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

FORM 20-F

(Mark One)

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

OR

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2015

OR

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

o 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)

Israel
(Jurisdiction of incorporation or organization)

7 Sapir St.
Kiryat Weizmann Science Park
P.O Box 4081
Ness Ziona 7414002
Israel
(Address of principal executive offices)

Amir London, Chief Executive Officer
7 Sapir St., Kiryat Weizmann Science Park
P.O Box 4081, Ness Ziona 74140002, 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, 2015, the Registrant had 36,418,741 Ordinary Shares outstanding (excluding treasury shares).

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

o Yes x 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.

o Yes x 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.

x Yes o 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).

x Yes o No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer.

Large accelerated filer o Accelerated filer o Non-accelerated filer x

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

U.S. GAAP o | International Financing Reporting Standards as issued by the International Accounting Standards Board x | Other o

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 o Item 18 o

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).

o Yes x No

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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 company," "our," and "Kamada" refer to Kamada Ltd., along with its consolidated subsidiaries.

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

- *our expectation that the number of patients treated by Glassia will double in the next three to four years compare to the number of patients in 2014 and that our revenues in the Proprietary Products segment will grow by approximately 75% by 2017 compared to such segment's revenues for 2015 and that we will achieve our midterm revenue goal of $100 million by 2017;*

- *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 Baxalta US Inc., ("Baxalta"), will continue without disruption;*

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

- *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 Alpha-1 Antitrypsin ("AAT") products will grow;*

- *the various uses of AAT products to potentially be effective against various diseases, including cystic fibrosis, bronchiectasis, type-1 diabetes and GvHD, as well as its ability to be used in connection with lung transplantations;*

- *the beneficial characteristics of Inhaled AAT for AATD, which we believe may result in our increased profitability;*

- *our belief that the potential world market for AAT products is significantly larger than current consumption indicates;*
- *our belief that we will be able to continue to meet our customers' demand for AAT;*
- *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 file a Marketing Authorization Application ("MAA") for our inhaled formulation of AAT for treatment of AAT deficiency ("Inhaled AAT for AATD") with the European Medicines Agency (the "EMA") during the first quarter of 2016 and our ability to receive marketing authorization and launch Inhaled AAT for AATD in 2018 in Europe;*
- *our plan to file a Biologics License Application ("BLA") for our KamRAB product for treatment of Prophylaxis of rabies disease with the U.S. Food and Drug Administration (the "FDA") by mid-2016, and our ability to receive marketing authorization and to launch KamRAB in the United States in 2017;*
- *our anticipation that we will complete our United States trial of Inhaled AAT for AATD by the end of the first quarter of 2016 and report top line data by mid-2016 and our intention to initiate discussions with the FDA in 2016 to identify the regulatory pathway for registration in the United States;*
- *our plan to start a Phase I/II clinical trial of our proprietary AAT treatment for the prevention of lung transplant rejection to be performed in Israel in the first half of 2016 in collaboration with Baxalta;*
- *our plan to further develop the GvHD indication including initiation of a phase II or III study in 2016;*
- *our expectations regarding the timing of the beginning of the production of Glassia by Baxalta;*
- *our anticipation that we will generate higher revenues as we diversify our revenue base by increasing the number of products we offer;*
- *our expectations regarding the future breakdown of our segments by revenue;*
- *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; and*
- *the impact of our research and development expenses as we continue developing product candidates.*

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 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, 2015, 2014 and 2013 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 3.902, the exchange rate published by the Bank of Israel as of December 31, 2015.

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, 2015, 2014 and 2013 and the consolidated balance sheets data as of December 31, 2015 and 2014 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, 2012 and 2011 and the summary consolidated balance sheet data as of December 31, 2013, and 2012 and 2011 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,				
	2015	2014	2013	2012	2011
	(in thousands, except per share data)				
Consolidated Statements of Operations Data:					
Revenues from Proprietary Products	$ 42,952	$ 44,389	$ 50,658	$ 46,445	$ 35,308
Revenues from Distribution	26,954	26,676	19,965	26,230	24,175
Total revenues	69,906	71,065	70,623	72,675	59,483
Cost of revenues from Proprietary Products	30,468	32,617	27,104	26,911	22,188
Cost of revenues from Distribution	23,640	23,406	17,112	23,071	20,574
Total cost of revenues	54,108	56,023	44,216	49,982	42,762
Gross profit	15,798	15,042	26,407	22,693	16,721
Research and development expenses	16,530	16,030	12,745	11,821	11,729
Selling and marketing expenses	3,652	2,898	2,100	1,853	2,331
General and administrative expenses	7,040	7,593	7,862	4,781	5,126
Operating income (loss)	(11,424)	(11,479)	3,700	4,238	(2,465)
Financial income	463	404	278	578	870
Income (expense) in respect of currency exchange and translation differences and derivatives instruments, net	625	-	(369)	(100)	937
Income (expense) in respect of revaluation of warrants to fair value	-	-	-	(576)	540
Financial expense	(934)	(2,086)	(3,142)	(3,357)	(3,597)
Income (loss) before taxes on income	(11,270)	(13,161)	467	783	(3,715)
Taxes on income	-	52	24	523	-
Net income (loss)	$ (11,270)	$ (13,213)	$ 443	$ 260	$ (3,715)
Income (loss) attributable to equity holders	$ (11,270)	$ (13,213)	$ 443	$ 260	$ (3,715)
Income (loss) per share attributable to equity holders:					
Basic	$ (0.31)	$ (0.37)	$ 0.01	$ 0.01	$ (0.13)
Diluted	$ (0.31)	$ (0.37)	$ 0.01	$ 0.01	$ (0.15)
Weighted-average number of ordinary shares used to compute income (loss) per share attributable to equity holders:					
Basic	36,245,813	35,971,335	32,714,631	28,078,996	27,550,643
Diluted	36,245,813	35,971,335	33,385,651	28,686,636	27,703,331
Consolidated Statements of Cash Flows:					
Cash flows from operating activities	$ (13,979)	$ (9,918)	$ (3,854)	$ (8,262)	$ 994
Cash flows from investing activities	11,253	(26,819)	(3,903)	(2,432)	(1,136)
Cash flows from financing activities	(6,355)	(7,640)	49,208	2,966	(403)
Consolidated Balance Sheet Data:					
Cash, cash equivalents, restricted cash and short-term investments	$ 28,306	$ 51,896	$ 74,177	$ 33,795	$ 42,686
Trade receivables	23,071	17,514	17,882	13,861	7,131
Working capital [1]	57,655	66,206	85,108	40,651	44,185
Total assets	101,992	119,140	139,379	89,114	85,114
Total liabilities	29,485	38,723	49,409	60,721	62,716
Total shareholders' equity	72,507	80,417	89,970	28,393	22,398
Other Data:					
Adjusted net income (loss)[2] [3]	$ (9,363)	$ (9,462)	$ 9,414	$ 2,103	$ (3,377)
Adjusted EBITDA[2]	$ (6,290)	$ (4,940)	$ 3,156	$ 8,549	$ 1,453

(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. Similarly, our management believes that excluding the non-cash income (expense) in respect of revaluation of our warrants to fair value is useful to investors because the valuation of our warrants is based on a number of subjective assumptions, the amount of the loss or gain is derived from market forces outside management's control, and it enables investors to compare our performance with other companies that have different capital structures.

