of a class of shares with preferential rights that may be authorized in the future (subject to applicable law and applicable stock exchange rules).

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. 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 two directors or one quarter of the serving members of our board of directors, or 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.

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.

Quorum

Pursuant to our articles of association, the quorum required for a meeting of our shareholders is the presence of two or more shareholders present in person, by proxy or by a voting instrument, who hold at least 25% of our voting power. A meeting adjourned for lack of a quorum is generally adjourned to one week thereafter at the same time and place, or to such other day, time and place, as our board of directors may indicate in the notice of the meeting to the shareholders. Pursuant to our articles of association, at the reconvened meeting, the meeting will take place with whatever number of participants present.

Resolutions

Under the Companies Law, unless otherwise provided in our articles of association or applicable law, all resolutions of the shareholders require a simple majority of the voting rights represented at the meeting, in person, by proxy or, with respect to certain resolutions, by a voting instrument, and voting on the resolution (excluding abstentions). Under Israeli law, a resolution for the voluntary winding up of the company requires the approval by the holders of 75% of the voting rights represented at the meeting, in person or by proxy and voting on the resolution (excluding abstentions). Under our articles of association, a merger shall require the approval of a special majority of the shareholders, as described below under "Merger."

Access to Corporate Records

Under the Companies Law, all shareholders generally have the right to review minutes of our general meetings, our shareholder register and register of significant shareholders (as defined in the Companies Law), our articles of association, our financial statements and any document we are required by law to file publicly with the Israeli Companies Registrar or with the Israel Securities Authority. In addition, any shareholder who specifies the purpose of its request may request to review any document in our possession that relates to: (i) any action or transaction with a related party which requires shareholder approval under the Companies Law; or (ii) the approval, by the board of directors, of an action in which an office holder has a personal interest. We may deny a request to review a document if we determine that the request was not made in good faith, that the document contains a commercial or technological secret or that the document's disclosure may otherwise impair our interests.

Acquisitions Under Israeli Law

Full Tender Offer

A person wishing to acquire shares of an Israeli public company and who would, as a result, hold over 90% of the target company's issued and outstanding share capital (or over 90% of the issued and outstanding share capital of a certain class of shares) is required by the Companies Law to make a tender offer to all of the company's shareholders (or all of the shareholders who hold shares of the same class) for the purchase of all of the issued and outstanding shares of the company or of a certain class. If the shareholders who do not respond to or accept the offer hold less than 5% of the issued and outstanding share capital of the company or of the applicable class of the shares, and more than half of the shareholders who do not have a personal interest in the offer accept the offer, all of the shares that the acquirer offered to purchase will be transferred to the acquirer by operation of law. However, a tender offer will also be accepted if the shareholders who do not accept it hold less than 2% of the issued and outstanding share capital of the company or of the applicable class of the shares.

Upon a successful completion of such a full tender offer, any shareholder that was an offeree in such tender offer, whether such shareholder accepted the tender offer or not, may, within six months from the date of acceptance of the tender offer, petition an Israeli court to determine whether the tender offer was for less than fair value and that the fair value should be paid as determined by the court. However, under certain conditions, the offeror may include in the terms of the tender offer that an offeree who accepted the offer will not be entitled to petition the Israeli court as described above.

If (a) the shareholders who did not respond or accept the tender offer hold at least 5% of the issued and outstanding share capital of the company or of the applicable class or the shareholders who accept the offer constitute less than a majority of the offerees that do not have a personal interest in the acceptance of the tender offer, or (b) the shareholders who did not accept the tender offer hold 2% or more of the issued and outstanding share capital of the company (or of the applicable class), the acquirer may not acquire shares of the company that will increase its holdings to more than 90% of the company's issued and outstanding share capital or of the applicable class from shareholders who accepted the tender offer.

Special Tender Offer

The Companies Law provides that an acquisition of shares of an Israeli public company must be made by means of a special tender offer if as a result of the acquisition the purchaser would become a holder of 25% or more of the voting rights in the company. This rule does not apply if there is already another holder of 25% or more of the voting rights in the company.

Similarly, the Companies Law provides that an acquisition of shares in a public company must be made by means of a special tender offer if as a result of the acquisition the purchaser would become a holder of more than 45% of the voting rights in the company, provided there is no other shareholder of the company who holds more than 45% of the voting rights in the company.

These requirements do not apply if the acquisition (i) occurs in the context of a private placement, that was approved by the company's shareholders and whose purpose is to give the acquirer at least 25% of the voting rights in the company if there is no person who holds 25% or more of the voting rights in the company, or as a private placement whose purpose is to give the acquirer 45% of the voting rights in the company, if there is no person who holds 45% of the voting rights in the company; (ii) was from a shareholder holding 25% or more of the voting rights in the company and resulted in the acquirer becoming a holder of 25% or more of the voting rights in the company; or (iii) was from a holder of more than 45% of the voting rights in the company and resulted in the acquirer becoming a holder of more than 45% of the voting rights in the company.

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A special tender offer must be extended to all shareholders of a company. The special tender offer may be consummated only if (i) at least 5% of the voting power attached to the company's outstanding shares will be acquired by the offeror, and (ii) the number of shares tendered in the offer exceeds the number of shares whose holders objected to the offer (excluding controlling shareholders, holders of 25% or more of the voting rights in the company and any person having a personal interest in the acceptance of the tender offer).

In the event that a special tender offer is made, a company's board of directors is required to express its opinion on the advisability of the offer or it may abstain from expressing any opinion if it is unable to do so, provided that it gives the reasons for its abstention.

An office holder in a target company who, in his or her capacity as an office holder, performs an action the purpose of which is to cause the failure of an existing or foreseeable special tender offer or is to impair the chances of its acceptance, is liable to the potential purchaser and shareholders for damages resulting from his acts, unless such office holder acted in good faith and had reasonable grounds to believe he or she was acting for the benefit of the company. However, office holders of the target company may negotiate with the potential purchaser in order to improve the terms of the special tender offer, and may further negotiate with third parties in order to obtain a competing offer.

If a special tender offer is accepted, then shareholders who did not respond to the special offer or had objected to the special tender offer may accept the offer within four days of the last day set for the acceptance of the offer.

In the event that a special tender offer is accepted, then the purchaser or any person or entity controlling it and any corporation controlled by them must refrain from making a subsequent tender offer for the purchase of shares of the target company and may not effect a merger with the target company for a period of one year from the date of the offer, unless the purchaser or such person or entity undertook to effect such an offer or merger in the initial special tender offer.

Merger

The Companies Law permits merger transactions if approved by each party's board of directors and, unless certain requirements described under the Companies Law are met, a majority of each party's shareholders. Under our articles of association, a merger shall require the approval of 66.6% 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.

The board of directors of a merging company is required pursuant to the Companies Law to discuss and determine whether in its opinion there exists a reasonable concern that as a result of a proposed merger, the surviving company will not be able to satisfy its obligations towards its creditors, taking into account the financial condition of the merging companies. If the board of directors has determined that such a concern exists, it may not approve a proposed merger. Following the approval of the board of directors of each of the merging companies, the boards of directors must jointly prepare a merger proposal for submission to the Israeli Registrar of Companies.

For purposes of the shareholder vote, unless a court rules otherwise, the merger will not be deemed approved if a majority of the shares voting at the shareholders meeting (excluding abstentions) that are held by parties other than the other party to the merger, any person who holds 25% or more of the outstanding shares or the right to appoint 25% or more of the directors of the other party, or any one on their behalf including their relatives or corporations controlled by any of them, vote against the merger.

In addition, if the non-surviving entity of the merger has more than one class of shares, the merger must be approved by each class of shareholders.

If the transaction would have been approved but for the separate approval of each class of shares or the exclusion of the votes of certain shareholders as provided above, a court may still rule that the company has approved the merger upon the request of holders of at least 25% of the voting rights of a company, if the court holds that the merger is fair and reasonable, taking into account the appraisal of the merging companies' value and the consideration offered to the shareholders.

Under the Companies Law, a merging company must send a copy of the proposed merger plan to its secured creditors no later than three days after the date on which the merger proposal was submitted to the Israeli Companies Registrar. Unsecured creditors are entitled to receive notice of the merger, as provided by the regulations promulgated under the Companies Law. Upon the request of a creditor of a merging company, the court may delay or prevent the merger if it concludes that there exists a reasonable concern that, as a result of the merger, the surviving company will be unable to satisfy the obligations of the target company. The court may also give instructions in order to secure the rights of creditors.

In addition, a merger may not be completed unless at least 50 days have passed from the date that a proposal for approval of the merger was filed with the Israeli Registrar of Companies and 30 days from the date that shareholder approval of both merging companies was obtained.

Anti-takeover Measures

The Companies Law allows us to create and issue shares having rights different from those attached to our ordinary shares, including shares providing certain preferred or additional rights to voting, distributions or other matters and shares having preemptive rights. We do not have any authorized or issued shares other than ordinary shares. In the future, if we do create and issue a class of shares other than ordinary shares, such class of shares, depending on the specific rights that may be attached to them, may delay or prevent a takeover or otherwise prevent our shareholders from realizing a potential premium over the market value of their ordinary shares. The authorization of a new class of shares will require an amendment to our articles of association which requires the prior approval of a majority of our shares represented and voting at a general meeting. Shareholders voting at such a meeting will be subject to the restrictions under the Companies Law described above in "— Ordinary Shares — Voting." Pursuant to the Israeli Securities Law, 5728-1968, a company whose shares are traded on the TASE may not have more than one class of shares except for preferred shares which may have a dividend preference but may not have any voting rights.

Tax Law

Israeli tax law treats some acquisitions, such as stock-for-stock swaps between an Israeli company and a foreign company, less favorably than U.S. tax law. For example, Israeli tax law may subject a shareholder who exchanges ordinary shares in an Israeli company for shares in a non-Israeli corporation to immediate taxation unless such shareholder receives authorization from the Israel Tax Authority for different tax treatment.

Modification of Class Rights

The Companies Law and our articles of association provide that the rights of a particular class of shares may not be modified without the affirmative vote at a separate meeting of such class of a majority of shares actually participating in such class meeting.

Transfer Agent and Registrar

The transfer agent and registrar for our ordinary shares is American Stock Transfer & Trust Company, LLC. The nominee company to the TASE in whose name most of our outstanding shares are held of record is Mizrahi Tefahot Registration Company Ltd.

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

Non-residents of Israel who hold our ordinary shares are able to receive any dividends, and any amounts payable upon the dissolution, liquidation and winding up of our affairs, freely repatriable in non-Israeli currency at the rate of exchange prevailing at the time of conversion. However, Israeli income tax is required to have 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 26.5% in 2014 and 2015 to 25% in 2016 and 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. 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.

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.

Law for the Encouragement of Capital Investments, 1959

Our 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 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.

In recent years the Investment Law has undergone major reforms and several amendments which were intended to provide expanded tax benefits and to simplify the bureaucratic process relating to the approval of investments qualifying under the Investment Law. 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 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

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 will apply 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%, 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. We have not used all the tax benefits under the Approved Enterprise status, yet.

Privileged Enterprise

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 is also eligible to tax benefits as a Privileged Enterprise under the "Tax Benefit Track," which will 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.

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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 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 are scheduled to expire at the end of 2020 and 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 taxpayer owning a Privileged Enterprise is entitled to a reduced corporate tax rate for income from the sale of products produced by the Privileged Enterprise in each tax year during the benefit period. In addition, the Privileged Enterprise is entitled to claim accelerated depreciation for manufacturing assets used by the Privileged Enterprise.

The tax benefits available to Privileged Enterprises under the "Tax Benefits Track" are as follows: An exemption from corporate tax may be available 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.

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 reduced 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 20% (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 to "Preferred Enterprises." The tax benefits granted to a Preferred Enterprise are determined depending on the location of the Preferred Enterprise within Israel. Amendment No. 68 imposes a reduced flat corporate tax rate which is not program-dependent and applies to the industrial enterprise's entire "preferred income" which is generated by its Preferred Enterprise.

According to the Investment Law, a uniform corporate tax rate will apply to all qualifying income of the Preferred Enterprise. Under an amendment to the Investment Law that became effective on January 1, 2014, the uniform corporate tax rate was 9% in areas in Israel designated as Development Zone A and 16% elsewhere in Israel, effective as of January 1, 2014. Under an amendment to the Investment Law that became effective on January 1, 2017, the uniform corporate tax rate in areas in Israel designated as Development Zone A was reduced to 7.5%.

