KAMADA LTD
Form 20-F
March 06, 2018

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, 2017

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 001-35548

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

Amir London, Chief Executive Officer
2 Holzman St., Weizmann 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, 2017, the Registrant had 40,262,819 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 report 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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post 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 Financing Reporting Standards as issued by the International Accounting Standards Board Other

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

Item 17 Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes No

TABLE OF CONTENTS

In this Annual Report on Form 20-F ("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," "our compan "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. 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," "pla "target," "likely," "will," "would," "could," and similar expressions or phrases. We have based these forward-looking statemen 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 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 13-17% in 2018 compared to our revenues for 2017 and that we will achieve our revenue goal of $116-120 million in 2018;

- 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 Shire plc. ("Shire"), and Kedrion S.p.A ("Kedrion") will continue without disruption;

- our expectation that the minimum aggregate revenue for Glassia for the years 2018 to 2020 under our agreement with Shire will reach approximately $177 million and may be expanded to $228 million during that period;

- our expectation that our product offerings in our Proprietary Products segment will increase until 2020 (thereafter, Shire has no obligation to purchase a minimum amount of Glassia), that Shire will begin selling Glassia produced in its own manufacturing facility as early as 2021 and pay us royalties and that Shire will have an FDA approved production facility by 2021;

- our expectation that as Shire 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 Shire on sales of Glassia and continued increased sales of Glassia in rest of the world countries through local distributors and the KEDRAB product in the United States;

- our ability to launch our anti-rabies immunoglobulin product for prophylaxis treatment of rabies disease in the United States in 2018 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"), including that a recently signed supply agreement from November 2017 for marketing of KamRAB will generate total revenues through 2020 for our Company in the total amount of approximately $13 million;

- 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;

1

- our belief that we will be able to continue to meet our customers' demand for AAT and anti-rabies immunoglobulin;
- our belief that U.S-based and other healthcare providers would seek 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 grow;
- the beneficial characteristics of Inhaled AAT for AATD, which we believe may result in our increased profitability;
- our expectations are that our discussions with the U.S. Food and Drug Administration (the “FDA”) regarding the clinical and regulatory pathway for registration in the United States of Inhaled AAT for AATD, will materialize by mid-2018 and will lead to receiving the 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”);
- 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 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 interim results from the Phase II clinical study of our intravenous AAT product to prevent lung transplantation rejection in the second half of 2018 and top-line results in the second half 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;
- 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 ending December 31, 2017.

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, 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 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 on the date of this Annual Report. 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, 2017, 2016 and 2015 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 3.467, the exchange rate published by the Bank of Israel as of December 31, 2017.

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, 2017, 2016 and 2015 and the consolidated balance sheets data as of December 31, 2017 and 2016 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, 2014 and 2013 and the summary consolidated balance sheet data as of December 31, 2015, 2014 and 2013 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,				
	2017	2016	2015	2014	2013
	(in thousands, except per share data)				
Consolidated Statements of Operations Data:					
Revenues from Proprietary Products	$79,559	$55,958	$42,952	$44,389	$50,658
Revenues from Distribution	23,266	21,536	26,954	26,676	19,965
Total revenues	102,825	77,494	69,906	71,065	70,623
Cost of revenues from Proprietary Products	51,335	37,723	30,901	32,617	27,104
Cost of revenues from Distribution	19,402	18,411	23,640	23,406	17,112
Total cost of revenues	70,737	56,134	54,541	56,023	44,216
Gross profit	32,088	21,360	15,365	15,042	26,407
Research and development expenses	11,973	16,245	16,530	16,030	12,745
Selling and marketing expenses	4,398	3,243	3,652	2,898	2,100
General and administrative expenses	8,273	7,353	6,607	7,593	7,862
Operating income (loss)	7,444	(5,481)	(11,424)	(11,479)	3,700
Financial income	500	469	463	404	278
Income (expense) in respect of currency exchange and translation differences and derivatives instruments, net	(612)	127	625	-	(369)
Income (expense) in respect of revaluation of warrants to fair value	-	-	-	-	-
Financial expense	(162)	(126)	(934)	(2,086)	(3,142)
Income (loss) before taxes on income	7,170	(5,011)	(11,270)	(13,161)	467
Taxes on income	269	1,722	-	52	24
Net income (loss)	6,901	(6,733)	$(11,270)	$(13,213)	$443
Income (loss) attributable to equity holders	6,901	(6,733)	$(11,270)	$(13,213)	$443
Income (loss) per share attributable to equity holders:					
Basic	$0.18	$(0.18)	$(0.31)	$(0.37)	$0.01
Diluted	$0.18	$(0.18)	$(0.31)	$(0.37)	$0.01
Weighted-average number of ordinary shares used to compute income (loss) per share attributable to equity holders:					
Basic	37,970,697	36,418,833	36,245,813	35,971,335	32,714,631
Diluted	38,045,097	36,418,833	36,245,813	35,971,335	33,385,651
Consolidated Statements of Cash Flows:					
Cash flows from operating activities	$3,608	$1,897	$(13,979)	$(9,918)	$(3,854)
Cash flows from investing activities	(15,608)	1,637	11,253	(26,819)	(3,903)
Cash flows from financing activities	15,320	1,490	(6,355)	(7,640)	49,208
Consolidated Balance Sheet Data:					
Cash, cash equivalents, restricted cash and short-term investments	$43,019	$28,632	$28,306	$51,896	$74,177
Trade receivables	30,662	19,788	23,071	17,514	17,882
Working capital [(1)]	67,486	49,871	57,655	66,206	85,108

Total assets	122,110	99,696	101,992	119,140	139,379
Total liabilities	32,618	32,953	29,485	38,723	49,409
Total shareholders' equity	89,492	66,743	72,507	80,417	89,970
Other Data:					
Adjusted net income (loss)[2] [3]	$7,384	$(5,663)	$(9,363)	$(9,462)	$9,414
Adjusted EBITDA[2]	$11,450	$(909)	$(6,290)	$(4,940)	$3,156

(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 and plus a one-time management compensation payment associated with our successful U.S. initial public offering. 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. Our management believes that excluding the one-time management compensation payment associated with our successful U.S. initial public offering is useful to investors because of the extraordinary, non-recurring nature of the expense.

(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, and plus one-time management compensation payment. 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,				
	2017	2016	2015	2014	2013
	(in thousands)				
Net income (loss)	$6,901	$(6,733)	$(11,270)	$(13,213)	$443
Income tax expense	269	1,722	-	52	24
Financial expense, net	(338)	(343)	471	1,682	2,864
Depreciation and amortization expense	3,523	3,501	3,227	2,788	3,001
Non-cash share-based compensation expenses	483	1,071	1,907	3,751	1,327
Income (expense) in respect of translation differences and derivatives instruments, net	612	(127)	(625)	-	369
One-time management compensation payment		-	-	-	1,386
Adjusted EBITDA	$11,450	$(909)	$(6,290)	$(4,940)	$9,414

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 64%, 56% and 43% of our total revenues for the years ended December 31, 2017, 2016 and 2015 respectively. If Glassia were to lose significant sales, or was 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 Shire, pursuant to which Shire is the sole distributor of Glassia in the United States, Canada, Australia and New Zealand. Shire is a global specialty biopharmaceutical public company listed on the Nasdaq and London Stock Exchanges. 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. Revenue derived from our partnership with Shire, which consists of sales of Glassia and milestone revenue, accounted for approximately 59%, 52% and 37% of our total revenues in the years ended December 31, 2017, 2016 and 2015, respectively. Additionally, we depend upon Shire for the supply of fraction IV plasma for our production of Glassia to be sold in the United States. If our relationship with Shire were to deteriorate, our business would be adversely affected. See “—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 our Proprietary Products segment, we currently rely on Shire, which accounts for a significant portion of our total sales, and any disruption to our relationships with Shire would have an adverse effect on our results of operations and profitability.

Pursuant to our partnership arrangement with Shire, Shire is the sole distributor of Glassia in the United States, Canada, Australia and New Zealand. Sales to Shire accounted for approximately 59%, 52% and 37% of our total revenues in the years ended December 31, 2017, 2016 and 2015, respectively. We also depend upon Shire 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 comply with such requirements or comply with such requirements."

If we fail to maintain our relationship with Shire, we could face significant costs in finding a replacement distributor for the markets Shire 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 Shire consists of sales of Glassia. Pursuant to the Exclusive Manufacturing, Supply and Distribution Agreement, as amended, after 2020, Shire has no obligation to purchase a minimum amount of Glassia. Additionally, we estimate that Shire will begin selling Glassia produced in its own manufacturing facility as early as 2021, and pay us royalties. As Shire 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 Shire 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 and our operating results would be adversely impacted as we would continue to incur fixed costs relating to our manufacturing facility.

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. Based on receiving the FDA approval for KEDRAB in August 2017, we expect to launch KEDRAB in the United States in 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., Shire, Emergent BioSolutions (which acquired Cangene Corporation) and Grifols S.A., which acquired a previous competitor, Talecris Biotherapeutics, Inc., in 2011. 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 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 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.

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. In addition, we rely to a large extent on Shire 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 Shire to properly advise us regarding, or properly perform tasks related to, regulatory compliance requirements, could adversely affect us. If our relationship with Shire 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 KamRAB 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 KamRAB. 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%, 24% and 33% of our total revenues for the years ended December 31, 2017, 2016 and 2015, 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 primarily 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 primarily on our ability to win tender bids during the annual tender process in Israel, and our ability to win such 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 Products 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 have since, commenced discussions with the FDA and revised the protocol based on its feedback as well as are in the process of providing additional requested information to the agency. 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 plan to submit to the FDA 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.

Due to Clinical and Preclinical Related 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.

Due to Regulatory Related Reasons:

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

Due to Commercial Reasons:

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 AATD and the risk/benefit balance to patients based on that data. Those 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 and lung transplantation rejection 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.

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 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, 2017 we may continue to incur losses in the future and thus may never achieve sustained profitability.

As of December 31, 2017, our cash and cash equivalents and short-term investments were $43 million. Since inception, we have incurred significant operating losses. Our net profit was $6.9 million for the year ended December 31, 2017, while for the years ended December 31, 2016 and 2015 we incurred net losses of $6.7 million and $11.3 million respectively. As of December 31, 2017, we had an accumulated deficit of $104.6 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, 2017, we had cash and short-term investments of approximately $43.0 million, compared to cash and short-term investments of approximately $28.6 million as of December 31, 2016. Historically, we have funded our operations primarily through cash flow from operations (including sales of our approved proprietary products and sales of distributional products), payments received in connection with strategic partnerships (including milestone payments from collaborating agreements), sales of ordinary shares (including our 2005 initial public offering on the Tel-Aviv Stock Exchange, our 2013 initial public offering on NASDAQ and our ordinary share offering which closed in August 2017), 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 distributed 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 may restrict our operations or require us to relinquish rights.