(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,				
	2015	2014	2013	2012	2011
			(in thousands)		
Net income (loss)	$ (11,270)	$ (13,213)	$ 443	$ 260	$ (3,715)
Non-cash share-based compensation expenses	1,907	3,751	1,327	1,267	878
One-time management compensation payment	-	-	1,386	-	-
Expense (income) in respect of revaluation of warrants to fair value	—	—	—	576	(540)
Adjusted net income (loss)	$ (9,363)	$ (9,462)	$ 3,156	$ 2,103	$ (3,377)

	Year Ended December 31,				
	2015	2014	2013	2012	2011
			(in thousands)		
Net income (loss)	$ (11,270)	$ (13,213)	$ 443	$ 260	$ (3,715)
Income tax expense	-	52	24	523	—
Financial expense, net	471	1,682	2,864	2,779	2,727
Depreciation and amortization expense	3,227	2,788	3,001	3,044	3,040
Non-cash share-based compensation expenses	1,907	3,751	1,327	1,267	878
Income (expense) in respect of translation differences and derivatives instruments, net	(625)	—	369	100	(937)
Expense (income) in respect of revaluation of warrants fair value	—	—	—	576	(540)
One-time management compensation payment	—	—	1,386	—	—
Adjusted EBITDA	$ (6,290)	$ (4,940)	$ 9,414	$ 8,549	$ 1,453

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.

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 deficiency ("AATD") products comprised approximately 43%, 42% and 49% of our total revenues for the years ended December 31, 2015, 2014 and 2013 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 or sales of Glassia, our business would be adversely affected.

We have a partnership arrangement with Baxalta US Inc., ("Baxalta")[1] pursuant to which Baxalta is the sole distributor of Glassia in the United States, Canada, Australia and New Zealand. Revenue derived from our partnership with Baxalta, which consists of sales of Glassia and milestone revenue, accounted for approximately 37%, 36%, and 40% of our total revenues in the years ended December 31, 2015, 2014 and 2013, respectively. Additionally, we depend upon Baxalta for the supply of fraction IV plasma for our production of Glassia to be sold in the United States. If our relationship with Baxalta were to deteriorate, or if Baxalta's sales of Glassia were to decline, 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."

We rely heavily upon sales from the United States, which comprised approximately 38%, 37% and 41% of our total revenues for the years ended December 31, 2015, 2014 and 2013, respectively. If our U.S. sales were significantly impacted by either material changes to government or private payor reimbursement, by other regulatory developments, by competition or other factors, then our business would be adversely affected.

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.

Pursuant to our partnership arrangement with Baxalta, Baxalta is the sole distributor of Glassia in the United States, Canada, Australia and New Zealand. Sales to Baxalta accounted for approximately 37%, 36% and 40% of our total revenues in the years ended December 31, 2015, 2014 and 2013, respectively. We also depend upon Baxalta 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."

Currently, revenue derived from our relationship with Baxalta consists of sales of Glassia, which we incur cost of revenues to produce, and milestone revenue. Pursuant to the fourth amendment to the Exclusive Manufacturing, Supply and Distribution Agreement, after 2018, Baxalta has no obligation to purchase a minimum amount of Glassia; however, Baxalta's failure to purchase a specified minimum amount of Glassia over a period of 24 consecutive months beginning in 2016 until the expiration of the agreement, provides us with the right to terminate the agreement. Additionally, Baxalta is not expected to begin producing Glassia itself before 2019 at the earliest, at which point it will pay us royalties. While we would generate higher margins from royalties, as we would not incur cost of revenues, we will receive lower revenues per unit sold. We plan to replace that revenue by producing other products, including for sales in Europe, and increases in the volume of units sold. If we cannot obtain regulatory approval for such other products and make such sales in Europe or were unable to increase sales of our other products generally, our revenues would be adversely impacted, and our operating results would be adversely impacted as we would continue to incur fixed costs relating to our manufacturing facility.

[1]Baxalta is an independent public company listed on the New York Stock Exchange, which spun-off from Baxter International Inc. ("Baxter") on July 1, 2015. The partnership agreement was originally executed with Baxter. During 2015, Baxter assigned all its rights under the partnership agreement to Baxalta.

In addition, for Inhaled AAT for AATD, we intend to rely on our relationship with Chiesi for the distribution of such product in Europe and to obtain reimbursement for such product in Europe. Chiesi's failure to adequately distribute or obtain reimbursement will have a material adverse effect on our expected profitability from sales of Inhaled AAT for AATD in Europe.

If our relationship with Baxalta were to deteriorate, our sales through this channel and our supply of fraction IV could be adversely affected. If we fail to maintain our relationship with Baxalta or Chiesi, we could face significant costs in finding a replacement distributor for the markets Baxalta and Chiesi serve for Glassia and Inhaled AAT for AATD, respectively, and a replacement supplier of fraction IV 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.

On January 11, 2016, Baxalta announced that the boards of directors of Baxalta and Shire plc ("Shire") have reached an agreement under which Shire will acquire Baxalta. The parties expect the transaction to close mid-2016. Although we believe that our agreement with Baxalta in regards to our Glassia product is of good fit to Shire's rare disease and orphan products strategy, such transaction may adversely affect our business due to possible changes in the short term and/or long term strategy of Shire in regards to our agreement with Baxalta and changes in key personnel.

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. In particular, obtaining marketing approval of our Inhaled AAT for AATD from the European Medicines Agency (the "EMA") is critical to our business plan. However, obtaining regulatory approval in any jurisdiction, including from the EMA, 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. 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, 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 collaboration 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 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 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; and the failure to obtain sufficient intellectual property rights for our products.

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

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

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

Preclinical and clinical testing is expensive, is difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more of our clinical trials can occur at any stage of testing. We have experienced unforeseen events that have delayed our ability to receive regulatory approval for certain of our product candidates, and may in the future experience similar or other unforeseen events during, or as a result of, preclinical testing or the clinical trial process that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates, including that:

- regulators may not authorize us to commence or conduct a clinical trial within a country or at a prospective trial site;
- the regulatory requirements for product approval may not be explicit, may evolve over time and may diverge among jurisdictions;
- 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;
- our third-party contractors, such as contract research organizations, may fail to comply with regulatory requirements or meet their contractual obligations to us;
- 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;
- 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 trials may be greater than we anticipate;
- an audit of preclinical 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 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, will not need to be restructured or will 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 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.

Even if preclinical 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.

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.

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, and to the extent they are not successfully commercialized. If such products are not eventually commercialized, the significant expense and lack of associated revenue could materially adversely affect our business.

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 many 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.

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. For example, in 2014 we had to discard a material amount of inventory that did not pass our inspections due to deviations in the production process that created a higher risk of contamination or that had a short shelf life. 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 cGMP 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 by our quality operations unit 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. Our manufacturing processes and facilities are not currently approved by the EMA, and we will need to obtain such approval prior to beginning manufacture of products (including Inhaled AAT for AATD) to be marketed and sold in Europe. 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 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. 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. 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 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 Baxalta 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 Baxalta to properly advise us regarding, or properly perform tasks related to, regulatory compliance requirements could adversely affect us. If our relationship with Baxalta 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, 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.

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 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 European Union, 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.

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 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 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 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 and the EMA and 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 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 and 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 a robust 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.