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 (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 zone A.

A dividend distributed from income which is attributed to a Preferred Enterprise/Special Preferred Enterprise will 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. A company owning a Privileged Enterprise or an Approved Enterprise that made such election by July 30, 2015, is entitled to distribute income generated by the Approved/Privileged Enterprise to its Israeli corporate shareholders tax free. 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.

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 our certificate of approval with respect to our Approved Enterprise and our tax ruling with respect to our Privileged Enterprise, 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.

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 five research and development programs, in the aggregate amount of approximately $1.7 million as of December 31, 2018, which amount has accrued aggregate interest of approximately $8,252 as of such date, and we had paid aggregate royalties to the IIA for these programs in the amount of approximately $1.0 million and had a contingent liability to the IIA in the amount of approximately $0.7 million (excluding any interest thereon) as of December 31, 2018.

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

This discussion does not address the tax consequences applicable to shareholders that own, or have owned at any time, directly or indirectly, 10% or more of our shares ("Controlling Shareholders"), and such shareholders should consult their tax advisers as to the tax consequences of owning or disposing of our shares.

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 (which was 26.5% in 2014 and 2015, reduced to 25% in 2016 and 24% in 2017 and reduced to 23% in 2018 and thereafter).

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 48% in the years 2014-2016 and 47% from 2017).

Furthermore, an additional tax liability at the rate of 2% in the years 2014-2016 and 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 803,520 in 2016, and NIS 640,000 in 2017 and NIS 641,880 in 2018.

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 20%, upon the distribution of a dividend attributed to an Approved/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 an Approved/Privileged Enterprise, the following withholding tax rates will 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) — 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, the withholding rate will not be reduced under the Israel-U.S.A. Double Tax Treaty.

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, 2018 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

You may inspect our securities filings, including this Annual Report and the exhibits and schedules thereto, without charge at the offices of the SEC at 100 F Street, N.E., Washington, D.C. 20549. You may obtain copies of all or any part of the Annual Report from the Public Reference Section of the SEC, 100 F Street, NE, Washington, D.C. 20549 upon the payment of the prescribed fees. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. 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 this website.

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 arising from our financial assets as our financial debt bears fixed interest rates. We invest our cash balance in interest-bearing deposits. We have exposure to investments in deposits or securities bearing fixed interest, which expose us to interest rate risk with respect to fair value.

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, 2018, 2017 and 2016, 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 used, 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, 2018, we had open transactions in derivatives in the amount of approximately $21.4 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, 2016	(1.2)
Year ended December 31, 2017	(6.3)
Year ended December 31, 2018	8.1

As of December 31, 2018, we had excess liabilities over assets denominated in NIS in the amount of $0.4 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 devalues against the NIS, we recognize financial revenues.

As of December 31, 2018, we had foreign currency exposures to currencies other than U.S. dollars 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 $1.2 million, $1.3 million and $1.3 million as of December 31, 2018, 2017 and 2016, 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

Initial Public Offering

On June 5, 2013, we completed an initial public offering in the United States on Nasdaq of our ordinary shares, par value NIS 1.00 per share, pursuant to a Registration Statement on Form F-1, as amended (File No. 333-187870), which became effective on May 30, 2013. Morgan Stanley & Co. LLC and Jefferies LLC acted as representatives of the underwriters. We registered 5,582,636 ordinary shares in the offering and granted the underwriters a 30-day over-allotment option to purchase up to 837,395 additional ordinary shares from us. The option to purchase additional ordinary shares was exercised in full on June 4, 2013.

Pursuant to the initial public offering, we sold a total of 6,420,031 ordinary shares (including the shares sold pursuant to the over-allotment option) at a price of $9.25 per share. The aggregate offering price of the shares sold (including the over-allotment option) was approximately $59.4 million. The total expenses of the offering, including underwriting discounts and commissions, were approximately $6.6 million. The net proceeds we received from the offering (including the over-allotment option) were approximately $52.8 million. We paid a one-time management compensation payment associated with the initial public offering of approximately $1.1 million.

As of December 31, 2018, we have used a large portion of the net proceeds of our initial public offering. We intend to use the remaining net proceeds we received from our initial public offering as disclosed in our Registration Statement on Form F-1.

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, 2018, 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, 2018 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, 2018. The report of Kost Forer Gabbay & Kasierer 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 16A. Audit Committee Financial Expert

Our board of directors has determined that Avraham Berger 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

In November 2011, we 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, 2018 and 2017, 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:

	Year Ended December 31,	
	2018	2017
Audit Fees(1)	$260,000	$190,000
Audit-Related Fees(2)	-	110,000
Tax Fees (3)	14,702	5,023
Other (4)	39,728	2,977
Total	$314,430	$308,000

(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, consultations on various accounting issues and audit services provided in connection with other statutory or regulatory filings. In 2018, audit fees include fees in connection with the auditor attestation report on the effectiveness of our internal control over financial reporting as we ceased to be an emerging growth company as of December 31, 2018.

(2) Audit-related fees in 2017 are for services rendered by our auditors in connection with our 2017 underwritten public offering.

(3) Tax services in 2017 rendered by our auditors were for equity incentive awards. Tax services in 2018 rendered by our auditors were for compliance with tax regulation.

(4) Other fees are for services rendered in connection with business continuity methodology support and policy implementation of new regulation.

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 must 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.

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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, 2018, neither the company nor any affiliated purchaser (as defined in the Exchange Act) purchased any of the company's 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:

- 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").

- 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 intend to follow certain home country corporate governance practices, our shareholders may not have the same protections afforded to shareholders of companies 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 also listed for trade on an exchange outside Israel.

Item 16H. Mine Safety Disclosure

Not applicable.

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-57, 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	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 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†	Distribution Agreement, dated as of August 2, 2011, by and between Kamada Ltd. and TUTEUR S.A.C.I.F.I.A. (incorporated by reference to Exhibit 10.11 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on April 11, 2013).
4.11	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).
4.12	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).
4.13	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 Administration and Kamada Nehasim (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).
4.14†	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).
4.15	Registration Rights Agreement, dated as of April 14, 2013, by and among Kamada Ltd. and the individuals and entities identified therein (incorporated by reference to Exhibit 10.19 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on May 15, 2013).
4.16	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).
4.17	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).
4.18†	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).
4.19†	First Amendment to the Technology License Agreement, dated as of May 14, 2013, by and between Kamada Ltd. and Baxter Healthcare Corporation (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).

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4.20†	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).
4.21†	First Amendment to the Distribution Agreement dated as of August 19, 2014, by and between Kamada Ltd. and TUTEUR S.A.C.I.F.I.A (incorporated by reference to Exhibit 4.26 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on April 28, 2015).
4.22†	Third Amendment to the Amended and Restated Fraction IV-1 Paste Supply Agreement executed on June 19, 2015 by and between Kamada Ltd. and Baxalta US 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).
4.23†	Fourth Amendment to the Exclusive Manufacturing, Supply and Distribution Agreement, dated as of October, 2015, by and between Kamada Ltd. and Baxalta US 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).
4.24†	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).
4.25†	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)
4.26	Compensation Policy
4.27	Kamada Ltd. 2011 Israeli Share Award Plan (incorporated by reference to Exhibit 4.2 to the Form S-8 filed with the Securities and Exchange Commission on February 9, 2017).
4.28†	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).
4.29†	2nd Addendum to Supply And Distribution Agreement dated October 11, 2018 between Kamada Ltd., and Kedrion S.p.A.
4.30	Termination Agreement dated as of November 14, 2017 by and between Kamada Ltd. and Chiesi Farmaceutici 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 March 6, 2018).
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.

† Portions of this exhibit have been omitted pursuant to a request for confidential treatment and the non-public information has been filed separately with the Securities and Exchange Commission.

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: February 27, 2019

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Kamada Ltd. and its subsidiaries

Kamada Ltd.

Consolidated Financial Statements as of December 31, 2018

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Kamada Ltd. and its subsidiaries

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OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of KAMADA LTD.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Kamada Ltd (and subsidiary) (the Company) as of December 31, 2018 and 2017, the related consolidated statements of comprehensive income, shareholders' equity and cash flows for each of the three years in the period ended December 31, 2018, 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, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards 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, 2018, 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 February 27, 2019 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.

/s/ KOST FORER GABBAY & KASIERER
A Member of Ernst & Young Global

We have served as the Company‘s auditor since 2005.
Tel-Aviv, Israel
February 27, 2019

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Kamada Ltd. and its subsidiaries

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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's (and subsidiary) internal control over financial reporting as of December 31, 2018, 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 subsidiary) (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, 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 balance sheets of the Company as of December 31, 2018 and 2017, the related consolidated statements of comprehensive income, shareholders' equity and cash flows for each of the three years in the period ended December 31, 2018, and the related notes and our report dated February 27, 2019 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 Ernst & Young Global

Tel-Aviv, Israel
February 27, 2019

Kamada Ltd. and its subsidiaries

CONSOLIDATED BALANCE SHEETS

		As of December 31,	
		2018	2017
Assets	Note	U.S. Dollars in thousands	
Current Assets			
Cash and cash equivalents	5	$18,093	$12,681
Short-term investments	6	32,499	30,338
Trade receivables, net	7	27,674	30,662
Other accounts receivables	8	3,308	2,132
Inventories	9	29,316	21,070
Total Current Assets		110,890	96,883
Non-Current Assets			
Property, plant and equipment, net	10	25,004	25,178
Other long term assets	11	174	49
Deferred taxes	21	2,048	-
Total Non-Current Assets		27,226	25,227
Total Assets		$138,116	$122,110
Liabilities			
Current Liabilities			
Current maturities of loans and capital leases	14	562	614
Trade payables	12	17,285	18,036
Other accounts payables	13	5,261	5,820
Deferred revenues	17a,b	461	4,927
Total Current Liabilities		23,569	29,397
Non-Current Liabilities			
Loans and capital leases	14	716	1,370
Deferred revenues	17	668	707
Employee benefit liabilities, net	16a,b	787	1,144
Total Non-Current Liabilities		2,171	3,221
Shareholder's Equity	19		
Ordinary shares		10,409	10,400
Additional paid in capital net		179,147	177,874
Capital reserve due to translation to presentation currency		(3,490)	(3,490)
Capital reserve from hedges		(57)	46
Capital reserve from securities measured at fair value through other comprehensive income		34	(4)
Capital reserve from share-based payments		9,353	9,566
Capital reserve from employee benefits		4	(337)
Accumulated deficit		(83,024)	(104,563)
Total Shareholder’s Equity		112,376	89,492
Total Liabilities and Shareholder’s Equity		$138,116	$122,110

The accompanying notes are an integral part of the Consolidated Financial Statements.

Kamada Ltd. and its subsidiaries

Consolidated Statements of Profit or Loss and Other Comprehensive Income (Loss)

	Note	For the Year Ended December 31, 2018	2017	2016
		U.S. Dollars in thousands, except for share and per share data		
Revenues from proprietary products		$90,784	$79,559	$55,958
Revenues from distribution		23,685	23,266	21,536
Total revenues	22a,b	114,469	102,825	77,494
Cost of revenues from proprietary products		52,796	51,335	37,723
Cost of revenues from distribution		20,201	19,402	18,411
Total cost of revenues	22c	72,997	70,737	56,134
Gross profit		41,472	32,088	21,360
Research and development expenses	22d	9,747	11,973	16,245
Selling and marketing expenses	22e	3,630	4,398	3,243
General and administrative expenses	22f	8,525	8,273	7,353
Other expense		311	-	-
Operating income (loss)		19,259	7,444	(5,481)
Financial income	22g	820	500	469
Income (expense) in respect of currency exchange differences and derivatives instruments, net		602	(612)	127
Financial expenses	22g	(340)	(162)	(126)
Income (loss) before tax on income		20,341	7,170	(5,011)
Taxes on income	21	(1,955)	269	1,722
Net Income (loss)		22,296	6,901	(6,733)
Other Comprehensive Income (loss) :				
Items that may be reclassified to profit or loss in subsequent periods:				
Gain (loss) from securities measured at fair value through other comprehensive income		51	(23)	(54)
Gain (loss) on cash flow hedges		(176)	329	47
Net amounts transferred to the statement of profit or loss for cash flow hedges		70	(256)	(73)
Items that will not be reclassified to profit or loss in subsequent periods:				
Actuarial gain (loss) from defined benefit plans		340	(256)	(22)
Deferred tax		(9)	-	-
Total comprehensive income (loss)		$22,572	$6,695	$(6,835)

Income (loss) per share attributable to equity holders of the Company:	23			
Basic income (loss) per share		$0.55	$0.18	$(0.18)
Diluted income (loss) per share		$0.55	$0.18	$(0.18)

The accompanying notes are an integral part of the Consolidated Financial Statements.