On November 28, 2016, we filed a registration statement on Form F-3 with the U.S. Securities and Exchange Commission ("SEC") utilizing a "shelf" registration process. 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.

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;

23

- 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.

24

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 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. 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 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 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 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, Shire has no obligation to purchase a minimum amount of Glassia, and we estimate that Shire will begin selling Glassia produced in its own manufacturing facility as early as 2021 and paying us royalties. As Shire 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 and our operating results may be

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. 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 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. The healthcare reform law imposes new 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. 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. 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 will need to adopt 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 Restrictive Trade Practices Law, 5758-1988 (the "Restrictive Trade Practices 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. 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 Antitrust 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 Israeli Restrictive Trade Practices Law with respect to certain of our products. Furthermore, following an amendment to the Restrictive Trade Practices Law that became effective in August 2015, which repealed the statutory exemption that existed under the Restrictive Trade Practices 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 Antitrust 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 could 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 facility and the Histadrut (General Federation of Labor in Israel), which expired in December 2017. We are currently in the process of negotiating the renewal of the collective bargaining agreement. In the process of negotiating the initial collective bargaining agreement in 2013, two work stoppages occurred, and additional work stoppages may occur during the current process of negotiating the renewal of the collective bargaining agreement. In October 2016, the General Federation of Labor in Israel authorized our employees' committee to declare a labor dispute, which led to short-term work stoppages and if such disputes are authorized in the future it may lead to the occurrence of work stoppages or labor strikes. Although work stoppages have not had a material adverse effect on our business or financial condition in the past, 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.

Recently enacted 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 two 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 2018 and 2027. 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, particularly after we are no longer an "emerging growth company."

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 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.

As an "emerging growth company," as defined in the JOBS Act, we take advantage of certain temporary exemptions from various reporting requirements, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of SOX (and the rules and regulations of the SEC thereunder). When these exemptions cease to apply, we expect to incur additional expenses and devote increased management effort toward ensuring compliance with them. We will cease to be an emerging growth company on or before December 31, 2018 (See "—We are an "emerging growth company" with reduced reporting requirements that may make our ordinary shares less attractive to investors.").

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, 2017, we had 40,262,819 ordinary shares outstanding.

On November 28, 2016, we filed a registration statement on Form F-3 with the SEC utilizing a "shelf" registration process. 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 for total gross proceeds of approximately $17.3 million.

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, 2017, as well as the 2,572,372 ordinary shares issuable upon exercise of outstanding options and the 76,512 restricted shares granted to certain managers, are freely tradable in the United States without restrictions or further registration under the Securities Act. Approximately 21% 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.

In addition, according to the provisions of a certain registration rights agreement, Damar Chemicals Inc., a company registered in Panama ("Damar"), Leon Recanati, Gov Financial Holdings Ltd., a company organized under the laws of the State of Israel ("Gov") and wholly-owned by Mr. Recanati, and David Tsur and their respective affiliates, are entitled, until no later than June 2018, to require that we register their 8,386,561 ordinary shares under the Securities Act for resale into the public markets in the United States. All shares sold pursuant to an offering covered by such registration statement will be freely tradable in the United States, except for shares purchased by affiliates.

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, 9.1% and 8.35% of our outstanding ordinary shares, respectively, as of December 31, 2017. 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, 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.

We are a foreign private issuer and are not subject to the same requirements that are imposed upon U.S. domestic issuers by the SEC. Under the Exchange Act, we are subject to reporting obligations that, in certain respects, are less detailed and less frequent than those of U.S. domestic reporting companies. For example, we are not required to issue quarterly reports, 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 officers, directors and principal shareholders are exempt from the requirements to report short-swing profit recovery contained in Section 16 of the Exchange Act.

As we are a "foreign private issuer" and 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.

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

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

We have not recently 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.

We are an "emerging growth company" with reduced reporting requirements that may make our ordinary shares less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and have taken advantage of certain exemptions from various reporting requirements that are applicable to public companies generally. For example, for so long as we remain an emerging growth company, we have elected not to have our independent registered public accounting firm provide an attestation report on the effectiveness of our internal control over financial reporting, as would otherwise be required by Section 404(b) of SOX. This may increase the risk that we fail to detect and remedy any weaknesses or deficiencies in our internal control over financial reporting.

In general, these reduced reporting requirements allow us to refrain from disclosing information that you may find important. It is also possible that investors may generally find our ordinary shares less attractive because of our status as an emerging growth company and our more limited disclosure. Any of the foregoing could adversely affect the price and liquidity of our ordinary shares.

We anticipate taking advantage of these disclosure exemptions until we are no longer an "emerging growth company." We will cease to be an "emerging growth company" upon the earliest of:

- December 31, 2018, which is the last day of the fiscal year in which the fifth anniversary of our initial public offering in the United States has occurred;

- the last day of the fiscal year in which our annual gross revenues are $1.07 billion or more;

41

- the date on which we have, during the previous three-year period, issued more than $1 billion in non-convertible debt securities; or

- the date we qualify as a "large accelerated filer" with at least $700 million of equity securities held by non-affiliates.

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, 2017, we had 413 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.

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 Israeli 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 Shire, or the grant to Shire 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 has further decreased to 23% in 2018. For more information about applicable Israeli tax regulations, see "Item 10. Additional Information — E. Taxation — Israeli Tax Considerations and Government Programs."

In the future, we may not be eligible to receive additional tax benefits under the Investment Law if we increase certain of our activities outside of Israel. Additionally, in the event of a distribution of a dividend from the abovementioned tax exempt income, in addition to withholding tax at a rate of 20% effective as of 2014 (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. Substantially all 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 to appoint or prevent the appointment of an office holder in 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 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, Israeli tax law may impose 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., Weizmann 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.

Emerging Growth Company

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act (the "JOBS Act"). Thus, we may take advantage of certain exemptions from various reporting requirements that are applicable to public companies generally. For example, we have elected not to have our independent registered public accounting firm provide an attestation report on the effectiveness of our internal control over financial reporting, as would otherwise be required by Section 404(b) of the Sarbanes-Oxley Act ("SOX").

We will cease to be an "emerging growth company" upon the earliest of:

- December 31, 2018, which is the last day of the fiscal year in which the fifth anniversary of our initial public offering in the United States has occurred;
- the last day of the fiscal year in which our annual gross revenues are $1.07 billion or more;
- the date on which we have, during the previous three-year period, issued more than $1 billion in non-convertible debt securities; or
- the date we qualify as a "large accelerated filer" with at least $700 million of equity securities held by non-affiliates.

The JOBS Act also provides that an "emerging growth company" can utilize the extended transition period provided in Section 7(a)(2)(B) of the Securities Act, for complying with new or revised accounting standards. However, we have chosen to "opt out" of such extended transition period, and, as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for companies that are not "emerging growth companies." Section 107 of the JOBS Act provides that our decision to opt out of the extended transition period for complying with new or revised accounting standards is irrevocable.

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 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 produce our plasma-derived protein therapeutics in our advanced cGMP compliant, FDA-approved, large scale 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 at the board, 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, 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 innovator in this field by developing different therapeutic approaches to AATD independently, or through collaborations with strategic partners. In addition, we decided that the development of AAT for indications other than AATD, such as GvHD, T1D, lung transplantation rejection, etc. will be performed through strategic collaborations. For that purpose we plan to continue investing in the additional indications, only to the point of developing sufficient data to potentially attract such strategic partners.

Our flagship product, Glassia, is 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 Shire in the United States, under which the minimum aggregate revenue for Glassia for the years 2018 to 2020 is expected to reach approximately $177 million and may be expanded to $228 million during that period. Pursuant to the Exclusive Manufacturing, Supply and Distribution Agreement, as amended, after 2020, Shire has no obligation to purchase a minimum amount of Glassia. Additionally, we estimate that Shire will begin selling Glassia produced in its own manufacturing facility as early as 2021, and pay us royalties. We also market Glassia in other counties through local distributors. 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.

In addition to Glassia, we are developing 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 further reducing the risk of infection, 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 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 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.

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 resubmit the MAA 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. However, it is not certain when we will initiate such Phase III clinical trial, as the FDA expressed concerns and questions regarding the safety and efficacy of the treatment, and we are currently in discussions with the FDA regarding the regulatory path forward. See "—Our Product Pipeline and Development Program—Inhaled Formulations of AAT—AATD" and "Risk Factors— Risk Related to Development, Regulatory Approval and Commercialization of New Products Candidates Including Inhaled AAT."

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. We expect to launch KamRAB in the United States, under the trademark "KEDRAB," in 2018.

In November 2017, we signed a supply agreement for marketing of KamRAB with an undisclosed international organization. The agreement extends through 2020 and is expected to generate total revenues through 2020 for our Company in the total amount of approximately $13 million.

Additionally, 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.

In November 2016, we initiated a Phase II/III clinical trial for the treatment of aGvHD in collaboration with Shire 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 to evaluate our AAT product for preemption of steroid refractory aGvHD.

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. We also announced that the next interim report is expected in the second half of 2018, following completion of one year of treatment, and top-line results are anticipated in the second half of 2019. 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.

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

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 approximately eight 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, most of which are produced from plasma or its derivative products. Our product sales in our Proprietary Products segment are predicted to increase until 2020; thereafter, Shire has no obligation to purchase a minimum amount of Glassia, and we estimate that Shire will begin selling Glassia produced in its own manufacturing facility as early as 2021, and pay us royalties. As Shire 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.

We derived approximately 59%, 52% and 38% of our total revenues in the years ended December 31, 2017, 2016 and 2015, respectively, from sales in the United States, approximately 5%, 5% and 5% of our total revenues in the years ended December 31, 2017, 2016 and 2015, respectively, from sales in Europe, approximately 5%, 4% and 4% of our total revenues in the years ended December 31, 2017, 2016 and 2015, respectively, from sales in Asia (excluding Israel) and 5%, 5% and 9% of our total revenues in the years ended December 31, 2017, 2016 and 2015, respectively, from sales in Latin America.

Our Product Portfolio

Our products include plasma-derived protein therapeutics that are either produced in our Proprietary Products segment or marketed and sold in our Distribution segment.