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.

We have been required to conduct post-approval clinical trials of Glassia as a condition to marketing the product 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 we expect will begin in 2016. The 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, this could result in 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 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.

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 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.

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 Bioproducts Laboratories Ltd. and Biotest A.G., which are sold in our Distribution segment, together represented approximately 33%, 36% and 26% of our total revenues for the years ended December 31, 2015, 2014 and 2013, respectively. While we have distribution agreements with each of these 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, we could lose exclusivity or the 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.

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.

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 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., Baxalta, 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 manufacture plasma and its products or own companies that collect or produce raw materials such as plasma.

Other than our AAT products, 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 there are two main competitors in the AAT market: Grifols and CSL. We estimate that Grifols' AAT by infusion product for the treatment of AATD, Prolastin A1PI, accounts for 50% market share in the United States and more than 70% of sales in the worldwide market for the treatment of AATD and is the only product that is allowed to be sold in both Europe and the United States. CSL's intrevenous AAT product is mainly sold in the United States and was recently granted centralized marketing authorization in Europe, but CSL has not yet commenced sales of this product in Europe. Apart from its sales through Talecris, Grifols is also a local producer of the product in the Spanish market and operates in Brazil. There is another, smaller local producer in the French market, LFB S.A.

Similarly, if a new AAT formulation with a significantly improved rate of administration is adopted (including, for example, aerosol inhalation or one that can demonstrate statistically significant efficacy), 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 could adversely impact our revenue and growth of sales of Glassia, our current AATD product.

In addition, our plasma-derived protein therapeutics face competition from existing non-plasma products and other courses of treatments. For example, we believe our main competitor for KamRho(D) (IM and IV) is Kedrion, which in 2012 acquired the Anti-Rh product line of Ortho-Clinical Diagnostics, Inc., formerly our main competitor for KamRho(D) (IM or IV). Kedrion sells a product that we estimate accounts for approximately 50% of sales in the U.S. anti-Rh market. We believe there are three additional competitors in this market: Cangene, Grifols and CSL. Additionally, in 2008, GlaxoSmithKline plc and Amgen Inc. launched thrombopoietin inhibitors targeting immune thermobocytopunic purpura patients, which may reduce the demand for KamRho(D) (IV) to treat immune thermobocytopunic purpura. 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 versions of AAT, but we cannot be certain that such products will ever be approved or commercialized. The main advantage of recombinant AAT is its potentially higher availability at lower price per raw material. As a result, our product offerings may remain plasma-derived, even if our competitors offer competing recombinant or other non-plasma products or treatments.

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. In 2010 through 2012, we benefitted from the temporary suspension of two of our competitors from selling their IVIG products in Israel. This suspension has been lifted and both competitors are now able to distribute plasma-derived protein therapeutics in the Israeli market. As these competing IVIG products returned to the market at the end of 2012, we experienced increased competition for our Distribution segment products. For example, we participated in 2013 in a public tender in Israel with these competitors. During this public tender process, some of our customers from prior years chose to purchase their supply requirements from our competitors. As a result of these competitors returning to the market, revenues from our Distribution segment decreased in 2013 and may further decrease in the future. 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. 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.

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

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

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

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

In addition, we sell and distribute third-party products in Israel, and the laws of Israel could also expose us to product liability claims for those products. Furthermore, the presence of a defect 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 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 we have directed and for the indications described on the labeling. To the extent any off-label uses and departures from our administration directions become pervasive and produce results such as reduced efficacy or other adverse effects, the reputation of our products in the marketplace may suffer. In addition, off-label uses may cause a decline in our revenues or potential revenues, to the extent that there is a difference between the prices of our product for different indications.

Furthermore, while physicians may choose to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those approved by regulatory authorities, our ability to promote the products is limited to those indications that are specifically approved by the FDA or other regulators. Although regulatory authorities generally do not regulate the behavior of physicians, they do restrict communications by companies on the subject of off-label use. If our promotional activities fail to comply with these regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, failure to follow FDA rules and guidelines relating to promotion and advertising can result in the FDA's refusal to approve a product, 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, David Tsur, our former Chief Executive Officer and our Active Deputy Chairman of the Board of Directors, 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 in 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.

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. We were affected by the Russian Ruble devaluation during 2015, which led to a decrease in the income from sales of our products in Russia. Fluctuation in the USD-Euro exchange rate may affect revenues and expenses mainly in our Distribution Segment, and we may experience increased sensitivity to the USD-Euro exchange rate as we increase the portion of our products marketed and sold in Europe.

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. 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 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 the loss of customers during such period.

Failure to timely increase our manufacturing capacity may have a material adverse effect on our business.

As our product offerings in our Proprietary Products segment increase, 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 the loss of future customers and orders.

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, an act of terrorism, a 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, an act of terrorism, a 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.

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, 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. In addition, we are a party to certain license agreements that may impose various obligations upon us as a licensee, including the obligation 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.

Our patents also may not afford us protection against competitors 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 or its foreign counterparts to determine priority of invention. In 2012, the Leahy-Smith America Invents Act, or 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. We filed an *inter partes review* petition at the Patent Trial and Appeal Board on June 4, 2014, challenging the validity of a patent owned by Grifols, Inc., the manufacturer of Prolastin and Prolastin-C, competitors to Kamada's Glassia product. The patent, U.S. Patent No. 6,462,180, entitled "Precipitation; Passing Eluted Solution Through Anionic and Cationic Exchange Resins" ("the '180 patent") is directed to a process of purifying alpha-1 proteinase inhibitor from aqueous solutions. The petition asserted that the patent is invalid in view of several prior art references. The *inter partes review* was instituted on December 18, 2014. The institution decision included, inter alia, the finding that certain claims of the '180 patent are invalid based on the cited prior art. These claims have also undergone ex parte reexamination at the United States Patent and Trademark Office ("USPTO") and have also been found to be invalid in that proceeding. On October 27, 2015, the USPTO rejected all the pending claims in the ex parte reexamination proceeding and on December 18, 2015, the Patent Trial and Appeal Board gave its final decision in which it was held that the claims in respect of the '180 patent are invalid. On February 16, 2016 Grifols filed a Patent Owner's Notice of Appeal.

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 or employment agreements that contain non-disclosure and non-use provisions, as well as ownership provisions, with our employees, consultants, 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 and suppliers 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, 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.

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 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 own patents and patent applications in areas relating to critical aspects of our business and technology, including the separation and purification of proteins, 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 or sales of the product or product candidate that is the subject of the dispute or suit.

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 U.S. Patent and Trademark Office 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 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.

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

Our operations are highly dependent on our information technology 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.

The implementation of the 2010 healthcare reform law in the United States may adversely affect our business.

Our industry is highly regulated and changes in law may adversely impact our business, operations or financial results. 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"), is 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) addresses 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) increases 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) establishes 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) establishes 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 January 21, 2016, the Centers for Medicare and Medicaid Services issued final regulations to implement the changes to the Medicaid Drug Rebate Program under the healthcare reform law. These regulations become effective on April 1, 2016. We are evaluating the potential impact of these regulations on our business and operations. In addition, the new law establishes 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. Over the past few years, President Obama has submitted budget proposals seeking to reduce the exclusivity period for biosimilars from 12 years to seven years.