Kamada Ltd. and its subsidiaries

Statements of Changes in Equity

	Share capital	Additional paid in capital	Capital reserve from Available for sale financial assets	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, 2015	$9,320	$162,238	$ 73	$ (3,490)	$ (1)	$9,157	$ (59)	$ (104,731)	$72,507
Net income								(6,733)	(6,733)
Other comprehensive income (loss)	-	-	(54)	-	(26)	-	(22)		(102)
Total comprehensive income (loss)	-	-	(54)	-	(26)	-	(22)	(6,733)	(6,835)
Exercise and forfeiture of share-based payment into shares	*	433	-			(433)	-	-	*
Cost of share-based payment						1,071	-	-	1,071
Balance as of December 31, 2016	$9,320	$162,671	$ 19	$ (3,490)	$ (27)	$9,795	$ (81)	$ (111,464)	$66,743
Net income	-	-	-	-	-	-	-	6,901	6,901
Other comprehensive income (loss)	-	-	(23)	-	73	-	(256)	-	(206)
Total comprehensive income (loss)	-	-	(23)	-	73	-	(256)	6,901	6,695
Exercise and forfeiture of share-based payment into shares	3	712	-	-	-	(712)	-	-	3
Issuance of ordinary shares, net of issuance costs	1,077	14,491	-	-	-	-	-	-	15,568
Cost of share-based payment	-	-	-	-	-	483	-	-	483
Balance as of December 31, 2017	$10,400	$177,874	$ (4)	$ (3,490)	$46	$9,566	$ (337)	$ (104,563)	$89,492
Cumulative effect of initially applying IFRS 15	-	-	-	-	-	-	-	(757)	(757)
	10,400	177,874	(4)	(3,490)	46	9,566	(337)	(105,320)	88,735

Balance as at January 1, 2018 (after initially applying IFRS 15)									
net income	-	-	-	-	-	-	-	22,296	22,296
Other comprehensive income, net	-	-	38	-	(103)	-	341	-	276
Total comprehensive income (loss)	-	-	38	-	(103)	-	341	22,296	22,572
Exercise and forfeiture of share-based payment into shares	9	1,161	-	-	-	(1,161)	-	-	9
Cost of share-based payment	-	-	-	-	-	948	-	-	948
Deferred taxes	-	112	-	-	-	-	-	-	112
Balance as of December 31, 2018	$10,409	$179,147	$ 34	$ (3,490)	$ (57)	$9,353	$ 4	$ (83,024)	$112,376

* Represent an amount lower than $1 thousands.

The accompanying notes are an integral part of the Consolidated Financial Statements

Kamada Ltd. and its subsidiaries

Consolidated Statements of Cash Flows

	Note	For the year ended December 31, 2018	2017	2016
		U.S. Dollars in thousands		
Cash Flows from Operating Activities				
Net income (loss)		$22,296	$6,901	$(6,733)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:				
Adjustments to the profit or loss items:				
Depreciation, amortization and impairment	10	3,703	3,523	3,501
Financial expenses (income), net		(1,082)	274	(470)
Cost of share-based payment	20	948	483	1,071
Taxes on income	21	(1,955)	269	1,722
Loss (gain) from sale of property and equipment		55	(52)	(18)
Change in employee benefit liabilities, net		(16)	166	(87)
		1,653	4,663	5,719
Changes in asset and liability items:				
Decrease (increase) in trade receivables, net		2,311	(9,967)	3,489
Decrease (increase) in other accounts receivables		(1,336)	328	211
Decrease (increase) in inventories		(8,246)	4,524	742
Decrease (increase) in deferred expenses		235	594	(433)
Decrease in trade payables		(1,116)	(838)	(2,650)
Increase (decrease) in other accounts payables		(658)	71	1,520
Decrease in deferred revenues		(5,256)	(2,930)	1,035
		(14,066)	(8,218)	3,914
Cash received (paid) during the year for:				
Interest paid		(54)	(21)	(60)
Interest received		739	399	842
Taxes paid		(22)	(116)	(1,785)
		663	262	(1,003)
Net cash provided by operating activities		$10,546	$3,608	$1,897

The accompanying notes are an integral part of the Consolidated Financial Statements.

Kamada Ltd. and its subsidiaries

Consolidated Statements of Cash Flows

	Note	For the year ended December 31, 2018	2017	2016
		U.S. Dollars in thousands		
Cash Flows from Investing Activities				
Investment in short term investments, net		$(2,322)	$(11,501)	$4,236
Purchase of property and equipment and intangible assets	10	(2,884)	(4,167)	(2,641)
Proceeds from sale of property and equipment		30	60	42
Net cash used in investing activities		(5,176)	(15,608)	1,637
Cash Flows from Financing Activities				
Proceeds from exercise of share base payments		9	3	*
Receipt of long-term loans		-	279	1,701
Repayment of long-term loans		(596)	(530)	(211)
Proceeds from issuance of ordinary shares, net		-	15,568	-
Net cash provided by (used in) financing activities		(587)	15,320	1,490
Exchange differences on balances of cash and cash equivalent		629	(607)	(103)
Increase in cash and cash equivalents		5,412	2,713	4,921
Cash and cash equivalents at the beginning of the year		12,681	9,968	5,047
Cash and cash equivalents at the end of the year		$18,093	$12,681	$9,968
Significant non-cash transactions				
Purchase of property and equipment through capital lease		-	282	132
Purchase of property and equipment		$720	$1,681	$1,968

* Represent an amount lower than $1 thousands.

The accompanying notes are an integral part of the Consolidated Financial Statements.

Kamada Ltd. and its subsidiaries

Notes to the Consolidated Financial Statements

Note 1: - General

a. General description of the Company and its activity

Kamada Ltd. ("the Company") a plasma-derived protein therapeutics company focused on orphan indications, has a commercial product portfolio and a late-stage product pipeline. The Company uses its proprietary platform technology and know-how for the extraction and purification of proteins from human plasma to produce Alpha-1 Antitrypsin (AAT) in a high purity, liquid form, as well as other plasma-derived proteins. The Company's flagship product is "GLASSIA®" Kamada markets GLASSIA in the U.S. through a strategic partnership with Shire plc, now part of Takeda, and in other counties through local distributors. In addition, the Company's rabies immune globulin (Human) product received FDA approval for Post-Exposure Prophylaxis against rabies infection in August 2017 and was launched in the US in April 2018 under the brand name KEDRAB® and through a collaboration agreement with Kedrion Biophamra. Kamada has a product line consisting of six other products which are marketed in more than 15 countries, including Israel, Russia, Brazil, India and other countries in Latin America and Asia.

The Company's activity is divided into two operating segments:

Proprietary Products	Develop and manufacture plasma-derived therapeutics and market them in more than 15 countries.
Distribution	Distribute imported drugs in Israel, which are manufactured by third parties, majority of which are produced from plasma or its derivative products.

The Company's securities are listed for trading on the Tel Aviv stock exchange and on the NASDAQ.

b. The Company has two wholly-owned subsidiaries – Kamada Inc which is not active and Kamada Biopharma Limited. In addition the Company owns 74% of Kamada Assets Ltd ("Kamada Assets"). See note 26 with respect to a new wholly owned subsidiary establish post December 31, 2018.

c. 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 IAS 24.
USD/$	-	U.S. dollar.
NIS	-	New Israeli Shekel

Kamada Ltd. and its subsidiaries

Notes to the Consolidated Financial Statements

Note 2: - Significant 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 instruments (including derivatives) at fair value through profit or loss and other comprehensive income such as marketable securities financial assets, employee benefit assets and employee benefit liabilities.

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. The consolidated financial statements comprise the financial statements of companies that are controlled by the Company (subsidiaries). Control is achieved when the Company is exposed, or has rights, to variable returns from its involvement with the investee and has the ability to affect those returns through its power over the investee. The consolidation of the financial statements commences on the date on which control is obtained and ends when such control ceases.

The financial statements of the Company and of the subsidiaries are prepared as of the same dates and periods. The consolidated financial statements are prepared using uniform accounting policies by all companies in the Group. Significant intercompany balances and transactions and gains or losses resulting from intercompany transactions are eliminated in full in the consolidated financial statements.

d. 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.

Kamada Ltd. and its subsidiaries

Notes to the Consolidated Financial Statements

Note 2: - Significant Accounting Policies (cont.)

e. Cash and cash equivalents

Cash comprise of cash at banks and on hand. Cash equivalents are considered as highly liquid investments, including unrestricted short-term bank deposits with an original maturity of three months or less from the date of purchase, which are subject to an insignificant risk of changes in value.

f. Short-term investments:

Short-term bank deposits with a maturity of more than three months from the deposit date but less than one year and securities measured at fair value through other comprehensive income.

g. Allowance for doubtful accounts

The allowance for doubtful accounts is determined in respect of specific debts whose collection, in the opinion of the Company's management, is doubtful. Impaired debts are derecognized when they are assessed as uncollectible. As of December 31, 2018 and December 31, 2017 there was no allowance for doubtful accounts.

h. Inventories

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.

Cost of inventories is determined as follows:

Raw materials	- At cost using the first-in, first-out method. Fair value of raw material received at no charge is not included in the inventory value.
Work in process	- Direct and indirect costs including materials, labor and other direct and indirect manufacturing costs calculated at average costs for the quarter and allocated to the manufactured batches during that quarter based on predetermined allocation factors.
Finished products	- Direct and indirect costs including materials, labor and other direct and indirect manufacturing costs calculated at average costs and allocated to the manufactured finished products during that quarter based on predetermined allocation factors.
Purchased products	- At cost using the first-in, first-out method.

Kamada Ltd. and its subsidiaries

Notes to the Consolidated Financial Statements

Note 2: - Significant Accounting Policies (cont.)

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.

i. Research and development costs

Research 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.

An intangible asset arising from a development project or from the development phase of an internal project is recognized if the Company can demonstrate the technical feasibility of completing the intangible asset so that it will be available for use or sale; the Company's intention to complete the intangible asset and use or sell it; the Company's ability to use or sell the intangible asset; how the intangible asset will generate future economic benefits; the availability of adequate technical, financial and other resources to complete the intangible asset; and the Company's ability to measure reliably the expenditure attributable to the intangible asset during its development. Since the Company 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.

j. Revenue recognition

Regarding the initial adoption of IFRS 15, "Revenue from Contracts with Customers" ("the Standard"), the Company elected to adopt the provisions of the Standard using the modified retrospective method with the application of certain practical expedients and without restatement of comparative data. Revenues are recognized in profit or loss when the revenues can be measured reliably, it is probable that the economic benefits associated with the transaction will flow to the Company and the costs incurred or to be incurred in respect of the transaction can be measured reliably. 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. The revenue recognition occurs at a point in time when control of the asset is transferred to the customer, generally on delivery of the goods. Customers payment terms are as acceptable in the industry. Some contracts with customers provide variable consideration such as a right of return, trade discounts,volume rebates and marketing contribution. The Company recognizes revenue from sale of goods measured at the fair value of the consideration received or receivable, net of returns and allowances, trade discounts and volume rebates. If revenue cannot be reliably measured, the Company defers revenue recognition until the uncertainty is resolved.

Agreements with strategic partner that include upfront and milestone payments contain a performance obligation that is satisfied over time given that the customer simultaneously receives and consumes the benefits provided by the Company. The Company recognizes revenue for upfront payments over time rather than at a point of time. The Company identified the existence of a significant financing component resulting from an upfront payment and recorded revenue against finance expense in the financial statements of 2018.

Kamada Ltd. and its subsidiaries

Notes to the Consolidated Financial Statements

Note 2: - Significant Accounting Policies (cont.)

In the tables below is the impact of IFRS 15 on the financial statements:

	As of January 01, 2018 before implementation of IFRS 15	Difference	As of January ,01 2018 according to IFRS 15
	U.S. Dollars in thousands		
Accumulated deficit	$(104,563)	$ (757)	$(105,320)

	According to the previous accounting policy	Difference	As presented in the financial statements
	U.S. Dollars in thousands		
As of December 31, 2018			
Current Liabilities			
Deferred revenues	$1,129	-	$ 1,129
Accumulated deficit	(83,024)	-	(83,024)

	According to the previous accounting policy	Difference	As presented in the financial statements
	U.S. Dollars in thousands		
For the Year ended on December 31, 2018			
Total revenues	$113,652	$ 817	$ 114,469
Financial expenses	(280)	(60)	(340)
Net income	21,539	757	22,296

In cases where the Company operates as a principal supplier and it exposed to the risks and rewards associated with the transaction, revenues are presented on a gross basis.