Proprietary Products Segment

Our products in the Proprietary Products segment consist of plasma-derived protein therapeutics that are administered by injection or infusion. We also manufacture certain products from raw materials derived from animal sources.

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, 2017, 2016 and 2015, accounted for approximately 83%, 77% and 70% of our total revenues, in the Proprietary Products segment, respectively. Revenue from our intravenous AATD products comprised approximately 64%, 56%, and 43% of our total revenues for the years ended December 31, 2017, 2016 and 2015, respectively. Sales of KamRAB and KamRho (D) for the years ended December 31, 2017, 2016 and 2015 accounted for the substantial balance of total revenues in the Proprietary Products segment.

Product	Indication	Active Ingredient	Geography
Respiratory			
Glassia (or Ventia in certain countries)	Intravenous AATD	Alpha-1 Antitrypsin (human)	United States, Israel, Russia, Brazil, Argentina, Turkey, Colombia**
Immunoglobulins			
KamRAB	Prophylaxis of rabies disease	Anti-rabies immunoglobulin (human)	Israel, India, Thailand, El Salvador*, South Africa, Bosnia, Afghanistan, Russia*, Mexico*, Georgia*, Ukraine** and South Korea
KamRho (D) IM	Prophylaxis of hemolytic disease of newborns	Rho(D) immunoglobulin (human)	Israel, Brazil, India, Argentina, Paraguay, Chile*, Russia, Kenya, 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			
Heparin Lock Flush	To maintain patency of indwelling IV catheter designed for intermittent injection therapy or blood sampling	Heparin sodium	Israel*
Kamacaine 0.5%	Local or regional anesthesia or analgesia during surgery, diagnostic and therapeutic procedures and obstetrical procedures. Spinal anesthesia for surgery	Bupivacaine HCl	Israel
Human transferrin (diagnostical grade)	Not for human use	Transferrin	United States, Israel, and France

*We have regulatory approval, but did not market the product in this country in 2017.
** 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 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 to 190,000 patients suffering from AATD, of which less than 10% have been diagnosed. According to a 2013 report of the Marketing Research Bureau, the annual cost to the patient of AATD treatment is between $80,000 and $100,000 per 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 increase going forward as awareness of AAT increases.

Glassia is the first AAT product in the world that is 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. Pursuant to our agreement with Shire, the Phase IV clinical trials are financed and managed by Shire, 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 Shire.

We market Glassia in the United States through our partnership with Shire. We market Glassia in Israel by ourselves and in the other countries through our local distributors. Sales to Shire accounted for approximately 59%, 52% and 37% of our total revenues in the years ended December 31, 2017, 2016 and 2015, 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 $65.93 million in 2017, representing 80% 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 the United States and Canada. 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, where sales of the product have steadily increased. We sell KamRAB in nine countries, received regulatory approval to market KamRAB in four other countries, including, since August 2017, in the United States. 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." We expect to launch KamRAB in the United States (under the trademark "KEDRAB" in the United States) in 2018 through our collaboration with Kedrion. 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 ex-US with an undisclosed international organization. The agreement extends through 2020 and is expected to generate total revenues for our company in the total amount of approximately $13 million through 2020.

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), and are selling it in ten countries in 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 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 sold additional critical care products including Heparin, an anticoagulant, and Kamacaine, an anesthetic for surgery or obstetric procedures and Transferrin, which is used as a cultural medium for diagnostic assays and cell cultures. Due to low demand, Heparin was not sold in 2017.

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. Most 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 54%, 61% and 61% of total revenues in the Distribution segment for the years ended December 31, 2017, 2016 and 2015, respectively. Sales of IVIG accounted for approximately 12%, 17% and 24% of our total revenues for the years ended December 31, 2017, 2016 and 2015, 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
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)
Critical Care		
Heparin sodium injection	Treatment of thrombo-embolic disorders such as deep vein thrombosis, acute arterial embolism or thrombosis, thrombophlebitis,	Heparin sodium

	pulmonary embolism, fat embolism. Prophylaxis of deep vein thrombosis and thromboembolic events	
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 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 clinical trials:

* Recombinant AAT for AAT Deficiency in early development stages
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 FDA expressed concerns and questions about that data, 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 would allow us to proceed with additional clinical development of Inhaled AAT in the United States. 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 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 both FDA and EMA 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.

55

Upon conclusion of these discussions and subject to FDA's authorizing our IND, we intend to initiate the new pivotal Phase III clinical trial in the United States in the second half of 2018, and resubmit the MAA after such clinical trial is successfully completed, with the data to be collected in such clinical trial.

Recombinant AAT

According to our strategic decision to focus on AATD, and in preparation for future increased demand for AAT 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 of a favorable expression system and growth conditions required to successfully develop an effective rhAAT and we are exploring potential collaborations with third parties in the development of rhAAT.

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 November 2016, we initiated a Phase II/III clinical trial in aGvHD in collaboration with Shire. This Phase II/III clinical trial was planned to be a two-part, multi-center, prospective study to evaluate the safety and efficacy of our AAT IV as an add-on biopharmacotherapy to conventional steroid treatment in up to 168 patients with acute GvHD with lower gastrointestinal involvement (LGI-aGvHD). However, 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 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.

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 Shire 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, Shire and we collaborate in the development and funding of the study.

This Phase II study was initiated in April 2016 and in January 2018, we reported the interim results for such Phase II 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.

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.

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. 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 in further product development.

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.

Shire (Glassia)

On August 23, 2010, we entered into a strategic partnership 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 the acquisition of Baxalta, and as a result, all Baxalta's rights under the partnership agreement have been assigned to Shire.

The partnership arrangement with Shire includes three main agreements: (1) a distribution agreement, pursuant to which Shire is the sole distributor of Glassia in the United States, Canada, Australia and New Zealand; (2) a licensing agreement, which grants Shire licenses to use our knowledge and patents to produce, develop and sell Glassia and other products administered by transfusion; and (3) an agreement for Shire to supply us with fraction IV plasma, a plasma derivative, produced by Shire, as discussed under "— Manufacturing and Supply — Raw Materials — Fraction IV plasma for Glassia." As between us and Shire, 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 Shire to extend the period of minimum purchases by Shire 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 Shire accounted for approximately 59%, 52% and 37% of our total revenues for the years ended December 31, 2017, 2016 and 2015, 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, Shire is obligated to purchase a minimum amount of Glassia per year until the end of 2020. Pursuant to Shire'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 Shire. We expect that from 2021, Shire will start marketing Glassia in the United States to be produced at its production facility and pay us royalties, 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, Shire will have no further obligation to purchase a minimum amount of Glassia; however, Shire'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. Shire 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 Shire as a result of Shire achieving an undisclosed sales milestone for Glassia. We have committed to reimburse Shire 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. Shire 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 Shire infringes upon our intellectual property.

Following termination of the agreement, Shire 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 Shire, 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 Shire's production and sale of Glassia in the United States, Canada, Australia and New Zealand. Shire 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 Shire per year beginning on the first year of commercial sales of Glassia produced by Shire.

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 Shire 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 Shire 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 Shire under the agreement that is not considered an improvement on the licensed technology. Additionally, Shire 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. Shire 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 Shire of its obligations. We have the right to terminate the agreement, upon prior written notice: (i) if Shire 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 Shire, 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 Shire did not occur by June 15, 2017 and Shire 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 Shire a non-exclusive, perpetual, royalty free license.

Chiesi Farmaceutici S.p.A ("Chiesi") (Inhaled AAT for AATD product)

On August 2, 2012, we entered into an exclusive distribution agreement with Chiesi, pursuant to which we granted Chiesi the exclusive right to commercialize Inhaled AAT for AATD in the European Union and Turkey, as well as certain other European and Asian countries, including certain ex-Soviet Union countries.

In November 2017, we and Chiesi mutually agreed to terminate the exclusive distribution agreement. Following the withdrawal of the MAA for the Inhaled AAT for AATD product candidate with the EMA, a European distribution agreement within the pact's defined timeframe was not warranted. We maintain full, worldwide commercial rights in Inhaled AAT for AATD. There were no financial implications related to the termination of such agreement and we are not required to return any payment previously granted to us by Chiesi in the scope of the exclusive distribution agreement which was terminated.

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.

Kedrion (KamRAB)

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, 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.

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. We expect to launch KamRAB in the United States in first half of 2018 under the trademark "KEDRAB". See "Item 4. Information on the Company — immunoglobulins — KamRAB".

The agreement provides exclusive rights to Kedrion to market and sell KEDRAB in the United States. We retain intellectual property rights to KamRAB. 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.

Manufacturing and Supply

We have a production plant located in Beit Kama, Israel, which we believe is fully cGMP compliant. We operate the main production facility on schedules 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 a new logistic facility in our plant in Beit Kama that will support our activities during the coming years. During each year we have routine maintenance shut downs of our plant, which may last up to a few weeks.

Our production plant passed inspection by the FDA in 2010, and our plant and laboratories also successfully passed a quality assurance audit by the Russian Ministry of Health and similar authorities in Brazil, Kenya and Mexico. 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 and February 2016, 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.

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.

Other than Shire, in the years ended December 31, 2017, 2016 and 2015, there were two suppliers who accounted for 10% or more of the total purchases of raw materials in our Proprietary Products Segment. 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.”

In the years ended December 31, 2017, 2016 and 2015, we incurred $19.9 million $18.4 million and $19.0 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 Shire, we signed an agreement with Shire for the supply of fraction IV plasma for use in the production of Glassia to be sold in the United States. Under this agreement, Shire 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. Shire receives no payment for the supply of fraction IV plasma to be used by us for the manufacture of Glassia to be sold to Shire. If we require fraction IV for other purposes, we are entitled to purchase it from Shire at a predetermined price. While we are dependent on Shire for the supply of fraction IV plasma, Shire 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 Shire 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 Shire 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. Shire 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 Shire, Shire 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 recombinant human Alpha 1 Antitrypsin ("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 $12 million, $16.2 million and $16.5 million research and development expenses in the years ended December 31, 2017, 2016 and 2015, 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 Shire 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 cash in advance. 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 cash) 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.

Customers

For the year ended December 31, 2017, sales to Shire 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 Shire and Kupat Holim Clalit accounted for 52% and 13%, respectively, of our total revenues. For the year ended December 31, 2015, sales to Shire and Kupat Holim Clalit accounted for 37% and 15%, respectively, of our total revenues. No other customer accounted for greater than 10% of our total revenues in the year ended December 31, 2017, 2016 and 2015.