The reforms imposed by the healthcare reform law will significantly impact the pharmaceutical industry; however, the full effects of the healthcare reform law cannot be known until these provisions are fully implemented and the Centers for Medicare and Medicaid Services and other federal and state agencies complete their issuance of applicable regulations or guidance. Moreover, in the coming years, additional changes could be made to governmental healthcare programs that could significantly impact the success of our products. We will continue to evaluate the healthcare reform law, as amended, the implementation of regulations or guidance related to various provisions of the healthcare reform law by federal agencies, as well as trends and changes that may be encouraged by the legislation and that may potentially impact on our business over time.

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 (the "PHS 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 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 $11,000 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. Data collection obligations under this rule commenced on August 1, 2013, and the first disclosures under the law were due in 2014. On February 5, 2013, the Centers for Medicare and Medicaid Services (“CMS”) issued final regulations to implement these provisions. A number of states have similar laws in place. Additional and stricter prohibitions could be implemented by federal and state authorities. Where practices have been found to involve improper incentives to use products, government investigations and assessments of penalties against manufacturers have resulted in substantial damages and fines. Many manufacturers have been required to enter into consent decrees, corporate integrity agreements, or orders that prescribe allowable corporate conduct. Failure to satisfy requirements under the FDCA can also result in penalties, as well as requirements to enter into consent decrees or orders that prescribe allowable corporate conduct.

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 increasingly focused on regulating the 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, but 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, the 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.

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 Israeli Ministry of Health ("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 is deemed to be a monopoly. The 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 need to amend such agreements or seek a specific exemption from the Israeli Antitrust Authority for such arrangements, and we may not be successful in 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 as a result of any disputes in connection with such agreement.

In February 2013, we were notified by the Histadrut (General Federation of Labor in Israel) that more than one-third of our employees at our Beit Kama facility had decided to join the Histadrut and that they have established an employees' committee. Following negotiation we signed, in December 2013, a collective bargaining agreement with the employees' committee and the Histadrut. In the process of negotiating such agreement, two work stoppages occurred. Although such work stoppages did not have a material adverse effect on our business or financial condition, any future disputes with the committee and the Histadrut over the implementation 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.

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 U.S. Securities and Exchange Commission (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 ("S-OX"). 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. S-OX 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 S-OX (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.

Our share price may be volatile.

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

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

- 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 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, 2015, we had 36,418,741 ordinary shares outstanding.

Except for shares held by our affiliates as contemplated by Rule 144 and the Securities Act of 1933, as amended (the "Securities Act"), all of the ordinary shares that are outstanding as of December 31, 2015, as well as the 2,281,493 ordinary shares issuable upon exercise of outstanding options are freely tradable in the United States without restrictions or further registration under the Securities Act. Approximately 23.03% 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, until no later than June 2018, 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 to require that we register their 8,706,464 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 own, directly and indirectly, 10.91% and 10.00% of our outstanding ordinary shares, respectively, as of December 31, 2015. 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 (resulting from 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 do not intend to pay dividends.

We have not recently declared or paid any cash dividends on our ordinary shares and do not intend to pay any cash dividends. Any future agreements 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 S-OX. 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 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.

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. Most recently, 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, still 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, 2015, we had 319 employees, all of whom were based in Israel. 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 most recent 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 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 has "Approved Enterprise" status granted by the Investment Center of the Ministry of Economy (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 will expire 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 2021.

In order to remain eligible for the tax benefits of an Approved/Privileged Enterprise, we must continue to meet certain conditions stipulated in the Investment Law and its regulations, as amended. In addition, in order to remain eligible for the tax benefits available to the Approved Enterprise, we must also comply with the criteria set forth in the applicable certificate of approval, and in the case of the Privileged Enterprise, we 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 Baxalta, or the grant to Baxalta 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 25% in 2013, increased to 26.5% for 2014 and 2015 and decreased to 25% in 2016. 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. Except for Dr. Michael Berelowitz, none of our directors or executive officers are residents of the United States and the Israeli experts named in this Annual Report are located in Israel. 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, 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 66% 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 founded in Israel in 1990. 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 7 Sapir St., Kiryat Weizmann Science Park, P.O. Box 4081, Ness Ziona 7414002, 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 ("S-OX").

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 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 an orphan drug focused, plasma-derived protein therapeutics company with an existing marketed product portfolio and a robust 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 and only liquid, ready-to-use, intravenous plasma-derived AAT product approved by the FDA. We market Glassia through a strategic partnership with Baxalta US Inc. in the United States. Additionally, we have a product line consisting of about ten other injectable pharmaceutical products which are marketed, in addition to Glassia, in more than 15 countries, including Israel, Russia, Brazil, India and other countries in Latin America, Eastern Europe, Africa and Asia. We currently have six plasma-derived protein products in our development pipeline, including Inhaled AAT for AATD, for which we completed a pivotal Phase II/III clinical trial in Europe and are expecting to file the Marketing Authorization Application ("MAA") with the EMA in March 2016. We are also conducting a Phase II clinical trial of our Inhaled AAT for AATD in the United States, in which we recently have completed the enrollment of the patients for this trial. See “—Our Product Pipeline and Development Program—Inhaled Formulations of AAT—AATD.” In addition we have completed a pivotal Phase II/III US clinical trial for anti-rabies immunoglobulin as a post-exposure prophylaxis, which successfully met the trial’s primary endpoint of non-inferiority when measured against an IgG reference product. We expect to file a Biologics License Application (BLA) with the U.S. Food and Drug Administration (FDA) in mid-2016 for this product. In addition to our propriety products, we leverage our expertise and presence in the plasma-derived protein therapeutics market by distributing 14 complementary products in Israel that are manufactured by third parties.

Glassia is an intravenous AAT product that is indicated for chronic augmentation and maintenance therapy in adults with emphysema due to AATD. AAT is a naturally occurring protein found in a derivative of plasma known as fraction IV. AAT regulates the activity of certain white blood cells known as neutrophils and reduces cell inflammation. Patients with genetic AATD suffer from a chronic inflammatory state, lung tissue damage and a decrease in lung function. We believe that our second generation AAT product, Inhaled AAT for AATD, 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. Additionally, we have successfully completed a Phase I/II clinical study in Israel for newly diagnosed Type-1 diabetes (“T1D”) and have initiated a Phase II clinical study for this indication in Israel. We have also initiated a proof-of-concept (“POC”) Phase I/II clinical study with our intravenous AAT product to treat GvHD in cooperation with Baxalta, conducted at the Fred Hutchinson Cancer Research Center in Seattle, Washington. We have also completed Phase II clinical studies in Israel for additional novel indications, using formulations of AAT through Inhalation, for cystic fibrosis and bronchiectasis. We are also initiating a Phase I/II clinical study with our intravenous AAT product to prevent lung transplant rejection.

Our 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 state-of-the-art, cGMP compliant, FDA-approved, large scale production facility located in Beit Kama, Israel.