In events when the Company receives at no charge raw material, that is required for manufacturing one of the Company's products, the Company recorded the fair value of the raw material used and sold as revenue and charged the same fair value to cost of revenue.

Deferred revenues

Deferred revenues include unearned amounts received from customers not yet recognized as revenues.

k. Taxes on income

Taxes on income in profit or loss comprise of current and deferred taxes. Current or deferred taxes are recognized in profit or loss, except to the extent that the tax arises from items which are recognized directly in other comprehensive income or in equity.

1. Current taxes:

The current tax liability is measured using the tax rates and tax laws that have been enacted or substantively enacted by the end of reporting period as well as adjustments required in connection with the tax liability in respect of previous years.

Note 2: - Significant Accounting Policies (cont.)

2. Deferred taxes:

Deferred taxes are computed in respect of temporary differences between the carrying amounts in the financial statements and the amounts attributed for tax purposes.

Deferred taxes are measured at the tax rates that are expected to apply when the asset is realized or the liability is settled, based on tax laws that have been enacted or substantively enacted by the end of the reporting period.

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. 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.

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.

l. Leases

The criteria for classifying leases as finance or operating leases depend on the substance of the agreements and are made at the inception of the lease in accordance with the following principles as set out in IAS 17.

The Group as lessee:

1. Finance lease

Finance leases transfer to the Company substantially all the risks and benefits incidental to ownership of the leased asset. At the commencement of the lease term, the leased assets are measured at the fair value of the leased asset or, if lower, at the present value of the minimum lease payments.

The leased asset is depreciated over the shorter of the lease term and the expected life of the leased asset.

2. Operating lease

Lease agreements are classified as an operating lease if they do not transfer substantially all the risks and benefits incidental to ownership of the leased asset. Lease payments are recognized as an expense in profit or loss on a straight-line basis over the lease term.

m. Property, plant and equipment

Property, plant and equipment are measured at cost, including directly attributable costs and financing costs, less accumulated depreciation, accumulated impairment losses 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.

Note 2: - Significant Accounting Policies (cont.)

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. In contrast, software that adds functionality to the hardware is classified as an intangible asset.

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.

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.

The useful life, depreciation method and residual value of an asset are reviewed at the year-end and any changes are accounted for prospectively as a change in accounting estimate.

Depreciation of an asset ceases at the earlier of the date that the asset is classified as held for sale and the date that the asset is derecognized.

n. Impairment of non-financial assets

The Company evaluates 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.

An impairment loss of an asset, 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, shall 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.

Kamada Ltd. and its subsidiaries

Notes to the Consolidated Financial Statements

Note 2: - Significant Accounting Policies (cont.)

o. Financial instruments

Regarding the initial adoption of IFRS 9, "Financial Instruments" ("the Standard"), the Company elected to adopt the provisions of the Standard retrospectively without restatement of comparative data.

1. Financial assets

Financial assets are classified, at initial recognition, and subsequently measured at amortized cost, fair value through other comprehensive income (OCI), and fair value through profit or loss. The classification of financial assets at initial recognition depends on the financial asset's contractual cash flow characteristics and the Company's business model for managing them. With the exception of trade receivables that do not contain a significant financing component or for which the Company has applied the practical expedient, the Company initially measures a financial asset at its fair value plus, in the case of a financial asset not at fair value through profit or loss, transaction costs.

After initial recognition, the accounting treatment of financial assets is based on their classification as follows:

Debt financial instruments are subsequently measured at fair value through profit or loss (FVPL), amortized cost, or fair value through other comprehensive income (FVOCI). The classification is based on two criteria: the Company's business model for managing the assets; and whether the instruments' contractual cash flows represent 'solely payments of principal and interest' on the principal amount outstanding (the 'SPPI criterion').

The classification and measurement of the Company's debt financial assets are as follows:

- Debt instruments at amortized cost for financial assets that are held within a business model with the objective to hold the financial assets in order to collect contractual cash flows that meet the SPPI criterion. This category includes the Company's Trade and other receivables.

- Debt instruments at FVOCI, with gains or losses recycled to profit or loss on derecognition. Financial assets in this category are the Company's quoted debt instruments that meet the SPPI criterion and are held within a business model both to collect cash flows and to sell. Interest earned whilst holding AFS financial investments is reported as interest income using the effective interest rate method.

Financial assets at FVPL comprise derivative instruments unless they are designated as effective hedging instruments.

a. Impairment of financial assets

The Company assesses at the end of each reporting period whether there is any objective evidence of impairment of a financial asset or group of financial assets. The Company records an allowance for expected credit loss ("ECL") for all debt financial assets not held at FVPL.

ECLs are based on the difference between the contractual cash flows due in accordance with the contract and all the cash flows that the Company expects to receive. For other debt financial assets (i.e., debt securities at FVOCI), the ECL is based on the 12-month ECL. The 12-month ECL is the portion of lifetime ECLs that results from default events on a financial instrument that are possible within 12 months after the reporting date. As of December 31, 2018

there is no ECL allowance.

Kamada Ltd. and its subsidiaries

Notes to the Consolidated Financial Statements

Note 2: - Significant Accounting Policies (cont.)

2. Financial liabilities

Financial liabilities within the scope of IFRS 9 are initially measured at fair value.

After initial recognition, the accounting treatment of financial liabilities is based on their classification as follows:

a. Financial liabilities measured at amortized cost

Loans, including capital leases, 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. Transaction costs are recognized in profit or loss.

3. Fair value measurement

Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date.

Fair value measurement is based on the assumption that the transaction will take place in the asset's or the liability's principal market, or in the absence of a principal market, in the most advantageous market.

The fair value of an asset or a liability is measured using the assumptions that market participants would use when pricing the asset or liability, assuming that market participants act in their economic best interest.

A fair value measurement of a non-financial asset takes into account a market participant's ability to generate economic benefits by using the asset in its highest and best use or by selling it to another market participant that would use the asset in its highest and best use.

The Company uses valuation techniques that are appropriate in the circumstances and for which sufficient data are available to measure fair value, maximizing the use of relevant observable inputs and minimizing the use of unobservable inputs.

All assets and liabilities for which fair value is measured or disclosed in the financial statements are categorized within the fair value hierarchy, described as follows, based on the lowest level input that is significant to the fair value measurement as a whole:

- Level 1 - quoted prices (unadjusted) in active markets for identical assets or liabilities.
- Level 2 - inputs other than quoted prices included within Level 1 that are observable either directly or indirectly.
- Level 3 - inputs that are not based on observable market data (valuation techniques which use inputs that are not based on observable market data).

Kamada Ltd. and its subsidiaries

Notes to the Consolidated Financial Statements

Note 2: - Significant Accounting Policies (cont.)

4. Offsetting financial instruments

Financial assets and financial liabilities are offset and the net amount is presented in the statement of financial position if there is a legally enforceable right to set off the recognized amounts and there is an intention either to settle on a net basis or to realize the asset and settle the liability simultaneously.

The right of set-off must be legally enforceable not only during the ordinary course of business of the parties to the contract but also in the event of bankruptcy or insolvency of one of the parties. In order for the right of set-off to be currently available, it must not be contingent on a future event, there may not be periods during which the right is not available, or there may not be any events that will cause the right to expire.

5. De-recognition of financial instruments

a. Financial assets

Financial assets are derecognized when the contractual rights to the cash flows from the financial asset expire or the Company has transferred its contractual rights to receive cash flows from the financial asset or assumes an obligation to pay the cash flows in full without material delay to a third party and has transferred substantially all the risks and rewards of the asset, or has neither transferred nor retained substantially all the risks and rewards of the asset, but has transferred control of the asset.

b. Financial liabilities

A financial liability is derecognized when it is extinguished, that is when the obligation is discharged or cancelled or expires. A financial liability is extinguished when the debtor (the Company) discharges the liability by paying in cash, other financial assets, goods or services or is legally released from the liability.

p. 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. 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 immediately in profit or loss.

Kamada Ltd. and its subsidiaries

Notes to the Consolidated Financial Statements

Note 2: - Significant Accounting Policies (cont.)

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.

If the forecast transaction or firm commitment is no longer expected to occur, amounts previously recognized in other comprehensive income are reclassified to profit or loss. If the hedging instrument expires or is sold, terminated or exercised, or if its designation as a hedge is revoked, amounts previously recognized in other comprehensive income remain in other comprehensive income until the forecast transaction or firm commitment occurs.

q. Accrued expenses

A provision in accordance with IAS 37 is recognized when the Group 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.

r. 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 and 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.

The Company has defined contribution plans pursuant to Section 14 to 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.

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Note 2: - Significant Accounting Policies (cont.)

In addition the Company operates a defined benefit plan in respect of severance pay pursuant to the Israeli Severance Pay Law. According to the 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 severance pay obligation to certain of its employees, the Company makes current deposits in pension funds and insurance companies ("the 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.

Re-measurements of the net liability are recognized in other comprehensive income in the period in which they occur.

s. Share-based payment transactions

The Company's employees and Board of Directors members are entitled to remuneration in the form of equity-settled share-based payment transactions.

Equity-settled transactions

The cost of equity-settled transactions (options and restricted shares) with employees and Board of Directors members 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 fair value of restricted shares is determined using the share price at the grant date.

The cost of equity-settled 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 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.

In the event that the Company modifies the conditions on which equity-instruments were granted, an additional expense is calculated and recognized over the remaining vesting period for any modification that increases the total fair value of the share-based payment arrangement or is otherwise beneficial to the employee/ Director at the modification date.

Kamada Ltd. and its subsidiaries

Notes to the Consolidated Financial Statements

Note 2: - Significant Accounting Policies (cont.)

t. Earnings (loss) per Share

Earnings (loss) per share are calculated by dividing the net income (loss) attributable to Company shareholders by the weighted number of ordinary shares outstanding during the period. Ordinary shares underlying shares options or restricted shares are only included in the calculation of diluted income (loss) per share when their impact dilutes the income (loss) per share. Furthermore, potential ordinary shares converted during the period are included under diluted income (loss) per share only until the conversion date, and from that date on are included under basic income (loss) per share.

Note 3: - Significant accounting judgments, estimates and assumptions used in the preparation of the financial statements

In the process of applying the significant accounting policies, the Group has made the following judgments which have the most significant effect on the amounts recognized in the financial statements:

a. Judgments

Revenue

The Company assesses the criteria for recognition of revenue related to up-front payments and milestones as outlined by IFRS 15. Judgment is necessary to determine over which period the Company will satisfy its performance obligations related to up-front payments and milestones and whether financing component exists. For additional information, refer to Note 17a.

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.

- 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.

- 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 others, 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.)

- Determining the fair value of share-based payment transactions

Estimating fair value for share-based payment transactions requires determination of the most appropriate valuation model, which depends on the terms and conditions of the grant. This estimate also requires determination of the most appropriate inputs to the valuation model including the expected life of the share option or appreciation right, volatility and dividend yield and making assumptions about them.

- Provisions for clinical trial and related expenses

Accrued expenses costs for clinical trial activities performed by third parties, are based on estimates on the progress of completion of the clinical trials or services, as of the end of each reporting period, pursuant to the contract with the third parties, and the agreed upon fee to be paid for such services.

- Capitalization of materials for clinical trials and 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 consumed. For products without an approved indication, drug product is charged to research and development expense.

- Recognition of deferred tax asset in respect of carry forward tax losses

The Company recorded a deferred tax asset in respect of carry forward tax losses based on effective tax rate calculation considering the Law for the Encouragement of Capital Investments and future taxable income estimation and the probability that in the future there will be taxable income against which the carry forwards losses can be utilized. This estimation can affect the recognition or reversal of deferred tax asset in the profit or loss. For information regarding deferred taxes recognition, please refer to note 21.

- Impairment test for the production facility

The Company performed an impairment test due to indications that can, in the future, result in a possible impairment. The Company calculated the recoverable amount of the production facility to determine whether the book value exceeds its recoverable amount. The impairment test was based on a DCF model using the Company's long term forecast. As of December 31, 2018 no impairment was recorded as the recoverable amount exceeded the book value.