Shire is our major customer in the Proprietary Products segment. Our other customers in the Proprietary Products segment are our distributors in Brazil, Argentina, Russia, Thailand and India, 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. We have not seen significant changes in the activities of our competitors in recent years. Additionally, our strategic alliance with Shire in the United States has strengthened our AAT 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 Shire 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 Shire is currently proactively marketing only 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. We believe that there are two main competitors for this anti-rabies product worldwide: Grifols, whose product we estimate comprises over 90% 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 this product. 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, Shire, CSL, Omrix Biopharmaceuticals Ltd. (a Johnson & Johnson company) and Emergent BioSolutions, 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 local representatives 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 foreign regulatory agency before it may be legally marketed in foreign countries.

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 Biologics License Application ("BLA") and approval or license by the FDA prior to being marketed in the United States. Manufacturers of biologics may also be subject to state regulation. Failure to comply with regulatory requirements, both before and after product approval, may subject us and/or our partners, contract manufacturers and suppliers to administrative or judicial sanctions, including FDA delay or refusal to approve applications, warning letters, product recalls, product seizures, import restrictions, total or partial suspension of production or distribution, fines and/or criminal prosecution.

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

1. preclinical laboratory tests and animal tests;

2. submission to the FDA of an IND application for human clinical testing, 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.

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.

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 (formerly the Health Care Financing Administration), other divisions of the United States Department of Health and Human Services (e.g., the Office of Inspector General), 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 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 who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states 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 "Sunshine" law 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. 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.

76

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;
- 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. 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.

Patents

As of December 31, 2017, 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, four PCT patent applications and five 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 and are expected to expire at various dates between 2018 and 2027. Our patent applications relate to the use of our products and their delivery methods. 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, KAMADA 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.”

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
Bio-Kam Ltd.	Israel
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—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, 2017, 2016 and 2015 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 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, is 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 Shire in the United States. In addition to Glassia, we have a product line consisting of eight 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. We expect to launch KamRAB in the United States, under the trademark "KEDRAB," in 2018. In addition to our propriety products we leverage our expertise and presence in the plasma-derived protein therapeutics market by distributing more than 10 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 the first quarter of 2016. 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. 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 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. Upon conclusion of these discussions 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 after such clinical trial is successfully completed, with the data to be collected in such clinical trial. 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 New Products Candidates Including Inhaled AAT.”

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, most 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 and financial expenses, net, each of which are managed on a group basis. 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. For the year ended December 31, 2015, we derived $42.9 million of revenues from our Proprietary Products segment, or 61% of total revenues, and $27.0 million of revenues from our Distribution segment, or 39% of total revenues.

81

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. In particular, in 2015, 2016 and 2017, our Glassia supplies to Shire increased by more than 33% each year, and based on our agreement with Shire we expect Glassia supplies to continue and increase through 2020. We expect that our revenues will grow in a range of approximately 13% to 17% in 2018, allowing us to achieve our revenue goal of $116 to $120 million by 2018 through increased sales of our existing products in the Proprietary Products segment, mainly driven from sales of Glassia and the launch of KEDRAB in the United States. as an anti-rabies prophylaxis treatment. As discussed below, after 2020, Shire 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 Shire on sales of Glassia and continued increased sales of Glassia in rest of the world countries through local distributors and KEDRAB product in the United States.

The AAT augmentation market for AATD in the U.S., which is the primary market for Glassia, has grown by more than 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 growth in sales in 2017 compared to 2016 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 Shire (formerly Baxter and Baxalta) for the marketing and distribution of Glassia in the United States, Canada, Australia and New Zealand and for the licensing of our technology, granting Shire 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 Shire in September 2010. From the inception of the strategic arrangement through December 31, 2017, we have received $39.5 million from Shire 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, 2017 from Shire in the amount of $248 million. We currently generate revenues from sales of Glassia to Shire, 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, Shire may begin producing Glassia in its own manufacturing facility as early as 2021, and pay us royalties. As Shire 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 Shire 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 is expected to be launched in the United States in the first quarter of 2018. 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 Shire for the clinical trials for Glassia in the United States and Kedrion for the clinical trials for KEDRAB in the United States. See “Item 4. Information on the Company — Strategic Partnerships — Shire (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, 2017, 2016 and 2015, we incurred significant research and development expenses related to clinical trials related to Inhaled AAT for AATD in Europe and the United States and AAT for the treatment of newly diagnosed Type-1 diabetes and lung transplantation rejection. 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 Shire, we have not seen significant changes in these producers’ activities in the market. Additionally, our strategic alliance with Shire has strengthened our competitive positioning in the market and we believe this will contribute to increased revenues in the future. However, this assumes the continuation of our strategic partnership with Shire. 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 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. In addition, in recent years, we have seen an increase in the development efforts for new plasma-derived products.

83

Historically, we have not been subject to significant pricing fluctuations for plasma or fraction IV due to the consolidation of plasma suppliers or increased development efforts. Additionally, in order to attempt to prevent future price fluctuations and ensure the availability of plasma and fraction IV, we have secured supply of plasma and fraction IV from multiple suppliers at fixed prices (subject to adjustments for inflation or product concentration) for predetermined quantities.

In our Distribution segment, our costs are for the purchase of products for sale from our distributors. Our annual purchases are forecasted each year with each distributor, but individual product purchases during the year are made on a purchase order basis. For these instances, we do not 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 from the licensing of our technology. Historically, we have derived most of our revenues from the sale of products and to a lesser extent from payments by the Israeli government related to our snake bite antiserum product. We derived a significant portion of our total revenues from sales of Glassia to Shire. Sales to Shire accounted for approximately 59%, 52% and 37% of our total revenues in the years ended December 31, 2017, 2016 and 2015, respectively. Revenue from all sales of Glassia comprised approximately 64%, 56% and 43% of our total revenues for the years ended December 31, 2017, 2016 and 2015, respectively. We expect revenues attributable to the sale of Glassia to Shire will grow in the next three years, in line with the expected Glassia orders by Shire pursuant to the fifth amendment to the Manufacturing, Supply and Distribution Agreement, until Shire begins production of Glassia, at which time our sales to Shire will be reduced and be replaced by royalties from Shire.

In our Distribution segment, we generate revenues from the sale in Israel of imported products produced by third parties. In the past three years, sales of IVIG have decreased due to growing competition. Sales of IVIG accounted for approximately 12%, 17% and 24% of our total revenues for the years ended December 31, 2017, 2016 and 2015, 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, the expected launch of KEDRAB in the United States in 2018 and the potential launch, if approved, of new AAT products currently in different development phases.

Cost of Revenues and Gross Profit

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 partnership with Shire and successful penetration to the U.S. market, we have focused during the years ended December 31, 2017, 2016 and 2015 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 Shire 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 production processes must be approved by the FDA.

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 (35%, 33% and 28% for the years ended December 31, 2017, 2016 and 2015, respectively) than in our Distribution segment (17%, 15%, 12% for the years ended December 31, 2017, 2016, and 2015, 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.

Research and Development Expenses

Research and development expenses are incurred for the development of new products and processes and include conducting clinical trials, development materials, payroll, 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 2018 to reflect our plan to fund certain additional clinical trials for AAT for certain additional indications including Inhaled AAT for AATD . However, actual spending could differ as our plans change and we invest in other drugs or potentially reduce our anticipated funding on research for existing products or partner with other parties to fund development.

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 direct sales force. We market our products in our Distribution segment to health maintenance organizations and hospitals in Israel and recently also began to market products directly to patients.

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, 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 changes in fair value of financial instruments at fair value through profit or loss.

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, changes in the fair value of financial assets or liabilities at fair value through profit 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 payment made during 2016 of $1.3 million to the Israel Tax Authority as a settlement agreement for the tax years 2004-2006.

One of our Israeli facilities has Approved Enterprise status granted by the 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 Israeli 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.

We anticipate that 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, 2017, we have net operating loss carryforwards of approximately $90.1 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,		
	2017	2016	2015
	(in thousands, except per share data)		
Revenues from Proprietary Products segment	$79,559	$55,958	$42,952
Revenues from Distribution segment	23,266	21,536	26,954
Total revenues	102,825	77,494	69,906
Cost of revenues from Proprietary Products segment	51,335	37,723	30,901
Cost of revenues from Distribution segment	19,402	18,411	23,640
Total cost of revenues	70,737	56,134	54,541
Gross profit	32,088	21,360	15,365
Research and development expenses	11,973	16,245	16,530
Selling and marketing expenses	4,398	3,243	3,652
General and administrative expenses	8,273	7,353	6,607
Operating income (loss)	7,444	(5,481)	(11,424)
Financial income	500	469	463
Income (expense) in respect of currency exchange differences and derivatives instruments	(612)	127	625
Financial expense	(162)	(126)	(934)
Income (loss) before taxes on income	7,170	(5,011)	(11,270)
Taxes on income	269	1,722	-
Net income (loss)	6,901	$(6,733)	$(11,270)

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

Segment Results

			Change 2017 vs. 2016		
	2017	2016	Amount	Percent	
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.

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 the 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
	(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.

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 New Products Candidates Including Inhaled AAT.”

We will determine which programs to pursue and how much to fund each program in response to the scientific and clinical success 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, 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.

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 Israeli Tax Authorities for the tax years 2004-2006, pursuant to which we paid $1.3 million.

Year Ended December 31, 2016 Compared to Year Ended December 31, 2015

Segment Results

			Change 2016 vs. 2015	
	2016	2015	Amount	Percent
Revenues:				
Proprietary Products	$55,958	$42,952	$13,006	30.2 %
Distribution	$21,536	$26,954	(5,418)	(20.1)%
Total	$77,494	$69,906	$7,588	10.8 %
Cost of Revenues:				
Proprietary Products	$37,723	$30,901	$6,822	22 %
Distribution	$18,411	$23,640	(5,229)	(22.1)%
Total	$56,134	$54,541	$1,593	2.9 %
Gross Profit:				
Proprietary Products	$18,235	$12,051	$6,184	51.3 %
Distribution	$3,125	$3,314	(189)	(5.7)%
Total	$21,360	$15,365	$5,995	39.0 %

90

Revenues

In the year ended December 31, 2016, we generated $77.5 million of total revenues, compared to $69.9 million in the year ended December 31, 2015, an increase of $7.6 million, or approximately 10.9%. This increase was primarily due to a $13.0 million increase in our Proprietary Products segment revenues mainly due to an increase in sales of Glassia in United States, partially offset by a decrease of $5.4 million in our Distribution segment mainly attributable to decrease in sales of IVIG products due to increased competition for these products.