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 drugs manufactured by third-parties for critical use in Israel, most of which are produced from plasma or its derivative products. We have derived approximately 38%, 37% and 41% of our total revenues in the years ended December 31, 2015, 2014 and 2013, respectively, from sales in the United States, approximately 5%, 7% and 9.5% of our total revenues in the years ended December 31, 2015, 2014 and 2013, respectively, from sales in Europe, approximately 4% , 3% and 4% of our total revenues in the years ended December 31, 2015, 2014 and 2013, respectively, in Asia (excluding Israel) and 9%, 7% and 8.4% of our total revenues in the years ended December 31, 2015, 2014 and 2013, respectively, from 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 synthetic raw materials or 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, 2015, 2014 and 2013 approximately 70%, 66% and 54% of our total revenues, respectively, in the Proprietary Products segment. Revenue from our intravenous AATD products comprised approximately 43%, 42% and 49% of our total revenues for the years ended December 31, 2015, 2014 and 2013, respectively. Sales of KamRAB and KamRho (D) for the years ended December 31, 2015, 2014 and 2013 accounted for the substantial balance of total revenues in the Proprietary Products segment.

Product	Indication	Active Ingredient	Geography
Respiratory			
Glassia (or Respira/RespiKam/Ventia in certain countries)	Intravenous AATD	Alpha-1 Antitrypsin (human)	United States, Israel, Russia, Slovenia, Brazil, Argentina, Cuba, Colombia**
Immunoglobulins			
KamRAB	Prophylaxis of rabies disease	Anti-rabies immunoglobulin (human)	Israel, India, Thailand, El Salvador, Australia, Russia*, Mexico*, Georgia* and Korea
KamRho (D) IM	Prophylaxis of hemolytic disease of newborns	Rho(D) immunoglobulin (human)	Israel, Brazil, India, Argentina, Chile, Russia, Kenya, Nigeria, Sri Lanka* 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 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, Germany, France and Netherlands

* We have regulatory approval, but have not marketed the product in this country in 2015.
** Product was registered, but we have not yet started sales.

Respiratory — Glassia

Glassia is an intravenous AAT product produced from fraction IV 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-identified and under-treated, as we estimate that only approximately 6% and 2-3% of all potential cases of AATD are treated in the United States and Europe, respectively, with an aggregate of up to an estimated 200,000 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, underdiagnosis 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 only 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 competing products. 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.

Currently, Glassia has been approved in six countries. It is sold in five of those countries and also is sold in two additional countries, where it has not been approved, on a compassionate use 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 Baxalta, the Phase IV clinical trials are financed by Baxalta.

We market Glassia in the United States through our partnership with Baxalta. We market Glassia in Israel by ourselves and in five other countries through our local distributors. Sales to Baxalta accounted for approximately 37%, 36% and 40% of our total revenues in the years ended December 31, 2015, 2014 and 2013, 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 $30.0 million in 2015, representing a 92% 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 exposed to rabies 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, about 10 million people throughout the world require medical treatment against rabies every year after being bitten by or exposed to animals suspected of being infected. We believe that there are market opportunities for KamRAB in developing countries and in the United States. 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 is currently only one significant provider of anti-rabies immunoglobulin and we believe that healthcare providers may seek to diversify their source of supply if a competing high-quality product were approved for sale.

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 three other countries and are pursuing market approval in the United States. In April 2007, we received approval from the FDA to commence Phase II/III clinical trials of KamRAB and in January 2010, the FDA approved significantly shorter clinical trials. The trialbegan in the second quarter of 2013 and was completed in 2014. The trial evaluates the safety and effectiveness of KamRAB and assesses whether KamRAB interferes with the development of self-active antibodies. We announced that we successfully met the trial's primary endpoint of non-inferiority when measured against an IgG reference product. The Phase II/III clinical trial was a prospective, randomized, double-blind, non-inferiority study of 118 healthy subjects. The study evaluated pharmacokinetic (PK) parameters of anti-rabies IgG levels inserum at different time points and assessed whether Kamada's IgG interferes with the development of self-active antibodies. In addition, safety and tolerability were assessed. The trial's primary end point measured the anti-rabies titer on day 14 as well as on additional time points for secondary end points, following drug infusion and infusion of an active vaccine as recommended by the standard-of-care. The primary endpoint was designed to determine non-inferiority with a -10% margin. Top-line results showed that the primary endpoint of non-inferiority was met with a difference of -1.8% between the two therapies with variability between -8.2% and 3.1% (90% Confidence limit). Results showed that Kamada's IgG was safe and well tolerated with no drug-related Serious Adverse Events (SAEs) experienced. Based on the trial's results, we plan to submit a Biologics License Application ("BLA") with the FDA in 2016 and launch KamRAB in the United States in 2017, if approved by the FDA. In July 2011, we signed a strategic agreement with Kedrion S.p.A 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."

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 nine 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 renewable for up to ten additional one-year periods.

Other Products

We also sell 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.

Distribution Segment

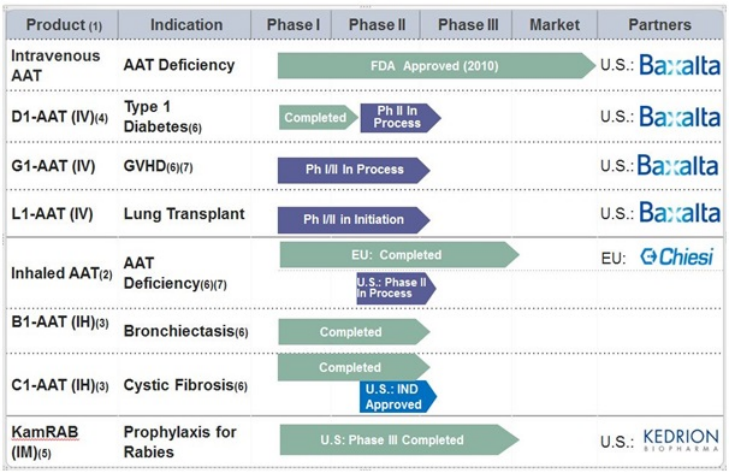
Our primary products in the Distribution segment include pharmaceuticals for critical use delivered by injection, infusion or inhalation. We leverage our expertise and presence in the plasma-derived protein therapeutics market to distribute products in Israel that we believe complement our products in 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. We distribute these products in Israel on an exclusive basis. IVIG is our primary product in the Distribution segment, comprising approximately 61%, 70% and 64% of total revenues in the Distribution segment for the years ended December 31, 2015, 2014 and 2013, respectively. Sales of IVIG accounted for approximately 24%, 18% and 26% of our total revenues for the years ended December 31, 2015, 2014 and 2013, 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, pulmonary embolism, fat embolism. Prophylaxis of deep vein thrombosis and thromboembolic events	Heparin sodium
Albumin	Maintains a proper level in the patient’s blood plasma	Human serum Albumin
Coagulation Factors		
Factor VIII	Treatment of Hemophilia Type A diseases	Coagulation Factor VIII (human)
Factor IX	Treatment of Hemophilia Type B disease	Coagulation Factor IX (human)

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:



(1) "IV" represents intravenous administration of the product. "IH" represents inhaled administration of the product. "IM" represents intramuscular administration of the product.

(2) Phase I and II are completed in Israel. Phase II/III is completed in Europe (Phase II began in first quarter of 2014 in the United States.)

(3) Phase I and II are completed in Israel. Received approval of investigational new drug ("IND") application in the United States.

(4) Phase II clinical trials in Israel for newly diagnosed cases of Type-1 diabetes began in first quarter of 2014.

(5) Phase II/III clinical trials are completed.

(6) Orphan drug designation in the United States.

(7) Orphan drug designation in the European Union.