Kamada Ltd. and its subsidiaries

Notes to the Consolidated Financial Statements

Note 4: - DISCLUSURE OF NEW STANDARDS IN THE PERIOD PRIOR TO THEIR ADOPTION

a. IFRS 16 – Leases

IFRS 16, replaces IAS 17 (Leases), and affects the accounting treatment for lessees with respect to leased assets. Pursuant to IFRS 16, all leases (except short term leases and small asset leases) will be recognized in the balance sheet. Initially, the lease liability and the right-of-use asset are measured at the present value of future lease payments (defined as economically unavoidable payments). The right-of-use asset is subsequently depreciated in a similar way to other assets such as tangible assets, i.e. typically in a straight-line over the lease term. Lessees will be required to separately recognize the interest expense on the lease liability and the depreciation expense on the right-of-use asset. Lessees will be also required to re-measure the lease liability upon the occurrence of certain events (e.g., a change in the lease term, a change in future lease payments resulting from a change in an index or rate used to determine those payments). The lessee will generally recognize the amount of the re-measurement of the lease liability as an adjustment to the right-of-use asset.

The new Standard is effective for annual periods beginning on or after January 1, 2019. Earlier application is permitted provided that IFRS 15, "Revenue from Contracts with Customers", is applied concurrently.

The Company plans to adopt IFRS 16 using the cumulative effect method without changing comparative information. The cumulative impact will adjust the opening balance of the equity at the date of initial application (i.e. January 1, 2019). The Company elects to apply the standard to contracts that were previously identified as leases applying IAS 17. The Company will therefore not apply the standard to contracts that were not previously identified as containing a lease applying IAS 17.

The Company elects to use the exemptions proposed by the standard with respect to lease contracts for which the underlying asset is of low value. The Company has leases of certain office equipment (i.e., printing and photocopying machines) that are considered of low value.

During 2018, the Company has performed a detailed impact assessment of IFRS 16. Impact on the statement of financial position (increase/(decrease)) as at January 1, 2019:

Assets	U.S. Dollars in thousands
Property, plant and equipment (right-of-use assets)	4,138
Lease liabilities	4,622
Net impact on equity	(484)

Pursuant to the adoption of IFRS 16, the Company’s operating expenses will be changed by the difference between the previously recognized lease costs and the depreciation costs on account of the Right-of-Use assets. In addition, the Company will begin to recognize interest expenses regarding the lease liability, which were not recognized in prior periods. Moreover, as of December 31, 2018 the effect of the initial adoption of the new Standard in 2019 is expected to result in a decrease in the Company's lease expenses of $967 thousands and an increase in the Company's depreciation and finance expenses of $804 thousands and $185 thousands, respectively. The total effect of the initial adoption of the new Standard in 2019 is expected to result in an increase of $163 thousands in operating income and a decrease of $22 thousands in income before taxes.

Kamada Ltd. and its subsidiaries

Notes to the Consolidated Financial Statements

Note 4: - DISCLUSURE OF NEW STANDARDS IN THE PERIOD PRIOR TO THEIR ADOPTION (CONT.)

b. IFRIC 23 - Uncertainty over Income Tax Treatment

IFRIC 23 clarifies application of recognition and measurement requirements in IAS 12 (Income Taxes) when there is uncertainty over income tax treatment. In determining taxable profit (tax loss), tax bases, unused tax losses, unused tax credits and tax rates, an entity must consider the probability that a taxation authority will accept an uncertain tax treatment. An entity has to determine whether to consider each uncertain tax treatment separately or together with one or more other uncertain tax treatments. The approach that better predicts the resolution of the uncertainty should be followed.

IFRIC 23 is effective for annual reporting periods beginning on or after 1 January 2019. The Company will apply the interpretation from its effective date. The Company evaluated the possible impact of IFRIC 23, reviewed its tax position taken, in the Company's tax returns for all tax years currently open to examination by a taxing authority. The Company believes the implementation of IFRIC 23 is not expected to have a material impact on its financial statements.

NOTE 5: - CASH AND CASH EQUIVALENTS

	December 31,	
	2018	2017
	U.S. Dollars in thousands	
Cash and deposits for immediate withdrawal	$18,018	$8,539
Cash equivalents in USD deposits (1)	-	4,001
Cash equivalents in NIS deposits (2)	75	141
	$18,093	$12,681

(1) The deposits bear interest of 1.53% per year, as of December 31, 2017 .

(2) The deposits bear interest of 0.16% per year, as of December 31, 2018 and 0.01% per year, as of December 31, 2017.

Note 6: - Short-Term Investments

	December 31,	
	2018	2017
	U.S. Dollars in thousands	
Fair value through other comprehensive income	$10,325	$8,597
Marketable securities (equity and debt) at fair value through profit or loss (2)	-	1,663
Bank deposits in USD (1)	22,174	20,078
	$32,499	$30,338

(1)

The deposits bear interest of 2.6%-3.5% and 1.7%-2.3% per year, as of December 31, 2018 and 2017, respectively.

(2) Following implementation of IFRS 9 all the investment portfolio is measured as fair value through other comprehensive income. As a result the Company reclassified from FVTPL to FVOCI as of January 1, 2018.

Kamada Ltd. and its subsidiaries

Notes to the Consolidated Financial Statements

Note 7: - Trade Receivables, net

	December 31,	
	2018	2017
	U.S. Dollars in thousands	
Open accounts:		
In NIS	$6,780	$8,263
In USD	20,814	22,284
	$27,594	$30,547
Checks receivable	80	115
	$27,674	$30,662
Less allowance for doubtful accounts	-	-
Trade receivables, net	$27,674	$30,662

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	30-60 Days	60-90 Days	90-120 Days	Over 120 days	Total
	U.S. Dollars in thousands						
December 31, 2018	$27,215	$337	$ 15	$15	$ 6	$ 6	$27,594
December 31, 2017	$29,692	$680	$ 21	$152	$ 2	-	$30,547

Note 8: - Other accounts Receivables

	December 31,	
	2018	2017
	U.S. Dollars in thousands	
Materials for clinical trials and inventory designated for R&D activities	$399	$635
Prepaid expenses	1,086	822
Government authorities	1,552	563
Accrued interest	66	66
Accrued income	193	33
Other	12	13
	$3,308	$2,132

Note 9: – Inventories

	December 31,	
	2018	2017
	U.S. Dollars in thousands	
Finished products	$7,023	$5,168
Purchased products	4,813	2,695
Work in progress	4,792	6,159
Raw materials	12,688	7,048
	$29,316	$21,070

(1) During the years 2018, 2017 and 2016, the Company recorded, as cost of revenues, an impairment of inventories of $61 thousands, $460 thousands and $544 thousands, respectively.

Kamada Ltd. and its subsidiaries

Notes to the Consolidated Financial Statements

Note 10: –Property, Plant and equipment

a. Composition and movement:

2018

	Land and Buildings	Machinery and Equipment (1) (2)	Vehicles	Computers, Software, Equipment and Office Furniture	Leasehold Improvements	Total
	U.S. Dollars in thousands					
Cost						
Balance at January 1, 2018	$28,399	$ 29,602	$ 66	$ 6,522	$ 1,273	$65,862
Additions	806	2,331	19	590	(132)	3,614
Sale and write-off	(38)	(1,547)	-	(619)	-	(2,204)
Balance as of December 31, 2018	29,167	30,386	85	6,493	1,141	67,272
Accumulated Depreciation						
Balance as of January 1, 2018	13,916	21,430	59	5,194	85	40,684
Depreciation and impairment	1,198	1,711	4	672	118	3,703
Sale and write-off	(38)	(1,462)	-	(619)	-	(2,119)
Balance as of December 31, 2018	15,076	21,679	63	5,247	203	42,268
Depreciated cost as of December 31, 2018	$14,091	$ 8,707	$ 22	$ 1,246	$ 938	$25,004

2017

	Land and Buildings	Machinery and Equipment (1) (2)	Vehicles	Computers, Software, Equipment and Office Furniture	Leasehold Improvements	Total
	U.S. Dollars in thousands					
Cost						
Balance at January 1, 2017	$27,618	$ 26,485	$ 94	$ 5,520	$ 1,052	$60,769
Additions	781	3,151	-	1,002	1,196	6,130
Sale and write-off	-	(34)	(28)	-	(975)	(1,037)
Balance as of December 31, 2017	28,399	29,602	66	6,522	1,273	65,862

Accumulated Depreciation						
Balance as of January 1, 2017	12,606	19,972	86	4,559	967	38,190
Depreciation and impairment	1,310	1,492	1	635	85	3,523
Sale and write-off	-	(34)	(28)	-	(967)	(1,029)
Balance as of December 31, 2017	13,916	21,430	59	5,194	85	40,684
Depreciated cost as of December 31, 2017	$14,483	$ 8,172	$ 7	1,328	$ 1,188	$25,178

Kamada Ltd. and its subsidiaries

Notes to the Consolidated Financial Statements

Note 10: –Property, Plant and equipment (cont.)

(1) Including labor costs charged in 2018 and 2017 to the cost of facilities, machinery and equipment in the amount of $514 thousands and $431 thousands, respectively.

(2) Including financing costs of $44 thousands capitalized in 2017 to the cost of machinery and equipment. During 2018 no financing costs were capitalized.

b. As for liens, refer to Note 18.

c. Capitalized leasing rights of land from the Israel land administration.

	December 31,	
	2018	2017
	U.S. Dollars in thousands	
Under finance lease	$1,004	$1,016

The Group has capitalized leasing rights from the Israel Land Administration for an area of 16,880 m² in Beit Kama, Israel, on which the Company's manufacturing plant and other buildings are located. The sum 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, the Company signed an agreement with the Israel Land Administration to consolidate its leasing rights and extend the lease period to 2058, including an extension option for additional 49 years thereafter.

Note 11: - other Long Term Assets

	December 31,	
	2018	2017
	U.S. Dollars in thousands	
Distribution right (1)	123	-
Long term pre-paid expenses	51	49
	$174	$ 49

(1) During 2018 the Company entered into agreement to obtain the distribution right of a certain therapeutic product to be distributed in Israel, subject to Israeli Ministry of Health ("IL MOH") marketing approval. Pursuant to the agreement, the Company was required to make certain upfront and milestone payments. These payments are accounted for as long term assets through obtaining IL MOH marketing authorization, and it will be amortized during the product's economic useful life.

Kamada Ltd. and its subsidiaries

Notes to the Consolidated Financial Statements

Note 12: - Trade Payables

	December 31,	
	2018	2017
	U.S. Dollars in thousands	
Open debts mainly in USD	$11,408	$11,246
Open debts in NIS	5,876	6,789
Sub-Total	17,284	18,035
Notes payable	1	1
	$17,285	$18,036

Note 13: -Other accounts Payables

	December 31,	
	2018	2017
	U.S. Dollars in thousands	
Employees and payroll accruals	$4,708	$4,735
Derivatives financial instruments	64	8
Accrued Expenses and Others	489	1,077
	$5,261	$5,820

Note 14: - Loans and capital leases

	December 31,	
	2018	2017
	U.S. Dollars in thousands	
Total loans and capital leases (1)	1,278	1,984
Less current maturities	562	614
Long term loans and capital leases	$716	$1,370

(1) Capital leases balance was $138 thousands and $274 thousands, as of December 31, 2018 and 2017, respectively.

Bank loans

The loans are payable over 60 equal monthly installments. The loans bear fixed interest rate in the range of 3.15% -3.55%. No new loans received in 2018. As for pledges, refer to Note 18.

Kamada Ltd. and its subsidiaries

Notes to the Consolidated Financial Statements

Note 15: - Financial Instruments

a. Classification of financial assets and liabilities

The financial assets and financial liabilities in the balance sheet are classified by groups of financial instruments pursuant to IFRS 9:

	December 31,	
	2018	2017
	U.S. Dollars in thousands	
Financial assets		
Financial assets at fair value:		
Marketable securities (equity and debt) – through profit or loss	-	$1,663
Financial assets at fair value through other comprehensive income:		
Financial assets at fair value through other comprehensive income	10,324	8,597
Financial assets at cost:		
Cash and cash equivalent	18,093	* 12,681
Short term bank deposits	22,175	*20,078
	$50,592	$43,019
Financial liabilities		
Derivatives instruments mainly measured at fair value through other comprehensive income	$64	$8
Financial liabilities measured at amortized cost:		
Bank loans and capital leases	1,278	1,984
	$1,342	$1,992

*Reclassified

Kamada Ltd. and its subsidiaries

Notes to the Consolidated Financial Statements

Note 15: - 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 utilized derivatives to hedge certain exposures to risk.