Cost of Revenues

In the year ended December 31, 2016, we incurred $56.1 million of cost of revenues, compared to $54.5 million in the year ended December 31, 2015, an increase of $1.6 million or approximately 3%. The cost of revenues in our Proprietary Products segment increased by $6.8 million, which was primarily due to increase of a $3.5 million in cost of products sold mainly due to increase in volume of sales and $ 2.6 million resulting from unexpected temporary shutdown of our manufacturing plant following a routine planned maintenance shutdown and inventory write-off occurred in the fourth quarter. The cost of revenues in our Distribution segment decreased by $5.2 million, which was primarily due to a decrease in volume of sales.

Gross profit in our Proprietary Products segment increased by $6.2 million in 2016, primarily due to an increase in sales of Glassia in United States, partially offset the unexpected temporary shutdown of our manufacturing plant and inventory write-off occurred in the fourth quarter of 2016. Gross profit in our Distribution segment remained stable. As a percentage of total revenues, gross margin increased to 27.6% from 21.97% for the years ended December 31, 2016 and 2015. Gross margin for the Proprietary Products segment, as a percentage of revenues from that segment, was 32.6% and 28% for the years ended December 31, 2016 and 2015, respectively. Gross margin for the Distribution segment, as a percentage of revenues from that segment, was 14.5% and 12.3% for the years ended December 31, 2016 and 2015. The increase in gross profit margin was primarily driven by an increase in the Proprietary Products segment revenues.

Research and Development Expenses

In the year ended December 31, 2016, we incurred $16.2 million of research and development expenses, compared to $16.5 million in the year ended December 31, 2015, a slight decrease of $0.3 million, or approximately 2%. This decrease was primarily due to a $1.5 million decrease in facility costs allocated to research and development partially offset by an increase of $0.5 million in labor costs and a $0.3 million increase in clinical trial and external consultant costs mainly relating the submission of the MAA to EMA and the BLA to FDA. . Research and development expenses accounted for approximately 21.0% and 23.6% of total revenues for the years ended December 31, 2016 and 2015, respectively.

Set forth below are the research and development expenses associated with our major development programs in the years ended December 31, 2016 and 2015:

	Year ended December 31,	
	2016	2015
	(in thousands)	
Inhaled AAT	$2,695	$4,939
AAT for newly diagnosed Type-1 Diabetes	2,320	1,753
AAT IV for lung transplantation rejection and for GvHD	194	-
Anti Rabies	1,772	-
Unallocated salary	5,237	4,566
Unallocated facility cost allocated to research and development	3,244	4,569
Unallocated other expenses	783	703
Total research and development expenses	$16,245	$16,530

Research and development expenses for Inhaled AAT for AATD decreased by $2.2 million due to the completion of the clinical trial and registration in the European Union that occurred in 2016 and the completion of phase II clinical trial in the U.S. Research and development expenses for Type-1 Diabetes increased by $0.6 million. In 2016, we had a $1.7 million expense due to BLA submission for our KamRAB product for Prophylaxis treatment of rabies disease in the United States. 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, 2016 and 2015, we incurred $5.2 million and $4.6 million, respectively, of unallocated salary expenses, $3.2 million and $4.6 million, respectively, of facility costs allocated to improvements in processes and $0.8 million and $0.7 million, respectively, of unallocated other expenses.

Selling and Marketing Expenses

In the year ended December 31, 2016, we incurred $3.2 million of selling and marketing expenses, compared to $3.7 million in the year ended December 31, 2015, a decrease of $0.5 million, or approximately 13%. This decrease was primarily due to a $0.3 million decrease in marketing support to distributors and $0.2 million decrease in marketing expenses. Selling and marketing expenses accounted for approximately 4.2% and 5.2% of total revenues for the years ended December 31, 2016 and 2015, respectively.

General and Administrative Expenses

In the year ended December 31, 2016, we incurred $7.4 million of general and administrative expenses, compared to $6.6 million in the year ended December 31, 2015, an increase of $0.8 million, or approximately 10.8%. This increase was primarily due to an increase of $0.5 million in labor costs. General and administrative expenses accounted for approximately 9.9% and 10.1% of total revenues for the years ended December 31, 2016 and 2015, respectively.

Financial Income

In the years ended December 31, 2016, and December 31, 2015 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, 2016, we incurred income of $0.1 million in respect of currency exchange differences on balances in other currencies versus the U.S. dollar compared to income of $0.6 million in the year ended December 31, 2015.

Financial Expenses

In the year ended December 31, 2016, we incurred $0.1 million of financial expenses, compared to $0.9 million in the year ended December 31, 2015, a decrease of $0.8 million, or approximately 88% associated with a decrease in financial expenses for our convertible debt which was fully repaid at the end of 2015.

Taxes on Income

In the year ended December 31, 2016, we had $1.7 million taxes on income mainly due to a settlement agreement with the Israeli Tax Authorities for the tax years 2004-2006, pursuant to which we paid $1.3 million. In the year ended December 31, 2015 we had no taxes on income.

Quarterly Results of Operations

The following tables set forth unaudited quarterly consolidated statements of operations data for the four quarters of fiscal years 2017 and 2016. 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, 2017	September 30, 2017	June 30, 2017	March 31, 2017	December 31, 2016	September 30, 2016	June 30, 2016	March 31, 2016
	(in thousands)							
Revenues from Proprietary Products	$28,991	$ 17,058	$26,874	$6,636	$ 17,688	$ 15,044	$12,106	$11,120
Revenues from Distribution	6,719	5,860	5,675	5,012	6,570	4,329	6,960	3,677
Total revenues	35,710	22,918	32,549	11,648	24,258	19,373	19,066	14,797
Cost of revenues from Proprietary Products	18,608	11,509	16,053	5,165	13,880	9,433	7,479	6,931
Cost of revenues from Distribution	5,472	4,961	4,784	4,185	5,700	3,644	5,958	3,089
Total cost of revenues	24,080	16,470	20,837	9,350	19,580	13,097	13,437	10,020
Gross profit	11,630	6,448	11,712	2,298	4,678	6,276	5,629	4,777
Research and development expenses	1,917	3,418	3,487	3,151	4,221	4,415	3,502	4,107
Selling and marketing expenses	1,265	1,021	1,084	1,028	686	866	856	835
General and administrative expenses	2,003	2,323	2,117	1,830	1,665	2,014	1,861	1,813
Operating income (loss)	6,445	(314)	5,024	(3,711)	(1,894)	(1,019)	(590)	(1,978)
Financial income	234	92	96	78	81	90	133	165
Income (expense) in respect of currency exchange differences and derivatives, net	(133)	-	(245)	(234)	259	(73)	90	(149)
Financial expense	(112)	(14)	(13)	(23)	(20)	(39)	(30)	(37)
Income (loss) before taxes on income	6,434	(236)	4,862	(3,890)	(1,574)	(1,041)	(397)	(1,999)
Taxes on income	182	-	-	87	234	-	1,188	300
Net income (loss)	$6,252	$ (236)	$4,862	$(3,977)	$ (1,808)	$ (1,041)	$(1,585)	$(2,299)

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 approved proprietary products and sales of distributional products), payments received in connection with strategic partnerships (including milestone payments from collaborating agreements), sales of ordinary shares (including our 2005 initial public offering on the Tel-Aviv Stock Exchange, our 2013 initial public offering on

NASDAQ and our ordinary share offering which closed in August 2017), 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, 2017, 2016 and 2015 totaled $43.0 million, $28.6 million and $28.6 million, respectively. We plan to fund our future operations through continued sale and distribution of our proprietary and distributed products, commercialization and or out-licensing of our pipeline product candidates, and raising additional capital through the sale 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, 2017, 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 — Shire (Glassia).”

In August 2017, we consummated an underwritten public offering of an aggregate of 3,833,334 ordinary shares (including the exercise of the underwriters’ overallotment option), at a price of $4.50 per share. We received net proceeds from the offering of approximately $15.6 million.

Our capital expenditures for the years ended December 31, 2017, 2016 and 2015 were $4.1 million, $2.6 million and $2.7 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.

One of Cash Flows from Operating Activities

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.

Net cash used in operating activities was $14.0 million for the year ended December 31, 2015. This net cash used in operating activities reflects a net loss of $11.3 million and non-cash expenses of $5.1 million partially offset by an increase in trade receivables of $5.6 million that were collected immediately after the end of 2015 and a decrease in deferred revenues of $2.4 million reflecting revenues that were collected in advance of 2015.

Cash Flows from Investing Activities

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.

Net cash provided by investing activities was $11.2 million for the year ended December 31, 2015. This net cash provided by investing activities reflects $13.9 million net cash proceeds from sale of short term investments, partially offset by investment in property, plant and equipment of $2.7 million.

Cash Flows from Financing Activities

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. The Company has pledged specific assets which are the subject of those loans.

Net cash used by financing activities was $6.3 million for the year ended December 31, 2015. This net cash used by financing activities reflects a $7.8 million repayment of convertible debentures offset by $1.2 million proceeds from the exercise of share options and by $0.2 million receipt of long term loan.

Contractual Obligations and Commitments

The following is a summary of our contractual obligations and commitments as of December 31, 2017 (in thousands):

	Total	Less than 1 Year	1 – 3 Years	4-5 Years	6 Year and thereafter
Purchase commitments	$37,948	-	-	-	-
Long-term debt obligations (1)	2,095	669	1,166	260	-
Operating lease obligations	6,432	1,033	1,504	1,354	2,541
Total	$46,475	$1,702	2,670	1,614	2,541

(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 agreement or purchase orders 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 2r 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.

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 and weaker in the rest of the quarters.

Off-Balance Sheet Arrangements

As of December 31, 2017, 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 measured at the fair value of the consideration received less any trade discounts, volume rebates and returns.

Revenues from the sale of goods are recognized when all the significant risks and rewards of ownership of the goods have passed to the buyer and the seller no longer retains continuing managerial involvement. The delivery date is usually the date on which ownership passes.

We estimate provisions for returns in arrangements allowing the customers to return expired inventory, or inventory that is close to its end of shelf life, based on historical experience of product returns and specific return exposure.

Milestone revenues are recognized when we meet the milestones.