Inhaled Formulations of AAT

We are in various stages of development of inhaled formulations of AAT administered through the use of a custom-designed 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 treatments 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 will 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 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, thereby further reducing the risk of infection, 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 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 emphysema. In addition, treatment by inhalation will enable the treatment of up to four to five times more patients with the same amount of AAT currently used by one patient for intravenous infusion. 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 Phase II/III pivotal trial under EMA guidance was completed in seven countries in Europe and in Canada in 2013. The trial, which was designed as a double blind placebo controlled and randomized trial, started in January 2010 and has been completed. A total of 168 patients were in the trial, with the last patient randomly selected in December 2012. 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 endpoints for the trial were exacerbation events. Other endpoints, which were secondary and tertiary, included 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 is complete.

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. We intend to initiate discussions with the FDA in 2016 to identify the regulatory pathway for registration in the United States.

Based on such results we have 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, and we plan to file a MAA for our Inhaled AAT for AATD during the first quarter of 2016. 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.

Safety data of Inhaled AAT for AATD in this Phase II/III trial remains supportive and consistent with previous Inhaled AAT for AATD studies conducted by us, and continues to demonstrate a high safety and tolerability profile.

In May 2015, we presented updated data to previously announced results, that focused on the statistically significant lung function beneficial effect, additional data on the nature of symptoms of the first exacerbation, a clinically important measurement, were reported during the panel session. In the study, three major exacerbation symptoms were used to describe the severity of an exacerbation: dyspnea, sputum volume and sputum color. These symptoms were scored by patients using a daily electronic diary device. The group that received the inhaled AAT treatment showed statistically significant lower symptoms score (for both dyspnea and volume) for patients who experienced first exacerbation versus the placebo group for such events:

- 0-10 days for dyspnea the AAT group scored 11.94 vs 12.25 for placebo, p=0.0243
- 0-14 days for dyspnea the AAT group scored 11.58 vs 11.78 for placebo, p=0.0817

- 0-10 for sputum volume the AAT group scored 1.27 vs 1.38 for placebo, p=0.0334
- 0-14 days for sputum volume the AAT group scored 1.23 vs 1.32 for placebo, p=0.0595

In addition, the inhaled AAT group had a lower percentage of patients who experienced all three symptoms during the first exacerbation (type I exacerbation) of the first exacerbation versus the placebo group (18.8% vs. 31.3%, p=0.06). Key highlights of the updated data set as noted in our previous news release include:

- Statistically significant lung function efficacy
- Change in the nature of exacerbations (reduction in number of Type 1-exacerbations (trend) and reduction in dyspnea score (statistically significant)
- The trial did not achieve statistical significance in primary endpoint of time to first exacerbation
- The drug is safe and tolerable

We plan to file MAA to the EMA by March 2016, for approval for our Inhaled AAT for AATD. If we receive marketing authorization, we hope to launch Inhaled AAT for AATD no later than 2018 in Europe.

During March 2014, we initiated Phase II trials in the United States. This trial may serve as a supplementary trial to the European Phase II/III trial and was designed to incorporate parameters required by the FDA. This is a Phase II, double-blind, placebo-controlled study to explore the ELF and plasma concentration as well as safety of Inhaled AAT in AATD subjects. The subjects receive 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 are 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. We expect to report top-line data by mid-2016.

An inhaled formulation of AAT was investigated in two separate Phase I trials (Phase Ia and Phase Ib). These trials were performed in accordance with the scientific advice provided by the EMA under the product's orphan designation status. In both trials, the inhaled formulation of AAT and the control product, a placebo, were administered using the "eFlow" nebulizer. Phase Ia was a single-blind, randomized, single-dose escalation, placebo-controlled study in 24 subjects. Phase Ib was a single-blind, randomized, repeated-dose, dose ranging, placebo-controlled study in 15 subjects. Both trials were targeted to explore safety and tolerability and were completed successfully, concluding high safety and tolerability of the product and no signs of immunogenicity or allergic reactions, allowing the continuation of the later development stages.

We conducted a Phase II lung deposition trial in three different subject populations: patients with cystic fibrosis, patients with emphysema and healthy subjects. The results of the Phase II trial indicated highly efficient deposition of AAT, including to periphery regions, lower lobes and mid and upper lobes. No safety issues were noted in this trial.

Cystic Fibrosis

We are currently developing an inhaled formulation of AAT for the treatment of cystic fibrosis, which formulation has been designated as an orphan drug in Europe and the United States. Cystic fibrosis is a congenital disease that causes mucus to build up in the lungs, digestive tract and other areas of the body. The Cystic Fibrosis Foundation estimates that approximately 70,000 people suffer from cystic fibrosis throughout the world. The rate of diagnosis of new patients in the United States is approximately 1,000 per year. Treatment of cystic fibrosis continues throughout the patient's life, and standard treatments are currently limited to inhaled antibiotics and, in severe cases, lung transplantation.

During the second half of 2012, we received FDA approval for IND Phase II trials for the inhaled formulation of AAT for the treatment of AATD and cystic fibrosis, which we are currently in the process of developing. A decision to start this trial has been postponed.

Previously, in August 2008, we completed a Phase II trial in 21 cystic fibrosis patients. The trial was a double-blind, randomized, placebo-controlled, Phase II trial that sought to explore the safety and efficacy of an inhaled formulation of AAT in cystic fibrosis patients, and consisted of treatment periods of 1 day, 7 days and 28 days. No serious adverse events were reported in any of the patients and the safety listings did not indicate any safety concerns. The trial concluded that the product was safe and well tolerated when inhaled daily for 28 days. A reduction of neutrophils and neutrophil elastase in sputum was observed in the group receiving the inhaled formulation of AAT while no such reduction was observed in the placebo group. The results, while not statistically significant due to small sample size, suggested an anti-inflammatory effect through the usage of the inhaled formulation of AAT in cystic fibrosis patients.

Bronchiectasis

We are also in the process of developing an inhaled formulation of AAT for the treatment of bronchiectasis, which formulation has been designated as an orphan drug in the United States. Bronchiectasis is an illness causing blockage and infection of the lungs. According to research conducted by the Cystic Fibrosis Foundation, in the United States alone, there are 100,000 persons suffering from bronchiectasis. Throughout the world, it is estimated that there are about 600,000 persons suffering from bronchiectasis. Treatment of bronchiectasis continues throughout the patient's life.

While we have not yet sought approval for clinical trials in the United States, we presented the findings to the FDA of a Phase II trial we conducted in Israel, which was a double-blind, randomized, placebo-controlled trial in 21 bronchiectasis patients and aimed to explore the safety and efficacy of an inhaled formulation of AAT in bronchiectasis patients for 12 weeks. The safety profile demonstrated was high and the product was determined as safe and tolerable for a period of 12 weeks in bronchiectasis patients. Efficacy results were not statistically significant due to the small number of patients in the study and to variability of the patients' disease severity, but suggested a positive effect of AAT on decreasing inflammation of the lungs.

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

We have commenced the development of an additional indication for our AAT IV for its usage in the treatment of newly diagnosed cases of Type-1 Diabetes. 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 persons 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. A number of studies conducted recently, including those conducted using Glassia, as discussed below, have suggested that use of AAT protein may delay the inflammatory process in the pancreatic cells and maintain or prolong cell function, which is increased by the secretion of insulin and glycemic control. We believe that the use of Glassia for the treatment of newly diagnosed Type-1 Diabetes, unlike the current standard of care insulin treatment, may prevent or slow the progression of the development of the disease. If demonstrated in further clinical studies, we believe that this product can slow progression and delay the complications of diabetes, such as retinopathy, nephropathy and heart disease.