Risk management is the responsibility of the Company CEO and 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

a) 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, 2018, the Company has a position in financial derivatives intended to hedge changes in the exchange rate of the USD vs. the NIS (see also f. below).

b) Price risk

As of December 31, 2018, the Company has financial instruments, classified as financial assets measured at fair value through other comprehensive income for which the Company is exposed to risk of fluctuations in the security price that is determined by reference to the quoted market price.

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, marketable securities, trade receivables and foreign currency derivative contracts.

a) 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 these debts such as letters of creditor and down payments. In addition, the Company partially insures its overseas sales with foreign trade risk insurance.

Note 15: - Financial Instruments (cont.)

The Company keeps constant track of customer debt and the Financial Statements include 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, 2018 and 2017 is the carrying amount of trade receivables.

b) Cash and cash equivalent and short term investments:

The Company holds cash, cash equivalents, short term deposits and other financial instruments at a major financial institutions in Israel. 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. The Company’s marketable securities consist of investment-grade corporate bonds, government bonds (Including U.S., Israeli and other government bonds). The Company’s investment policy, limits the amount the Company may invest in any one type of investment or issuer and the average maturities of the bond portfolio, thereby reducing credit risk concentrations.

The Company has not experienced any significant losses on its short term investments.

c) Foreign currency derivative contracts:

The Company is exposed to foreign currency exchange movements, primarily in Israel. Consequently, it enters into various foreign currency exchange contracts with major financial institutions (see also f. below).

3. Liquidity risk

The table below summarizes the maturity profile of the Company's financial liabilities based on contractual undiscounted payments:

December 31, 2018

	Less than one year	1 to 2	2 to 3	3 to 5	Total
	U.S. Dollars in thousands				
Trade payables	$17,285	-	-	-	$17,285
Other accounts payables	5,261	-	-	-	5,261
Long term loans and capital leases (including interest)	$595	$495	$209	$32	$1,331
	$23,141	$495	$209	$32	$23,877

Kamada Ltd. and its subsidiaries

Notes to the Consolidated Financial Statements

Note 15: - Financial Instruments (cont.)

December 31, 2017

	Less than one year	1 to 2	2 to 3	3 to 5	Total
	U.S. Dollars in thousands				
Trade payables	$18,036	-	-	-	$18,036
Other accounts payables	5,820	-	-	-	5,820
Long term loans and capital leases (including interest)	669	634	532	260	2,095
	$24,525	$634	$532	$260	$25,951

Changes in liabilities arising from financing activities

	January 1, 2018	Payments	Foreign exchange movement	Cash from new loans	New leases	December 31, 2018
	U.S. Dollars in thousands					
Bank loans	$1,710	(460)	(110)	-	-	1,140
Capital leases	274	(136)	-	-	-	138
Total	$1,984	$ (596)	$ (110)	-	-	$ 1,278

c. Fair value

The following table demonstrates the carrying amount and fair value of the financial instruments presented in the financial statements not at fair value:

	Carrying Amount		Fair Value	
	December 31,		December 31,	
	2018	2017	2018	2017
	U.S. Dollars in thousands			
Financial liabilities				
Bank loans and capital Leases	$1,278	$1,984	$1,275	$1,984

The fair value of the bank loans and capital leases was based on standard pricing valuation model such as DCF which considers the present value of future cash flows discounted at the 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.

Kamada Ltd. and its subsidiaries

Notes to the Consolidated Financial Statements

Note 15: - 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
	U.S. Dollars in thousands	
December 31, 2018		
Debt securities (corporate and government) measured fair value through other comprehensive income	$1,588	8,736
Derivatives instruments	-	(64)
	$1,588	$8,672

	Level 1	Level 2
	U.S. Dollars in thousands	
December 31, 2017		
Marketable securities at fair value through profit or loss:		
Equity shares	$77	
Mutual funds	456	
Debt securities (corporate and government)	1,130	
Derivatives instruments		(8)
Available for sale debt securities (corporate and government)		$8,597
	$1,663	$8,589

During 2018 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

Kamada Ltd. and its subsidiaries

Notes to the Consolidated Financial Statements

Note 15: - Financial Instruments (cont.)

	December 31,	
	2018	2017
	U.S. Dollars in thousands	
Sensitivity test to changes in market price of listed Securities		
Gain (loss) from change:		
5% increase in market price	$519	$513
5% decrease in market price	$(519)	$(513)
Sensitivity test to changes in foreign currency:		
Gain (loss) from change:		
5% increase in NIS	$(21)	$(143)
5% decrease in NIS	$21	$143
5% increase in Euro	$(197)	$(135)
5% decrease in Euro	$197	$135

e. Linkage terms of financial liabilities by groups of financial instruments pursuant to IFRS 9:

	December 31,	
	2018	2017
	U.S. Dollars in thousands	
In NIS:		
Bank loans measured at amortized cost	$1,140	$1,710
In USD:		
Capital leases measured at amortized cost	$138	$274

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 and inventory. 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, 2018 the fair value of the derivative instruments not designated as hedging was a liability of $6 thousands. The open transactions for those derivatives were in an amount of $5,009 thousands.

Cash flow hedges:

As of December 31, 2018, 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, 2018 the fair value of the derivative instruments designated as hedge accounting was a liability of $58 thousands. The open transactions for those derivatives were in an amount of $1,169 thousands.

Cash flow hedges of the expected salaries expenses in December 31, 2018 was estimated as highly effective and accordingly a net unrecognized loss was recorded in other comprehensive income in the amount of $99 thousands.

Kamada Ltd. and its subsidiaries

Notes to the Consolidated Financial Statements

Note 16: - Employee Benefit Liabilities, NET

Employee benefits consist of short-term benefits and post-employment benefits.

a. Post-employment benefits:

According to the labor laws and Severance Pay Law in Israel, 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 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 employees 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:

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 2018, 2017 and 2016 were $ 992 thousands, $ 884 thousands and $669 thousands, 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,		
	2018	2017	2016
	U.S. Dollars in thousands		
Current service cost	$292	$356	$359
Interest expenses, net	25	23	20
Current service cost (income) due to the transfer of real yield from the compensation component to the royalties' component in executive insurance policies before 2004	3	(7)	5
Total employee benefit expenses	320	372	384
Actual return on plan assets	$171	$119	$22

Kamada Ltd. and its subsidiaries

Notes to the Consolidated Financial Statements

Note 16: - Employee Benefit Liabilities, NET (cont.)

The expenses are presented in the Statement of Comprehensive income (loss) as follows

	Year Ended December 31,		
	2018	2017	2016
	U.S. Dollars in thousands		
Cost of revenues	$175	$211	$228
Research and development	50	57	62
Selling and marketing	75	*73	*67
General and administrative	20	*31	*27
	$320	$372	$384

*Reclassified

4. The plan liabilities, net:

	December 31,	
	2018	2017
	U.S. Dollars in thousands	
Defined benefit obligation	$4,987	$5,907
Fair value of plan assets	(4,200)	(4,763)
Total liabilities, net	$787	$1,144

5. Changes in the present value of defined benefit obligation

	2018	2017
	U.S. Dollars in thousands	
Balance at January 1,	$5,907	$5,235
Interest costs	110	151
Current service cost	292	356
Benefits paid	(645)	(641)
Demographic assumptions	(29)	(28)
Financial assumptions	(223)	254
Past Experience	(2)	6
Currency Exchange	(423)	574

Balance at December 31,	$4,987	$5,907

6. Plan assets

a) Plan assets

Plan assets comprise assets held by long-term employee benefit funds and qualifying insurance policies.

Kamada Ltd. and its subsidiaries

Notes to the Consolidated Financial Statements

Note 16: - Employee Benefit Liabilities, NET (cont.)

b) Changes in the fair value of plan assets

	2018	2017
	U.S. Dollars in thousands	
Balance at January 1,	$4,763	$4,513
Expected return	85	127
Contributions by employer	182	227
Benefits paid	(564)	(586)
Demographic assumptions	5	1
Financial assumptions	(2)	1
Past Experience	83	(11)
Current service cost due to the transfer of real yield from the compensation component to the royalties component in executive insurance policies before 2004	(3)	7
Currency exchange	(349)	484
Balance at December 31,	$4,200	$4,763

7. The principal assumptions underlying the defined benefit plan

	2018	2017	2016
	%		
Discount rate of the plan liability	2.02	2.27	3.72
Future salary increases	3.6	4	4

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 $189 thousands or increase by $241 thousands, 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 $229 thousands or decrease by $182 thousands, respectively.

Note 17: - Contingent Liabilities and commitments

a. On August 23, 2010, the Company entered into a 30 years collaboration agreement with Baxter Healthcare Corporation ("Baxter") with respect to obtaining the distribution rights the Company's AAT IV drug ("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, 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 raw materials 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 at a total amount of $ 60 million over the first five years of the Distribution Agreement. In addition, the Company is entitled to royalty payments, of no less than $5 million per year, on account of sales of GLASSIA that would be produced by Takeda in accordance with the License Agreement. Between 2013 and 2016, the parties amended the License Agreement and the Distribution Agreement to extend the supply of GLASSIA by the Company to Takeda and increase Takeda’s minimum purchase commitment.

As of December 31, 2018, the Company received a total of $39.5 million on account of the agreed upfront and milestone payments from Takeda pursuant to the Distribution and License Agreements as amended. Prior to the last amendment of the Distribution Agreement in October 2016, the net sums received were recorded as deferred revenues and were recognized as revenues based on the actual sales of GLASSIA and on a pro-rata basis. Starting October 2016, the balance of the deferred revenues is recognized on a straight line basis according to Takeda’s updated minimum purchase commitment through December 31, 2018, which was the term of the supply commitment period prior to the October 2016 amendment. Non-refundable revenues due to the achievement of milestones are recognized upon reaching the milestone.

Pursuant to the October 2016 amendment of the Distribution Agreement, the distribution period is currently extended through the end of 2020, with the start of GLASSIA production by Takeda in 2021.

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 condition, the Company will be required to participate in the funding of these clinical studies in a total amount not to exceed $10 million.

Kamada Ltd. and its subsidiaries

Notes to the Consolidated Financial Statements

Note 17: - Contingent Liabilities and commitments (cont.)

Pursuant to the Raw Material Supply Agreement Takeda undertook to provide the Company, free of charge, all quantities of raw materials 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 raw material 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 raw materials for its continued development, production, sale and distribution of GLASSIA by the Company outside the Territory.

b. The Company has engaged in operating lease agreements for office and storage spaces. These agreements will expire in 2026.

Minimum future lease fees for the office and storage spaces as of December 31, 2018 are as follows:

	U.S. Dollars in thousands
Year 1	$ 577
Year 2 to 5	2,365
Year 6 and thereafter	1,848
	$ 4,790

c. The Company has engaged in operating lease agreements for the vehicles in its possession. These agreements will expire between 2019 and 2021.

Minimum future lease fees for the existing vehicles as of December 31, 2018 are as follows:

	U.S Dollars in thousands
Year 1	$ 406
Year 2	209
Year 3	29
	$ 644

Note 17: - Contingent Liabilities and commitments (cont.)

d. In November 2006, the Company entered into an agreement with a third party in connection with a supply by the third party of a certain medical devise required for the development of a Company's product. Pursuant to the agreement, the Company was licensed to use developments made by the third party. Furthermore, the third party will provide the Company with devices for carrying out the 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 the third party royalties based on sales of the devices through the later of the medical device patents expiration period or 15 years from the first commercial sale of the Company's 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, the third party would be required to pay royalties to the Company of the total net sales of the medical device exceeding a certain sum, through the later of the medical device patents expiration period or 15 years from the first commercial sale of the Company's 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 are applicable to all indications mentioned above.

In addition, the parties entered into a commercialization and supply agreement, which ensures long-term regular supply of the device, including spare parts.

e. In August 2007, the Company entered into a long-term agreement with a third party for the purchase of a raw material used for the development, manufacture, sale and distribution of a Company's product at graded amounts and prices. In addition to the price paid by the Company for the raw material, the Company will pay the supplier an additional sum upon the sale of the product manufactured using the third party's raw material in specific territories as set in the agreement. As of December 31, 2018, there were no sales of the Company's product in these specific territories since marketing authorization from the relevant regulatory agencies was not yet obtained.

f. In July 2011, the Company entered into a strategic collaboration agreement with Kedrion Biopharma for clinical development, marketing, distribution and sales in the United States of KEDRAB, the Company's rabies immune globulin (Human). The product, KEDRAB, is developed, manufactured and marketed by the Company in other countries. The Company obtained U.S marketing approval from the FDA for KEDRAB in August 2017. Launch of the product in the US was initiated in 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 is still ongoing. The cost of the study is equally shared between the parties.