Contracts that are multiple element arrangements

We entered into strategic alliance agreements under which we grant to our strategic alliance partner an exclusive license to intellectual property rights for the development and commercialization of our proprietary products. The agreements contain multiple elements, including license fees, payments based on achievement of specified milestones, funding for research and development services and royalties on sales of our products.

Based on the type of element, revenues from these agreements are allocated to the various accounting units and recognized for each accounting unit separately. An element constitutes a separate accounting unit if and only if it has a separate value to the customer. Significant judgment is required to allocate elements to each accounting unit. Depending upon how such judgment is exercised, the timing and amount of revenue recognized could differ significantly. Revenue in the various accounting units containing elements is recognized when the criteria for revenue recognition regarding the elements of that accounting unit have been met according to their type and only to the extent of the consideration that is not contingent upon completion or performance of the remaining elements in the contract.

97

Recognizing revenue on a gross or net basis

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 individual 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 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.

We had no impairment of non-financial assets in 2017.

Share-based Payment Transactions

Our employees and other service providers are entitled to remuneration in the form of equity-settled share-based payment transactions (options and restricted shares).

The cost of equity-settled transactions with employees 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. For options granted to service providers, the fair value is remeasured as the services are received. 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 employees 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.

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 employee/other service provider 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 Severance Pay Law. See Note 2r 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.

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, financial assets held for trading at fair value through profit or loss that include equity investments and debt securities and Available for Sale ("AFS") financial investments that include debt securities. Debt securities in the category of AFS are those that are intended to be held for an indefinite period of time and that may be sold in response to needs for liquidity or in response to changes in the market conditions. After initial measurement, AFS financial investments are subsequently measured at fair value with unrealized gains and losses recognized in OCI and credits in the AFS reserve until the investment is derecognized, at which time the cumulative gain or loss is recognized in other operating income, or the investment is determined to be impaired, at which time the cumulative loss is reclassified from AFS reserve to the statement of profit or loss as a finance cost. Interest earned while holding AFS financial investments is reported as interest income using the EIR (Effective Interest Rate) method. For AFS financial investments, we assess at each reporting date whether there is objective evidence that an investment is impaired. We have classified all marketable securities as short-term, even though the stated maturity date may be one year or more beyond the current balance sheet date, because we may sell these securities prior to maturity to meet liquidity needs or as part of a risk versus reward assessment.

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 March 1, 2018.

Name	Age	Position
Executive Officers:		
Amir London	49	Chief Executive Officer
Chaime Orlev	47	Chief Financial Officer
Liliana Bar, PhD	63	Vice President, Research and Development and IP
Yael Brenner	54	Vice President, Quality
Shani Dotan	45	Vice President, Human Resources
Eran Nir	45	Vice President, Operations
Orit Pinchuk	53	Vice President, Regulatory Affairs and PVG
Dr. Michal Stein	44	Vice President, Medical Director for Immunology
Dr. Naveh Tov	53	Vice President, Clinical Development and Medical Director for Pulmonary Diseases
Directors:		
Leon Recanati*	69	Chairman
David Tsur	67	Director, Active Deputy Chairman
Dr. Michael Berelowitz*	73	Director
Avraham Berger*	66	Director, Chairman of Audit Committee
Asaf Frumerman*	33	Director
Jonathan Hahn	35	Director
Dr. Abraham Havron*	70	Director, Chairman of Compensation Committee
Prof. Itzhak Krinsky, Ph.D*	66	Director
Gwen A. Melincoff *	65	Director
Shmuel (Milky) Rubinstein*	78	Director

* Independent director under the Nasdaq listing requirements.

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. Liliana Bar has served as our Vice President, Research and Development and IP since June 2012. Prior to joining us, Dr. Bar was Director of the Development and Base Business Unit and Manager of the Development and Base Unit of Omrix from 2007. Dr. Bar holds a M.Sc. degree and PhD in Applied Chemistry from the Hebrew University of Jerusalem and was a Research Associate at the Biochemistry Department at Hadassah Medical School at the Hebrew University of Jerusalem and a Research Associate at the Biochemistry Department of University of Virginia.

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.

Shani Dotan has served as our Vice President, Human Resources since November 2013. Ms. Dotan has more than a decade of expertise in local and global organizations and in all HR aspects. Prior to joining us, Ms. Dotan served as the Human Resources Manager at Teva Pharmaceuticals at the Jerusalem plant from 2010 to 2013 and a Training Manager at Teva Pharmaceuticals at two plants from 2007 to 2010. Ms. Dotan holds an MA degree and a BA degree in Psychology, both from Ben-Gurion University.

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.

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, Govli Limited, Microbes Inc., RelTech Holdings Ltd., Legov Ltd., Insight Capital Ltd., and Shavit Capital Funds. He is currently 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 stock Exchanges. 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 in Business Management from the Hebrew University of Jerusalem.

103

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 Bachelor's 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 in 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.

Dr. Abraham Havron has served on our board of directors since March 2011. Mr. Havron was initially elected as an external director (within the meaning of the Companies Law) and served in such capacity until January 30, 2017, since which time he has served as an ordinary (non-external) director. From 2005 to 2014, Dr. Havron served as the Chief Executive Officer and a director of PROLOR Biotech Ltd., which in 2013 merged with OPKO Health Inc. Dr. Havron is a 35-year veteran of the biotechnology industry and was a member of the founding team and Director of Research and Development of Interpharm Laboratories Ltd. (a subsidiary of Merck Serono S.A.) from 1980 to 1987. Dr. Havron served as Vice-President Manufacturing and Process-Development of BioTechnology General Ltd., based in Rehovot, Israel (now, a subsidiary of Ferring Pharmaceuticals) from 1987 to 1999; and Vice President and Chief Technology Officer of Clal Biotechnology Industries Ltd. from 1999 to 2003. Since 2014, Dr. Havron has also served on the board of directors of MediWound Ltd. (Nasdaq: MDWD) and Enlivex Theraputics Ltd., a private company. Dr. Havron earned his PhD in Bio-Organic Chemistry from the Weizmann Institute of Science, and served as a Research Fellow at the Harvard Medical School, Department of Radiology.

Prof. Itzhak Krinsky, Ph.D, has served on our board of directors since December 2017. Mr. 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 in 2017. 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 at following companies: Wavelength Pharmaceuticals, since October 2017, Halo Pharmaceutical, Inc., since June 2017, Concordia International Corp., since May 2017, Achellos Therapeutics, since April 2017 and Exodos Life Sciences Limited Partnership, since April 2017. 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 and a Ph.D. in Economics from McMaster University in Canada.

Gwen A. Melincoff has served on our board of directors since February 2017. Ms. Melincoff has over 25 years of leadership experience in the biotechnology and pharmaceutical industries. Her experience has spanned public and private company boards, venture financing, business development, licensing, mergers and acquisitions, research operations, marketing, product management and project management. Ms. Melincoff is an advisor to Phase 1 Ventures and Verge Genomics. From August 2014 to September 2016, she served as Vice President of Business Development at BTG International Inc. a UK specialist healthcare company. From August 2004 to January 2013, Ms. Melincoff was Senior Vice President of Business Development at Shire Pharmaceuticals. Additionally, from 2010 to 2013 she led the Strategic Investment Group (SIG). Ms. Melincoff served as a board member/board observer at Tobira Therapeutics (acquired by Allergan), DBV Technologies, AM Pharma, ArmaGen Technologies, Promethera Biosciencs, Naurex Inc. (acquired by Allergan), Enterome. She is currently a member of the audit committee of PhotoCure ASA. Ms. Melincoff was named a “Top Women in Biotech 2013” by Fierce Biotech as well as being named to the Powerlist 100 of Corporate Venture Capital in 2012 and 2013. Prior to joining Shire, Ms. Melincoff held managerial and business development position at various pharmaceutical companies such as Adolor Corporation. Ms. Melincoff has a B.S in Biology, a Master’s of Science in Management, and has attained the designation of the Certified Licensing Professional (CLP™).

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 to June 2017. Mr. Rubinstein served as the Chief Executive Officer and General Manager at 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.

On November 9, 2017, we entered into a letter agreement with Brosh Capital Partners, L.P. and certain of its affiliates regarding, among other things, amending the agenda for our 2017 annual general meeting of shareholders with respect to director nominees and board composition. Pursuant to the terms of the letter agreement, we agreed to amend the agenda for the 2017 annual general meeting to, among other things: (i) fix the size of our Board of Directors at ten members; (ii) add Mr. Asaf Frumerman as a nominee for election to the Board of Directors by the shareholders at the meeting; and (iii) add two industry experts to be specified in a revised agenda for the meeting. Accordingly, we filed

an amended agenda for the 2017 annual general meeting, which included Mr. Asaf Frumerman and two industry experts, Prof. Itzhak Krinsky and Mr. Shmuel (Milky) Rubinstein, as director nominees for election by the shareholders at the meeting. For additional information regarding the foregoing letter agreement, see "Item 7. Major Shareholders and Related Party Transactions — Related Party Transactions — Brosh Letter Agreement." For information regarding the holdings of the Brosh Capital Partners group, see "Item 7. Major Shareholders and Related Party Transactions — Major Shareholders."

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 current board of directors consists of ten directors, eight 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 will hold 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 outside directors and that one outside 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 outside 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, following which our external directors serving at such time, Dr. Abraham Havron and Avraham Berger, continued to serve as ordinary (non-external) directors. In accordance with the exemption, Avraham Berger will continue to serve term as an ordinary (non-external) director until our 2018 annual general meeting, and may thereafter be re-elected as a director in accordance with the Companies Law. Dr. Havron's term as an external director was scheduled to expire in January 2017, and therefore, he was appointed by our board of directors to serve as an ordinary (non-external) director until our 2017 annual general meeting, at which meeting he was re-elected to serve as a director, and he may thereafter be re-elected as a director in accordance with the Israeli Companies Law. 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, Dr. Abraham Havron 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.

107

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.

Approval of Transactions with Related Parties

The approval of the audit committee is required for specified actions and transactions with office holders and controlling shareholders and their relatives, or in which they have a personal interest. See "— Fiduciary Duties and Approval of Specified Related Party Transactions under Israeli Law." The audit committee may not approve an action or a transaction with a controlling shareholder or with an office holder unless at the time of approval the majority of the members of the audit committee are present, of whom a majority must be independent directors, and at least one of whom is an external director, provided that this requirement shall not apply if a company has elected to avail itself from the requirement to appoint external directors under the Companies Law in accordance with an exemption provided under a recent amendment to regulations promulgated under the Companies Law (as described above). The audit committee is also required to determine whether certain related party transactions are "material" or "extraordinary" for purposes of determining which approvals are required for such transactions.