In December 2012, we completed Phase I/II clinical trials in Israel of human AAT (Glassia) for usage in the treatment of Type-1 Diabetes, which suggested that AAT may slow disease progression, allow continued functionality of beta cells and improve glycemic control. The objective of the trials was to examine the safety and efficacy of Glassia for treatment of newly diagnosed Type-1 Diabetes.

The study evaluated a pediatric population with recent onset type 1 diabetes (T1D) in a 37-week prospective, open-label, Phase I/II interventional trial, constituting 24 recently diagnosed subjects who received 18 infusions of 40, 60, or 80 mg/kg/dose of AAT over 28 weeks. The primary endpoints were safety and tolerability and secondary endpoints included glycemic control, C-peptide reserve, and autoantibody levels. Possible responders were defined as individuals with peak C-peptide levels that declined less than 7.5% below baseline. No serious adverse events, diabetic ketoacidosis (DKA), or severe hypoglycemic episodes were reported. Adverse events were dose-independent and transient. Glycemic control parameters improved during the study in all groups, independent of dosage. Hemoglobin A1c (HbA1c) decreased from 8.43% to 7.09% (mean, $p<0.001$). At the end of the study, 18 subjects (75%) had a peak C-peptide ≥0.2 pmol/mL. Eight subjects (33.3%) were considered possible responders and were characterized by shorter duration of T1D at screening (54.5 ± 34.3 vs. 95.9 ±45.7 days, $p=0.036$) and greater decrease in their HbA1c during the study period (−2.94± 1.55 vs.−0.95± 1.83%, $p=0.016$).

An extension for this Phase I/II trial was initiated in 2013 and 19 subjects were enrolled in the extension portion of the trials in either the treatment arm (n=10) or follow-up arm (n=9) and five subjects chose not to participate. The latest interim report from the extension study was presented following six additional AAT infusions for subjects in the AAT treatment arm. Interim data from an average of 26 months post T1D diagnosis show that mean peak C-peptide levels, a peptide which represents the endogenous insulin production and thereby the beta cell activity, were 0.40 pmol/ml and that 60% of these patients exhibited a level ≥ 0.2 pmol/ml, which is considered to be a clinically meaningful trough level, which negatively correlates with future serious diabetes complications. C- peptide data was not collected for the untreated patient group. In addition, patients receiving AAT continued to attain American Diabetes Association ("ADA") and International Society for Pediatric and Adolescent Diabetes ("ISPAD") treatment targets of 7.5% for HbA1C. This is considered the clinically desired level for glycemic control in pediatric diabetes patients who usually demonstrate a more severe or volatile form of T1D disease compared with adults. Treated patients demonstrated an average HbA1C of 7.5% in comparison to 7.9% for the untreated patients. The majority of treated patients (60%) had HbA1C levels lower or equal to 7.5% vs. 44% of the patients in the untreated group. Despite these important differences, these were not found to be statistically significant, as this study was not powered to show statistical significance. Median insulin intake for the treated patients group was lower than the untreated patient group, 0.6 IU/kg/d compared to 1.00 IU/kg/d, respectively (p = 0.025).

In March 2014, we began double-blind, randomized, placebo-controlled, multicenter Phase II/III trials evaluating the efficacy and safety of Glassia in the treatment of new onset Type-1 Diabetes. This study is conducted at four pediatric Type-1 Diabetes medical centers in Israel and was designed to evaluate beta cell functioning as measured by C-peptide parameters, glycemic control expressed in HbA1C levels, hypoglycemic events and insulin daily dose, among others. We planned to enroll 192 patients randomized into two groups receiving AAT and one placebo group. Interim analysis was planned to be performed during 2016.

In December 2015, we reported that we will un-blind the current clinical trial at the planned interim analysis. We are in the opinion that this change will accelerate the timeline for future commercialization of the product, should the analysis be positive. We managed to enroll about 70 patients by the end of 2015, and have determined that this will be sufficient to allow us to explore the differences between treatment groups without the limitations of the blinding. To date, the safety profile of AAT is excellent without any major adverse events both in the current trial, which includes pediatric patients, as well as in commercial settings, where the drug has been used to treat hundreds of patients for its FDA approved indication.

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

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. In April 2014, we announced the initiation of a POC Phase I/II clinical study with our intravenous AAT product to treat Graft-Versus-Host Disease (GvHD) in cooperation with Baxalta, to be conducted at the Fred Hutchinson Cancer Research Center in Seattle, Washington. We are evaluating whether our intravenous AAT product may decrease GvHD-related symptoms, including progressive tissue damage and thereby potentially increase the survival rates of this complication and possibly reduce or eliminate the need for "steroid" therapy. Results from this POC study in GvHD may also support global clinical development activities and may serve as a platform to apply for an expansion of the AAT indications with the regulatory authorities to include general organ transplantation, based on a similar mechanism of action.

The POC phase I/II study is enrolling 24 patients with steroid-resistant GvHD following allogeneic bone-marrow stem cell transplant who will receive six to ten doses of intravenously delivered AAT to determine safety, optimal dose and clinical response. To date, 12 patients with hematologic malignancies were enrolled, 6 of which were enrolled in the first cohort and 6 in the second. Patients showing no clinically satisfactory responses to steroids were given AAT at 90 mg/kg IV on day 1, followed by 30 mg/kg (first cohort) or 60 mg/kg (second cohort) every other day for a total of 8 doses (15 days). All subjects had GvHD of Grade III or IV with stage 4 intestinal involvement.

Preliminary results from the 1st cohort indicated that continuous administration of AAT as therapy for steroid resistant gut GvHD is feasible in the subject population. Healing of the bowel mucosa was evidenced by a decreased diarrhea, intestinal protein loss, including AAT, and endoscopic evaluation. Additionally, following examination of pro-inflammatory cytokines, in the preliminary results AAT administration suppressed serum levels of pro-inflammatory cytokines and interfered with GvHD biomarkers.

In January 2016, after receiving results from the 2nd cohort, we reported further positive interim data from this Phase I/II clinical trial. We reported on outcomes from the 12 subjects enrolled in cohorts 1 and 2 who were treated at two dose levels of AAT. The interim results showed that plasma AAT levels increased in both cohorts and remained stable for the duration of treatment. Treatment responses were evaluated as "peak" response and at day 28. Eight of the 12 subjects showed an overall response to treatment, four of which were complete responses and four were partial responses.

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 Eropean Union to develop the designated medicine for the rare indication.

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.

AAT for Treatment of Lung Transplant Rejection

We have entered into collaboration with Baxalta on a Phase I/II clinical trial of our proprietary alpha-1 antitrypsin (AAT) treatment for the prevention of lung transplant rejection that will be performed in Israel.

Under the agreement, Baxalta will collaborate in the development and funding of the study. The study will be initiated in first half of 2016.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.

Lung transplant 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).

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.

Other Indications

In addition, we believe that a number of additional potential indications may exist for this product candidate, including chronic obstructive pulmonary disease, islets transplantation and general organ transplantations.

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.