Kamada Ltd. and its subsidiaries

Notes to the Consolidated Financial Statements

Note 18: - Guarantees and charges

The Company provided a bank guarantees in the amount of $ 208 thousands in favor of the Lessor of its leased office facility in Rehovot, Israel, and for other obligation, as guarantee for meeting its obligations under the lease agreement.

The Company pledged specific purchased assets as collateral against loans, in the original amount of NIS 8,355 thousands, received to fund the purchase of such assets.

Note 19: - Equity

a. share capital

	December 31, 2018		December 31, 2017	
	Authorized	Outstanding	Authorized	Outstanding
ordinary shares of NIS 1 par value	70,000,000	40,295,078	70,000,000	40,262,819

b. 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.

c. Share options and restricted shares

During 2018 and 2017, 53,584 and 10,659 share options, respectively, were exercised, on a cash-less basis, into 8,686 and 1,988 ordinary shares of NIS 1 par value each and 23,572 and 7,656 restricted shares were vested for total consideration of $9 thousand and $3 thousands, respectively.

For additional information regarding options and restricted shares granted to employees and management in 2018, refer to Note 20 below.

d. 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.

Kamada Ltd. and its subsidiaries

Notes to the Consolidated Financial Statements

Note 20: - Share-Based Payment

On July 24, 2011, the Company's Board of Directors approved a new unregistered share options plan. In September 2016 the Company's Board of Directors approved an amendment to the plan, to cover issuance of restricted shares (“RS”) under the plan and named it the Israeli Share Award Plan ("2011 Plan").

Pursuant to the 2011 Plan, granted share options and RS generally vest over 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% options vest at the end of each quarter thereafter.

a. Expense recognized in the financial statements

The share based compensation expense that was recognized for services received from employees and Board of Directors members is presented in the following table:

	For the Year Ended December 31		
	2018	2017	2016
	U.S. Dollar in thousands		
Cost of revenues	$401	$179	$332
Research and development	224	138	134
Selling and marketing	51	48	71
General and administrative	272	118	534
Total share-based compensation	$948	$483	$1,071

b. Share options granted to the Company's Chief Executive Officer ("CEO")

On December 20, 2018, the Company’s general shareholders meeting approved the grant of 90,000 options exercisable into ordinary shares at an exercise price of NIS 18.93 per option and 30,000 RSs at no exercise price to Mr. Amir London, the Company’s CEO. The fair value of the options calculated on the date of grant using the binomial option valuation model was estimated at $156 thousands. The fair value of the RSs was estimated based on the market price of the shares on the grant date at $148 thousands.

c. Share options granted to Employees

1. During 2018the Company's Board of Directors approved the grant of 417,825options, respectively to employees and members of the Company’s management. The fair value of the options calculated on the date of grant using the binomial option valuation model was estimated at $795 thousands.

Kamada Ltd. and its subsidiaries

Notes to the Consolidated Financial Statements

Note 20:- Share-Based Payment (CONT.)

2. During 2018, the Company's Board of Directors approved the grant of 66,308 RSs to the Company's employees and management. The RSs do not have exercise price. The fair value of the RSs was estimated based on the market price of the share on the grant date at $344 thousands.

d. Share options granted to board of directors members

1. On December 20, 2018, the Company's general shareholders meeting approved the grant of a total of 110,000 options to the Company's board of director members. The options are exercisable into ordinary shares at a range of an exercise price of NIS 18.93 - 22.54 per option. The fair value of the options calculated on the date of grant using the binomial option valuation model was estimated at $170 thousands.

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:

	2018		2017		2016	
	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	2,572,372	32.47	2,487,236	35.20	2,281,493	38.96
Granted	617,825	19.02	458,950	21.10	401,275	15.17
Exercised	(53,584)	15.77	(10,659)	18.19	(8,398)	18.47
Forfeited	(691,016)	30.51	(363,155)	35.70	(187,134)	39.22
Outstanding at end of year	2,445,597	29.99	2,572,372	32.47	2,487,236	35.20
Exercisable at end of year	1,406,048	38.02	1,755,253	38.69	1,543,358	40.44
The weighted average remaining contractual life for the share options		3.63		3.22		3.62

The range of exercise prices for share options outstanding as of December 31, 2017 and 2018 were NIS 15- NIS 57. Exercise is by cashless method.

Kamada Ltd. and its subsidiaries

Notes to the Consolidated Financial Statements

Note 20:- Share-Based Payment (CONT.)

The following table lists the number of RSs and changes in RSs grants during the year:

	Number of RSs		
	2018	2017	2016
	U.S. Dollars in thousands		
Outstanding at beginning of year	76,512	27,333	-
Granted	96,308	58,835	29,333
End of restriction period	(23,572)	(7,656)	-
Forfeited	(9,542)	(2,000)	(2,000)
Outstanding at end of year	139,706	76,512	27,333
The weighted average remaining contractual life for the restricted share	5.79	5.92	6.20

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:

	2018	2017	2016
Dividend yield (%)	-	-	-
Expected volatility of the share prices (%)	25-39	37-45	32-51
Risk-free interest rate (%)	0.2 – 2.0	0.1 – 1.83	0.13 – 1.83
Contractual term of up to (years)	6.5	6.5	6.5
Exercise multiple	2	2	2
Weighted average share prices (NIS)	18.49-21.17	16.05-16.44	15.17
Expected average forfeiture rate (%)	1-5	1-5	0-5

NOTE 21: 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.

NOTE 21: TAXES ON INCOME (CONT.)

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 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 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. Until 2005, the designation required advance approval from the Investment Center of the Israel Ministry of Industry, Trade and Labor. Each certificate of approval for an Approved Enterprise ("Certificate of Approval") relates to a specific investment program, delineated both by the financial scope of the investment and by the physical characteristics of the facility or the asset.

Under the Approved Enterprise programs, a company is eligible for governmental grants (“Grants Track”). Under the Grants Track the Company is eligible for investments grants awarded at various rates according to the development area in which the plant is located: in Development Zone A the rate is 24% and in Development Zone B the rate is 10%. In addition to the above grants, the Company is eligible to tax exemption at the first two years of the benefit period (as define below) and is subject to reduced corporate tax of 10% to 25% during the remaining five to eight years (depending on the extent of foreign investment in the Company) of the benefit period. 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 benefit period for part of the Company plants has ended by 2017.

NOTE 21: TAXES ON INCOME (CONT.)

Under the Investment Law a company may elect to receive an alternative package comprised of tax benefits ("Alternative Track") instead of the above mentioned grants Track. Under the Alternative Track, a company's undistributed income derived from an Approved Enterprise is exempt from corporate tax for an initial period of two to ten years (depending on the geographic location of the Approved Enterprise within Israel which begins in the first year that the Company realizes taxable income from the Approved Enterprise following the year of operation (as define below). After expiration of the initial tax exemption period, the Company is eligible for a reduced corporate tax rate of 10% to 25% for the following five to eight years, depending on the extent of foreign investment in the Company (as shown in the table below). The benefits period is limited to 12 years from the Year of Operation, or 14 years from the year in which the certificate of approval was obtained, whichever is earlier.

Tax benefits under Amendment 60

On April 1, 2005, an amendment to the Investment Law was effected ("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).

Pursuant to the Amendment, to be entitled to receive the tax benefits, a company must make an investment in the Privileged Enterprise exceeding a certain percentage or a minimum amount specified in the Investments Law. Such investment may 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").

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. The Year of Election is 2009.The Company also obtained 2012 as a Year of Election.

The duration of tax benefits is subject to a limitation of the earlier of 7 to 10 years (depending on the extent of foreign investment in the company) 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. The amendment does not apply to investment programs approved prior to December 31, 2004. The new tax regime applies to new investment programs only.

Kamada Ltd. and its subsidiaries

Notes to the Consolidated Financial Statements

NOTE 21: TAXES ON INCOME (CONT.)

The tax benefits available under Approved Enterprise or Privileged Enterprise relate only to taxable income attributable to the specific Approved Enterprise or Privileged Enterprise, and the Company's effective tax rate will be the result of a weighted combination of the applicable rates.

Percent of Foreign Ownership	Rate of Reduced Tax	Reduced Tax Period	Tax Exemption Period
0-25%	25%	5/0 years	2/10 years
25-49%	25%	8/0 years	2/10 years
49-74%	20%	8/0 years	2/10 years
74-90%	15%	8/0 years	2/10 years
90-100%	10%	8/0 years	2/10 years

The benefits available to an Approved Enterprise and a Privileged Enterprise are conditioned upon terms stipulated in the Investment Law and the related regulations and the criteria (for an Approved Enterprise) set forth in the applicable certificate of approval. If the Company does not fulfill these conditions, in whole or in part, the benefits can be cancelled and may be required to refund the amount of the benefits, linked to the Israeli consumer price index plus interest. The Company believes that its Privileged Enterprise programs currently operate in compliance with all applicable conditions and criteria.

In the event that a company declares and pays dividends from tax-exempt income, the company will be taxed on the otherwise exempt income at the same reduced corporate tax rate that would have applied to that income. Payment of dividends derived from income that was taxed at reduced rates, but not tax-exempt, does not result in additional tax consequences to the company. Shareholders who receive dividends derived from Approved Enterprise or Privileged Enterprise income are generally taxed at a rate of 15%, which is withheld and paid by the company paying the dividend, if the dividend is distributed during the benefits period or within the following 12 years (the limitation does not apply to a Foreign Investors Company, which is a company that more than 25% of its shares owned by non-Israeli residents).

Preferred Enterprise

Tax Benefits under the 2011 Amendment

As of January 1, 2011 new legislation amending to the Investment Law was effected (the “2011 Amendment”). Pursuant to the amendment a new status of “Preferred Company” and “Preferred Enterprise”, replacing the existed status of “Privileged Company” and “Privileged Enterprise”. Similarly to “Beneficiary Company”, 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.

NOTE 21: TAXES ON INCOME (CONT.)

Under the 2011 Amendment, 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 and Beneficiary Enterprise during the
benefits period. The uniform corporate tax rate will be 7% in Development Area A, and 12.5% elsewhere in Israel.

On August 5, 2013, the "Knesset" issued the Law for Changing National Priorities (Legislative Amendments for Achieving Budget Targets for 2013 and 2014), which consists of Amendment 71 to the Encouragement Law ("the Amendment"). According to the Amendment, the tax rate on preferred income from a Preferred Enterprise in 2014 and onwards will be 9% in Development Area A, and 16% elsewhere in Israel.

The Amendment also prescribes that any dividends distributed to individuals or foreign residents from the preferred enterprise's earnings as above will be subject to tax at a rate of 20% from 2014 and onwards (or a reduced rate under an applicable double tax treaty). Upon a distribution of a dividend to an Israeli company, no withholding tax is remitted.

In December 2016, the Israeli "Knesset" amended the Investment Law. According to the amendment, effective from January 1, 2017 the tax rate on:

1. Preferred income from a preferred enterprise will be 16% (in development area A – 7.5% instead of 9%).
2. Preferred income resulting from IP in a preferred technology enterprise will be 12% (in development area A – 7.5%).
3. Preferred income resulting from IP in a special preferred technology enterprise will be 6%.
4. Any dividends distributed from technology enterprise earnings to a foreign company that qualifies the provisions that are detailed in the law, will be subject to tax at a rate of 4%.

The Company has evaluated the effect of the adoption of the Amendment on its tax position, and as of the date of the approval of the financial statements, the Company believes that it will not apply the Amendment. The Company may elect to adopt the amendment in the future.

b. Tax rates applicable to the Company (other than the applicable preferred tax)

In December 2016, the Israeli "Knesset" approved, as part of the economic efficiency law (Legislative Amendments for Achieving Budget Targets for 2017 and 2018), a reduction of the corporate tax rate in 2017 from 25% to 24%, and in 2018 from 24% to 23%.

NOTE 21: TAXES ON INCOME (CONT.)

c. Tax assessments

1. Finalized tax assessments

The Company has finalized tax assessments through the end of tax year 2013.