Compensation Committee

We have a compensation committee consisting of our Dr. Abraham Havron, Mr. Avraham Berger and Mr. Leon Recanati. Dr. Havron 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.

Finance Committee

Our finance committee currently consists of Mr. David Tsur, Mr. Avraham Berger and Mr. Jonathan Hahn. Mr. David Tsur serves as the chairman of the finance committee.

Our finance committee is responsible for considering and making recommendations to the board of directors on the management of our financial resources and financial strategies and transactions, including our capital structure and corporate finance activities, investment management and financial risk management (including foreign currency exchange and interest rate exposures).

Strategy Committee

Our strategy committee currently consists of Mr. Jonathan Hahn, who serves as the chairman of the strategy committee, Mr. Leon Recanati, Mr. David Tsur, Ms. Gwen Melincoff, Dr. Michael Berelowitz and Mr. Asaf Frumerman. Our strategy committee is responsible for assisting 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 virtue of his or her position; 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.

110

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. 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 initial compensation policy was approved by our shareholders on January 28, 2014 and amended by our shareholders on June 30, 2015. On August 30, 2016, our shareholders approved and adopted an amended and restated Compensation Policy, which was amended by our shareholders on November 30, 2017. 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.

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 (i) Avraham Berger, a former external director who currently serves as an ordinary (non-external) director, who is a financial expert under the Companies Law, an annual fee of NIS 114,155 (approximately $32,926), as well as a fee of NIS 4,390 (approximately $1,266) for each board or committee meeting attended in person, NIS 2,634 (approximately $760) for each board or committee meeting attended via telephone or videoconference and NIS 2,195 (approximately $633) for participation by written consent; and (ii) our other directors (other than Asaf Frumerman) an annual fee of NIS 85,705 (approximately $24,720), as well as a fee of NIS 3,300 (approximately $952) for each board or committee meeting attended in person, NIS 1,980 (approximately $571) for each board or committee meeting attended via telephone or videoconference and NIS 1,650 (approximately $476) 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 $12,980), 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 November 30, 2017, we granted options to each of our directors serving in such capacity prior to the 2017 annual general meeting and who were re-elected to serve as directors at the meeting or continued to serve following the meeting. The options shall be exercisable on a cashless basis based on an exercise price of NIS 21.99 (approximately $6.26) per share (equal to the higher of (i) the average closing price of our ordinary shares on the TASE during the 30 trading days immediately prior to the approval of the option grant by our board of directors plus 5%; and (ii) the closing price of our ordinary shares on the TASE on the date of the approval of the option grant by our board of directors). The 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 November 30, 2017.

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, 2017, was approximately $3.3 million. This amount includes approximately $110,255 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, former Deputy Chief Executive Officer and Chief Financial Officer, 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, 2017.

Name and Position	Salary	Bonus[1]	Value of Options Granted[2]	Other[3]	Total
	(in thousands)				
Amir London Chief Executive Officer	$293	$ 127	$ 79	$ 26	$525
Gil Efron Former Deputy Chief Executive Officer and Chief Financial Officer	$252	$ 146 [4]	$ 35 [5]	$ 22	$455
Dr. Naveh Tov Clinical Development and Medical Director for Pulmonary Diseases	$222	$ 39	$ 26	$ 21	$308
David Tsur Active Deputy Chairman of the Board of Directors	$210	$ -	$ 48	$ 42	$300

Eran Nir Vice President Operations	$192	$ 35	$ 31	$ 23	$281

(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, 2017 with respect to all options granted to such executive officer.

(3) Cost of use of company car.

(4) Includes retirement grant, annual bonus and special bonus for issuance of ordinary shares in an underwritten public offering.

(5) Includes Awards acceleration.

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.

Gil Efron, Former Deputy Chief Executive Officer and Chief Financial Officer. Mr. Efron served as our Deputy Chief Executive from July 2015 until November 30, 2017, along with the position of Chief Financial Officer in which he served from 2011. Effective as of September 1, 2011, we entered into an employment agreement with Mr. Efron with respect to his employment as our chief financial officer, which terminated on November 30, 2017. Following November 30, 2017, Mr. Efron shall remain employed by us until March 31, 2018.

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.

David Tsur, Active Deputy Chairman of the Board of Directors. Mr. Tsur has served as our Active Deputy Chairman of the Board of Directors since July 2015, on a half-time basis. Prior to that, Mr. Tsur served as our Chief Executive Officer and a director since our inception. Mr. Tsur's engagement terms as our Active Deputy Chairman 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 six months' prior written notice to the other party (payment in lieu of such notice period is permitted at our discretion), and we may terminate the agreement immediately for cause in accordance with Israeli law. In addition, 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.

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, 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. As of December 31, 2015, we employed 319 full-time employees, according to the following division: 159 in Operations (including Procurement Department), 79 in Quality, 18 in Research and Development, 17 in Regulation, 14 in Business Development, 8 in Medical, 10 in Human Resources and 14 in Finance. As of December 31, 2017, 2016 and 2015, all of our employees were located in Israel.

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. Approximately 55% of our employees, all of whom are located at our Beit Kama facility, currently work under the collective bargaining agreement signed in December 2013. 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. We are currently in the process of negotiating the renewal of the collective bargaining agreement.

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.

120

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 40,262,819 ordinary shares outstanding as of March 5, 2018 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)	137,375	*	
Chaime Orlev (2)	4,166	-	
Dr. Liliana Bar (3)	40,625	*	
Yael Brenner (4)	26,042	*	
Shani Dotan (5)	37,917	*	
Eran Nir (6)	10,739	*	
Orit Pinchuk (7)	30,917	*	
Dr. Michal Stein (8)	4,167	*	
Dr. Naveh Tov (9)	19,928	*	
Leon Recanati (10)	4,021,248	9.1	%
David Tsur (11)	1,147,537	2.8	%
Dr. Michael Berelowitz (12)	2,188	-	
Avraham Berger (13)	2,188	-	
Asaf Frumerman (14)	-	-	
Jonathan Hahn (15)	3,668,089	8.3	%
Dr. Abraham Havron (16)	23,930	*	
Prof. Itzhak Krinsky, Ph.D	5,250	*	
Gwen A. Melincoff	-	-	
Shmuel (Milky) Rubinstein	4,383	*	
Directors and Executive Officers as a group (19 persons)	9,186,689	18.6	%

_____

* Less than 1% of our ordinary shares.

(1) Includes 12,000 restricted shares and options to purchase 125,375 ordinary shares exercisable within 60 days of the date of this Annual Report, at a weighted average exercise price of NIS 26.90 (or $7.76) per share, which expire between May 15, 2020 and May 30, 2024. Does not include unvested options to purchase 58,125 ordinary shares that are not exercisable within 60 days of this Annual Report.

(2) Represents 4,166 restricted shares. Does not include unvested options to purchase 12,500 ordinary shares that are not exercisable within 60 days of this Annual Report.

(3) Includes options to purchase 40,625 ordinary shares exercisable within 60 days of the date of this Annual Report, at a weighted average exercise price of NIS 40.80 (or $11.77) per share, which expire between February 28, 2019 and October 27, 2023. Does not include unvested options to purchase 1,875 ordinary shares that are not exercisable within 60 days of this Annual Report.

121

(4) Includes 4,667 restricted shares and options to purchase 21,375 ordinary shares exercisable within 60 days of the date of this Annual Report, at a weighted average exercise price of NIS 18.31 (or $5.28) per share, which expire between October 27, 2021 and January 31, 2024. Does not include unvested options to purchase 17,625 ordinary shares that are not exercisable within 60 days of this Annual Report.

(5) Includes 4,667 restricted shares and options to purchase 33,250 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 January 31, 2024. Does not include unvested options to purchase 13,250 ordinary shares that are not exercisable within 60 days of this Annual Report.

(6) Represents 6,833 restricted shares and options to purchase 3,906 ordinary shares exercisable within 60 days of the date of this Annual Report, at an exercise price of NIS 22.08 (or $6.37) per share, which expire between May 24, 2023 and January 31, 2024.. Does not include unvested options to purchase 16,594 ordinary shares that are not exercisable within 60 days of this Annual Report.

(7) Includes 2,667 restricted shares and options to purchase 28,250 ordinary shares exercisable within 60 days of the date of this Annual Report, at an exercise price of NIS 43.86 (or $12.65) per share, which expire between July 13, 2020 and January 31, 2024. Does not include unvested options to purchase 13,250 ordinary shares that are not exercisable within 60 days of this Annual Report.

(8) Represents 4,167 restricted shares. Does not include unvested options to purchase 12,500 ordinary shares that are not exercisable within 60 days of this Annual Report.

(9) Includes 6,834 restricted shares and options to purchase 13,094 ordinary shares exercisable within 60 days of the date of this Annual Report, at an exercise price of NIS 31.85 (or $9.19) per share, which expire between May 14, 2020 and January 31, 2024. Does not include unvested options to purchase 23,406 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 48,125 ordinary shares exercisable within 60 days of the date of this Annual Report, at an exercise price of NIS 50.17 (or $14.47) per share, which expire between May 14, 2020 and May 30, 2024. Does not include unvested options to purchase 11,875 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 376,250 ordinary shares exercisable within 60 days of the date of this Annual Report, at a weighted average exercise price of NIS 43.94 (or $12.67) per share, which expire between June 8, 2018 and March 2, 2023. Does not include unvested options to purchase 5,625 ordinary shares that are not exercisable within 60 days of this Annual Report.

(12) Includes options to purchase 2,188 ordinary shares exercisable within 60 days of the date of this Annual Report, at a weighted average exercise price of NIS 15.20 (or $4.38) per share, which expire between March 2, 2023 and May 30, 2024. Does not include unvested options to purchase 7,813 ordinary shares that are not exercisable within 60 days of this Annual Report.

(13) Includes options to purchase 2,188 ordinary shares exercisable within 60 days of the date of this Annual Report, at a weighted average exercise price of NIS 15.20 (or $4.38) per share, which expire at March 2, 2023 and May 30, 2024. Does not include unvested options to purchase 7,813 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 25,938 ordinary shares exercisable within 60 days of this Annual Report, at an exercise price of NIS 47.90 (or $13.82) per share, which expire between May 14, 2020 and May 5, 2024. 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 Chemicals Inc. ("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 9,063 ordinary shares that are not exercisable within 60 days of this Annual Report.