2. Settlement of tax assessments

On July 10, 2016, the Company and the Israel Tax Authority (ITA) entered into a settlement agreement for the tax years 2004-2006. As part of the agreement, the Company paid NIS 5,000 million ($ 1.3 million) (including interest and CPI adjustment).

d. Carry forward losses for tax purposes and other temporary differences

As of December 31, 2018, the Company has carry forward losses and other temporary differences in the amount of $ 65,177 thousands. Final tax assessments for the years 2014 onwards could have an impact on the balance of carry forward tax losses for which deferred tax asset was not recognized. During 2018, the Company initially recorded deferred tax asset at an amount of $ 2, 048 thousands representing utilization of $ 37,224 thousands of its carry forward losses in the foreseeable future. The Company did not record deferred tax asset for the remaining portion of its carry forward losses due to estimation that their utilization in the foreseeable future is not probable.

e. Deferred taxes:

The Company initially recorded deferred tax assets for carry forward losses and other temporary differences, as their utilization in the foreseeable future is estimated to be probable. Below is the roll forward for deferred taxes:

	Total U.S Dollars in thousands
Balance at January 1, 2018	$ -
Amount carried to profit and loss	1,944
Amount carried to other comprehensive income	(8)
Amount carried to other capital reserve	112
Balance as of December 31, 2018	$ 2,048

Kamada Ltd. and its subsidiaries

Notes to the Consolidated Financial Statements

NOTE 21: TAXES ON INCOME(CONT.)

f. Taxes on income

	Year ended December 31,		
	2018	2017	2016
	U.S. Dollars in thousands		
Current taxes	$-	$129	$362
Deferred tax income	(1,944)	-	-
Taxes in respect of prior years	(11)	140	1,360
Taxes on income	$(1,955)	$269	$1,722

g. Theoretical tax:

The table below represent the reconciliation between the statutory tax rate and the effective tax rate as recorded in profit or loss

	Year ended December 31, 2018 U.S. Dollars in thousands	
Gain before taxes on income	$ 20,341	
Statutory tax rate	23	%
Tax calculated using the statutory tax rate	4,678	
Carry-forward tax losses utilization for which no deferred taxes were provided, net	(4,678)	
Temporary differences for which deferred taxes are initially recognized	(1,944)	
Prior year taxes	(11)	
Tax on income	$ (1,955)	
Effective tax rate	9.6	%

Kamada Ltd. and its subsidiaries

Notes to the Consolidated Financial Statements

Note 22: - Supplementary Information to the Statements of profit and loss

a. Additional information about revenues

	Year Ended December 31,		
	2018	2017	2016
	U.S. Dollars in thousands		
Revenues from major customers each of whom amount to 10% or more, of total revenues			
Customer A	$63,788	$60,383	$40,451
Customer B	-	-	10,225
Customer C	11,779	-	-
	$75,567	$60,383	$50,676

b. Revenues based on the location of the customers, are as follows:

	Year Ended December 31,		
	2018	2017	2016
	U.S. Dollars in thousands		
U.S.A	$75,331	$60,405	$40,585
Israel	28,093	26,355	25,340
Europe	3,594	5,348	3,825
Latin America	3,994	5,248	4,221
Asia	3,336	4,979	3,028
Others	121	490	495
	$114,469	$102,825	$77,494

c. Cost of goods sold

	Year Ended December 31,		
	2018	2017	2016
	U.S. Dollars in thousands		
Cost of materials	54,888	41,179	36,154
Salary and related expenses	14,867	13,137	10,596
Depreciation and amortization	2,859	2,504	2,443
Energy	1,426	1,202	959
Subcontractors	3,633	3,995	2,833
Other manufacturing expenses	989	1,572	1,057
	78,662	63,589	54,042
Decrease (increase) in inventories	(5,665)	7,148	2,092

	$72,997	$70,737	$56,134

d. Research and development

	Year Ended December 31,		
	2018	2017	2016
	U.S. Dollars in thousands		
Salary and related expenses	$5,823	$6,413	$5,237
Subcontractors	2,275	3,392	8,318
Materials and allocation of facility costs	1,131	1,101	1,907
Others	518	1,067	783
	$9,747	$11,973	$16,245

Kamada Ltd. and its subsidiaries

Notes to the Consolidated Financial Statements

Note 22: - Supplementary Information to the Statements of profit and loss (cont.)

e. Selling and marketing

	Year Ended December 31,		
	2018	2017	2016
	U.S. Dollars in thousands		
Salary and related expenses	$1,647	1,470	1,272
Marketing support	121	95	79
Packing, shipping and delivery	477	607	494
Marketing and advertising	424	627	337
Registration and marketing fees	470	1,162	796
Others	491	437	265
	$3,630	$4,398	$3,243

f. General and administrative

	Year Ended December 31,		
	2018	2017	2016
	U.S. Dollars in thousands		
Salary and related expenses	$3,085	$3,138	3,029
Employees welfare	1,151	2,182	1,465
Professional fees and public company expense	2,012	*1,549	*1,416
Depreciation, amortization and impairment	686	649	712
Communication and software services	675	*554	*362
Others	916	*201	*369
	$8,525	$8,273	$7,353

* Reclassified

g. Financial income/expense

	Year Ended December 31,		
	2018	2017	2016
	U.S. Dollars in thousands		

Financial incomes			
Interest income and gains from marketable securities	$820	$500	$469
Financial expenses			
Fees and interest paid to financial institutions	$340	$162	$126

Kamada Ltd. and its subsidiaries

Notes to the Consolidated Financial Statements

Note 23: - 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, 2018		2017		2016	
	Weighted Number of Shares	Income Attributed to equity holders of the Company U.S. Dollars in thousands	Weighted Number of Shares	Income Attributed to equity holders of the Company U.S. Dollars in thousands	Weighted Number of Shares	Loss Attributed to equity holders of the Company U.S. Dollars in thousands
For the computation of basic income (loss)	40,275,374	$ 22,296	37,970,697	$ 6,901	36,418,833	$ (6,733)
Effect of potential dilutive ordinary shares	170,043	-	74,400	-	-	-
For the computation of diluted income (loss)	40,445,417	$ 22,296	38,045,097	$ 6,901	36,418,833	$ (6,733)

b. The computation of the diluted income per share in 2018 and 2017 took into account the options and RSs due to their dilutive effect.

Note 24: - 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 Group is organized into operating segments based on the products and services of the business units and has two operating segments as follows:

Proprietary Products	Develop and manufacture plasma-derived therapeutics and market them in more than 15 countries.
Distribution	Distribute imported drugs 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 Group's headquarter assets, 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 group basis.

The segment liabilities do not include loans and financial liabilities as these liabilities are managed on a group basis.

b. Reporting on operating segments

	Proprietary Products	Distribution	Total
	U.S. Dollars in thousands		
Year Ended December 31, 2018			
Revenues	$90,784	$ 23,685	$114,469
Gross profit	$37,988	$ 3,484	$41,472
Unallocated corporate expenses			(22,213)
Finance income, net			1,082
Income before taxes on income			$20,341

Kamada Ltd. and its subsidiaries

Notes to the Consolidated Financial Statements

Note 24: - Operating Segments (cont.)

	Proprietary Products	Distribution	Total
	U.S Dollars in thousands		
Year Ended December 31, 2017			
Revenues	$79,559	$ 23,266	$102,825
Gross profit	$28,224	$ 3,864	$32,088
Unallocated corporate expenses			(24,644)
Finance expense, net			(274)
Income before taxes on income			$7,170

	Proprietary Products	Distribution	Total
	U.S. Dollars in thousands		
Year Ended December 31, 2016			
Revenues	$55,958	$ 21,536	$77,494
Gross profit	$18,235	$ 3,125	$21,360
Unallocated corporate expenses			(26,841)
Finance expense, net			470
Loss before taxes on income			$(5,011)

Note 25: - Balances and Transactions with Related Parties

a. Balances with related parties

	December 31, 2018	December 31, 2017
	U.S. Dollars in thousands	

Other accounts payables	$336	$ 292
Employee benefit liabilities, net	$80	$ 92
Trade receivable	$1,135	$ 2,382

Kamada Ltd. and its subsidiaries

Notes to the Consolidated Financial Statements

Note 25: - Balances and Transactions with Related Parties (cont.)

b. Transactions with employed/directors that accounts as related parties

	Year Ended December 31,		
	2018	2017	2016
	U.S. Dollars in thousands		
Salary and related expenses to those employed by the Company or on its behalf	$352	$460	$473
Remuneration of directors not employed by the Company or on its behalf	$366	$107	$122
Number of People to whom the Salary and remuneration Refer:			
Related and related parties employed by the Company or on its behalf	2	2	2
Directors not employed by the Company	8	2	3
	10	4	5

c. Transactions with key executive personnel (including non-related parties)

	Year Ended December 31,		
	2018	2017	2016
	U.S. Dollars in thousands		
Short-term benefits	$2,766	$2,959	$2,654
Share-based payment	285	310	460
Other long-term benefits	-	6	28
	$3,051	$3,275	$3,142

d. Transactions with related parties

	Year Ended December 31,		
	2018	2017	2016
	U.S. Dollars in thousands		
Sales	$3,529	$3,455	$2,230
Selling and marketing expenses	$313	$121	$101
General and administrative expenses	$408	$446	$503

Note 25: - Balances and Transactions with Related Parties (cont.)

e. Revenues and Expenses from Related and Interested Parties

Terms of Transactions with Related Parties

1. Sales to related parties are conducted at market prices. Open account that have yet to be repaid by the end of the year by a related party bear no interest and their settlement will be in cash and certain balances are guaranteed by letter of credit. For the years ended December 31, 2018, 2017 and 2016, the Company recorded no allowance for doubtful accounts for trade receivable from related parties.

On May 26, 2011, the Company announced its engagement in an amended agreement regarding the distribution of GLASSIA, that revises and replaces the distribution agreement signed in 2001 between the Company and Tuteur SACIFIA ("Tuteur"), a company registered in Argentina, currently under the control of the Hahn family. The amendment to the agreement was made as an arm's length transaction. On August 19, 2014 the Company amended the agreement in order to add KamRho(D) as an additional product to be distributed by Tuteur and expanded the territory to include Bolivia.

Pursuant to the distribution agreement, Tuteur serves as the exclusive distributor of GLASSIA and KamRho(D), in Argentina, Paraguay and Bolivia. In 2016 the Board of Directors approved a marketing contribution funding to Tuteur for reimbursement of costs associated with marketing activities aimed to locating new AATD patients and increasing the overall number of AATD patients treated with GLASSIA in Argentina. Such funding was paid by the Company in each of 2016 and 2017. In addition, in 2016 and in 2017 the Board of Directors approved extending a price discount to Tuteur for KamRho(D).

During 2019, a third amendment to the agreement was executed, which was effective as of July 1, 2018, pursuant to which the Company extended a per vial discount on the price of GLASSIA in exchange for obtaining a bank guarantee from Tuteur to cover any future supply of products to Tuteur.

2. On July 29, 2015 the Company's Board of Directors approved the entering into a distribution agreement with Khairi S.A. ("Khairi"), a company held, inter alia, by Mr. Leon Recanati, the Chairman of the Company's Board of Directors, and Mr. Jonathan Hahn, a director of the Company and his siblings, for the distribution of GLASSIA and KamRho(D) in Uruguay. This distribution agreement with Khairi is an arm's length transaction.

Note 25: - Balances and Transactions with Related Parties (cont.)

f. Chief executive officer employment terms

On June 30, 2015 the Company's shareholders approved the employment terms of Mr. Amir London in his position as the Company's Chief Executive Officer ("CEO"), effective as of July 1, 2015. Under the employment agreement, Mr. Amir London is entitled to a monthly gross salary of NIS 65,000 (or $16,658). On August 30, 2016 the general meeting of the shareholders approved the update of Mr. London's monthly gross salary to NIS 71,500 (or $18,430), effective as of July, 1 2016. On December 20, 2018 the general meeting of the shareholders approved the update of Mr. London's monthly gross salary to NIS 82,500 (or $22,627), effective as of July, 1 2018.

During 2018 the Company recorded approximately $139 thousands, as a bonus to Mr. London. As for the grant of options and restricted shares to Mr. London, refer to Note 20b.

Note 26: - EVENTS SUBSEQUENTS TO THE REPORTING PERIOD

a. On February 4, 2019 a wholly owned subsidiary of the Company named Kamada Ireland limited was established in Ireland.

b. As for the 3rd amendment of distribution agreement with Tuteur, refer to Note 25e.