(16) Includes 1,742 shares owned by Operon Consultants Ltd., which is wholly-owned by Dr. Havron. Dr. Havron also holds options to purchase 22,188 ordinary shares exercisable within 60 days of the date of this Annual Report, at an exercise price of NIS 52.82 (or $15.24) per share, which expire between May 14, 2020 and March 02, 2023. Does not include unvested options to purchase 2,813 ordinary shares that are not exercisable within 60 days of this Annual Report.

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.

On April 27, 2015, our board of directors approved an increase in the number of ordinary shares reserved for issuance under the 2011 Plan by 500,000 ordinary shares, on May 8, 2016, our board of directors approved a further increase in the number of ordinary shares reserved for issuance under the 2011 Plan by an additional 200,000 shares, and on December 14, 2017, our board of directors approved a further increase in the number of ordinary shares reserved for issuance under the 2011 Plan by an additional 760,000 shares. As of December 31, 2017, an aggregate of 530,660 ordinary shares were reserved for future issuance under the 2011 Plan (subject to certain adjustments specified in the 2011 Plan), and options to purchase 2,572,372 ordinary shares were outstanding under the 2011 Plan and 76,512 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 40,262,819 ordinary shares outstanding as of March 6, 2018. 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
Meitav Dash Group (1)	3,691,595	9.2 %
Leon Recanati (2)	4,021,248	9.1 %
Hahn Family (3)	3,668,089	8.3 %
Brosh Capital Partners L.P (4).	3,094,721	7.7 %
The Phoenix Holding Ltd. (5)	2,785,010	6.9 %

(1) Based solely upon, and qualified in its entirety with reference to, Schedule 13G filed with the SEC on January 8, 2018. According to the Schedule 13G, 2,803,229 of the ordinary shares are beneficially owned by provident funds of Meitav Dash Investments Ltd. group ("Meitav Dash Group"), 447,942 of the ordinary shares are beneficially owned by mutual of funds of the Meitav Dash Group and 440,424 of the ordinary shares are beneficially owned by ETFs of the Meitav Dash Group.

(2) 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, Mr. Recanati holds options to purchase 48,125 ordinary shares exercisable within 60 days of this Annual Report at an exercise price of NIS 50.17 (or $14.47 per share, which expire between May 14, 2020 and May 30, 2024. Does not include unvested options to purchase 11,875 ordinary shares that are not exercisable within 60 days of this Annual Report.

(3) Mr. Jonathan Hahn directly holds 313,841 ordinary shares and options to purchase 25,938 ordinary shares exercisable within 60 days of this Annual Report, at an exercise price of NIS 47.9 (or $13.82) per share, which expire between May 14, 2020 and May 30, 2024. 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 Chemicals Inc. ("Damar"), which directly holds 2,751,661 ordinary shares. We were informed that an additional 50% of the shares of Sinara are held by Mr. Hahn's siblings, who also directly hold an aggregate of 576,649 ordinary shares. Does not include unvested options to purchase 9,063 ordinary shares directly held by Mr. Jonathan Hahn that are not exercisable within 60 days of this Annual Report.

(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, (a) Brosh Capital Partners, L.P., a Cayman Islands limited partnership ("Brosh"), beneficially owns 2,411,175 ordinary shares; (b) Exodus Management Israel Ltd., 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. Esther 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) 233,663 ordinary shares owned by Mr. Biram and (iv) 294,174 ordinary shares owned by Ms. 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. 3 to Schedule 13G filed with the SEC on February 20, 2018. According to the Schedule 13G/A, 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 majority-owned 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 March 2, 2018, we had one shareholder of record who was registered with an address in the United States, holding approximately 25.5% 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, 2015 to the date of this Annual Report, the ownership percentage of Hahn family decreased by 4.0% from 12.35% to 8.35%. Mr. Leon Recanati's ownership percentage decreased by 1.96% from 11.04% to 9.08% during such period. The Phoenix Holdings Group ownership percentage decreased by 0.16% from 7.06% to 6.90% during such period. The DS Apex group's ownership percentage increased by 1.93% from 7.22% to 9.15% during such period. The Brosh Capital Partners group's ownership percentage increased from less than 5% to 7.7% 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.

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. 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.

126

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 2015 and 2016, Khari distributed our AAT product in Cuba in a non-material amount. In 2017, Khairi did not distribute any of our products. 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.

127

Registration Rights Agreement

We entered into a registration rights agreement on April 14, 2013 with Damar, Leon Recanati, Gov and David Tsur (collectively, the "Holders"), pursuant to which our ordinary shares held by them at such time, or that may be held in the future by the Holders and their respective affiliates, are entitled to certain registration rights, as described below.

Incidental Registration Rights. The Holders have the right to request the inclusion of their registrable shares in any registration statements filed by us in the future for the purposes of a public offering, subject to specified exceptions. In the event that the managing underwriter advises that the number of shares proposed to be included in the offering exceeds the number that can be sold in such offering without adversely affecting such underwriter's ability to effect the distribution of such shares or that marketing factors require a limitation of the number of shares to be underwritten, the shares to be included in the registration statement shall be allocated as follows: first, all shares sought to be registered by us for our own account, and second, all shares sought to be registered by the Holders, pro-rata to the number of registrable shares owned by each selling Holder, or in such other proportions as shall mutually be agreed to by all such selling Holders.

In connection with the shelf registration statement on Form F-3 that we filed with the SEC on November 28, 2016 (File No. 333-214816), all Holders waived their rights to include any of their registrable shares in the shelf registration statement.

Demand Registration. We may be required to effect up to two registrations on Form F-1 at the request of any of the Holders for all or any portion of their respective registrable shares, provided that each such registration includes shares with an anticipated aggregate offering price of not less than $5.0 million (after deduction of underwriter discounts and commissions, share transfer taxes and expenses of sale) ("Long-Form Registration"). We will not be required to effect any Long Form Registration requested within 180 days after the effective date of a previously effective registration of securities. In addition, we will be able to delay effecting a Long Form Registration once in any 12-month period for a period not to exceed 90 consecutive days from the date of the request if we are engaged or have plans to engage in a registered public offering or are engaged in any other activity which, in the good faith determination of our board of directors, would be adversely affected by the requested registration.

Form F-3 Registration. We may be required to effect an unlimited number of registrations at the request of any of the Holders on Form F-3 of all or any portion of their respective registrable shares provided that each such registration includes shares with an anticipated aggregate offering price of not less than $5.0 million (after deduction of underwriter discounts and commissions, share transfer taxes and expenses of sale) ("Short-Form Registration" and together with a Long-Form Registration, a "Demand Registration"). We will not be required to effect any Short Form Registration requested (i) within the nine month period after the effective date of a previously effective Short Form Registration, or (ii) during the period starting 60-days before our good faith estimate of the filing of any registration statement pertaining to our securities and ending three months following our good faith estimate of the effective date of any such registration statement (subject to limited exceptions). In addition, we will be able to delay the filing of a Form F-3 registration statement once in any 12-month period for a period not to exceed 90 consecutive days from the date of the request if, in the good faith determination of our board of directors, it would not be in our best interest or in the best interest of our shareholders for such registration statement to be filed or effected at such time.

We will be required to give notice of a Demand Registration from any Holder to the other Holders that will be entitled to registration rights and include their shares in the registration if they so request.

In the event that the managing underwriter advises that marketing factors require a limitation of the number of shares to be included in a Demand Registration, the shares to be included in the registration statement shall be allocated as follows: first, all shares sought to be registered by the Holders, pro-rata to the number of registrable shares owned by each selling Holder, or in such other proportions as shall mutually be agreed to by all such selling Holders, second, all shares sought to be registered by us for our own account, and third, any other shares sought to be registered.

128

Termination. All registration rights granted to each Holder will terminate upon the earlier of (i) five years after our initial public offering in the United States (i.e., June 5, 2018) and (ii) as to any Holder, such earlier time at which all registrable shares held by such Holder (and any affiliate of the Holder with whom such Holder must aggregate its sales under Rule 144) can be sold in any 90-day period without registration under the Securities Act.

Expenses. We will pay all expenses in carrying out the above registrations, including the reasonable fees and expenses of one counsel for the initiating Holders, other than underwriter discounts or commission with respect to Holders' shares.

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. Pursuant to the terms of the letter agreement, we agreed to amend the agenda for the 2017 annual general meeting to, among other things: (i) fix the size of our Board of Directors at ten members; (ii) add Mr. Asaf Frumerman, as a nominee for the election to the Board by the shareholders at the meeting; and (iii) add two industry experts to be specified in a revised agenda for the meeting. Pursuant to the letter agreement, for as long as Mr. Frumerman (or his substitute) serves on our Board of Directors, Brosh is prohibited from taking specified actions with respect to us and our securities, including, among others: (i) making or in any way participating in any solicitation of proxies to vote, or seeking to advise, encourage or influence any person with respect to the voting of, any of our securities; (ii) subjecting any of our shares to any arrangement or agreement with respect to the voting thereof, other than as set forth in the letter agreement; or (iii) seeking, alone or in concert with others, representation on our Board of Directors, except as provided for in the letter agreement. The prohibitions in the immediately preceding sentence will remain in effect until we notify our shareholders that (i) we are convening a general meeting and (ii) the agenda of that general meeting includes matters concerning the appointment or dismissal of members of the Board of Directors. For information regarding the holdings of the Brosh group, see "Item 7. Major Shareholders and Related Party Transactions — Major Shareholders.|

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:		
2017	$8.61	$3.75
2016	$6.29	$3.26
2015	$5.15	$3.09
2014	$17.95	$3.02
2013 (from May 30, 2013)	$17.07	$9.60
Quarterly:		
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
Fourth Quarter 2016	$6.29	$5.05
Third Quarter 2016	$5.34	$3.63
Second Quarter 2016	$4.19	$3.60
First Quarter 2016	$4.44	$3.26
Most Recent Six Months:		
February 2018 (through March 5, 2018)	$5.5	$4.65
January 2018	$5.75	$4.75
December 2017	$4.85	$4.26
November 2017	$4.85	$4.40
October 2017	$5.25	$4.65
September 2017	$4.85	$4.35

On March 5, 2018, the last reported sale price of our ordinary shares on the Nasdaq Global Select Market was $5.1 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 3.456, the exchange rate published by the Bank of Israel as March 5, 2018.

	NIS Price Per Ordinary Share		$ Price Per Ordinary Share	
	High	Low	High	Low
Annual:				
2017	29.20	14.81	8.45	