Baxalta (Glassia)

On August 23, 2010, we entered into a strategic partnership with Baxter. During 2015, Baxter assigned all of its rights under the relevant partnership agreement to Baxalta.

The partnership arrangement includes three main agreements: (1) a distribution agreement, pursuant to which Baxalta is the sole distributor of Glassia in the United States, Canada, Australia and New Zealand; (2) a licensing agreement, which grants Baxalta licenses to use our knowledge and patents to produce, develop and sell Glassia and other products administered by transfusion; and (3) an agreement for Baxalta to supply us with fraction IV, a plasma derivative, produced by Baxalta, as discussed under “— Manufacturing and Supply — Raw Materials — Fraction IV for Glassia.” As between us and Baxalta, we retain all rights, including distribution rights, to any inhaled formulation of AAT in development, including Inhaled AAT for AATD. On October 15, 2015, we signed a fourth amendment to the distribution agreement with Baxalta to extend the period of minimum purchases by Baxalta of Glassia until the end of 2018 and increase the minimum purchases under the distribution agreement. The minimum aggregate revenues expected under the agreements from 2010 to 2018 are expected to be at least $240 million (including $191 million of which we have already recognized as revenues through the end of 2015), excluding the royalty payments under the licensing agreement, which are not expected to begin prior to 2019.

Sales to Baxalta accounted for approximately 37%, 36% and 40% of our total revenues in the years ended December 31, 2015, 2014 and 2013, respectively.

Distribution Agreement

Pursuant to the distribution agreement, we received an upfront payment of $20 million related to distribution rights. Additionally, Baxalta is obligated to purchase a minimum amount of Glassia per year until the end of 2018. Pursuant to Baxalta's minimum purchase obligations, from 2015 until the end of 2018, we are entitled to receive minimum payments of between $17.5 million and $24.5 million per year from Baxalta (the total minimum revenue commitment for the years 2016 until 2018 is $97 million). After 2018, Baxalta has no obligation to purchase a minimum amount of Glassia; however, Baxalta's failure to purchase a specified minimum amount of Glassia over a period of 24 consecutive months beginning in 2016 until the expiration of the agreement provides us with the right to terminate the agreement. Baxalta 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.

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. Baxalta 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 Baxalta infringes upon our intellectual property.

Following termination of the agreement, Baxalta 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 Baxalta, 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 Baxalta's production and sale of Glassia in the United States, Canada, Australia and New Zealand. Baxalta agreed to pay us royalties at the rates specified in the agreement, which are in the low double digits during the first 15 years 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 2019. The technology license agreement sets forth a minimum amount of royalty payments of $5.0 million required to be made by Baxalta per year beginning on the first year of commercial sales of Glassia produced by Baxalta.

Pursuant to the technology license agreement, we are entitled to receive payments for the achievement of certain milestones for an aggregate of up to $25.0 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 Baxalta and $10.0 million are sales-based milestones.

The intellectual property rights for any improvements on the manufacturing process or formulations that we disclose to Baxalta 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 Baxalta under the agreement that is not considered an improvement on the licensed technology. Additionally, Baxalta 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. Baxalta 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 Baxalta of its obligations. We have the right to terminate the agreement, upon prior written notice: (i) if Baxalta 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 Baxalta, 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 Baxalta has not occurred by June 15, 2017 and Baxalta 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 Baxalta a non-exclusive, perpetual, royalty free license.

Chiesi (Inhaled AAT for AATD product)

On August 2, 2012, we entered into an exclusive distribution agreement with Chiesi, a fully integrated European-based pharmaceutical company focused on respiratory disease and special care products. Chiesi distributes its products in more than 60 countries and has 24 affiliates worldwide. It has a direct commercial presence in Europe, the United States and in many important emerging markets.

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. We retain all rights, including distribution rights, for additional indications for inhaled formulations of AAT, including indications for the treatment of cystic fibrosis and bronchiectasis. We also retain ownership of intellectual property rights for Inhaled AAT for AATD. Chiesi will be responsible for, among other things, product sales and marketing, patient recruitment and screening and obtaining reimbursement approvals for the product. Beginning in the second year after the receipt of certain required regulatory and reimbursement approvals, Chiesi is required to purchase a minimum amount of the Inhaled AAT for AATD product per year based on the number of countries in which regulatory and reimbursement approvals have been received, for a minimum amount of approximately $120 million for the first four years, subject to adjustments based on actual product price after regulatory approval.

We are entitled to receive payments upon the achievement of certain regulatory and sales target milestones for an aggregate of up to $60.0 million, including $20.0 million, consisting of an upfront payment we have already received and regulatory-based milestones, and $40.0 million of sales-based milestones.

The agreement expires on August 2, 2024. Either party may terminate the agreement (i) upon an uncured material breach by the other party, (ii) upon certain bankruptcy events of the other party or (iii) with prior notice if any regulatory approval in one or more countries covered by the distribution agreement is withdrawn or the application has been rejected, and the decision has not been reversed for a certain period thereafter, provided that the withdrawal or rejection was not primarily caused by the breach of the terminating party of its obligations. We have the right to terminate the agreement with prior notice if Chiesi does not meet its minimum purchase obligations, or if Chiesi infringes upon our intellectual property.

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. 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 our 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 II/III clinical trials in the United States of our product for rabies. Costs related to any Phase IV clinic 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. It was also agreed that the hyper-immune plasma required to produce the product would be supplied by KedPlasma LLC, a subsidiary of Kedrion. In 2014, the trial was completed and successfully met the trial's primary endpoint of non-inferiority when measured against an IgG reference product See "Item 4. Information on the Company — *immunoglobulins* — KamRAB".

The agreement provides exclusive rights to Kedrion to market and sell KamRAB in the United States, subject to regulatory approval. We retain intellectual property rights to KamRAB. Beginning shortly after receipt of FDA approval for KamRAB, if obtained, Kedrion will be obligated to purchase a minimum amount of KamRAB per year during the term of the agreement.

The term of the agreement is for six years following the receipt of FDA approval, if obtained, 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, if obtained, (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 KamRAB, (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 one product only. 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.

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 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 July 2013, the IMOH completed a successful cGMP audit of our facility and concluded that we comply with cGMP requirements of the IMOH.

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 Baxalta, in the years ended December 31, 2015, 2014 and 2013, there were two, two and one supplier(s), respectively, 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, 2015, 2014 and 2013, we incurred $19.0 million, $9.9 million and $14.5 million of expenses for the purchase of raw materials, respectively.

Fraction IV for Glassia

On August 23, 2010, in conjunction with the cooperation arrangement with Baxalta, we signed an agreement with Baxalta for the supply of fraction IV for use in the production of Glassia to be sold in the United States. Under this agreement, Baxalta also supplies us with fraction IV to continue the development and trials of Glassia and for the production, sale and distribution of Glassia in jurisdictions other than the United States or for the production, sale and distribution of other products in any territory. Baxalta receives no payment for the supply of fraction IV to be used by us for the manufacture of Glassia to be sold to Baxalta. If we require fraction IV for other purposes, we are entitled to purchase it from Baxalta at a predetermined price. While we are dependent on Baxalta for the supply of fraction IV, Baxalta is currently dependent on us to produce Glassia for sale in the United States, as it does not have its own production capacity for Glassia. 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 Baxalta to supply additional fraction IV manufactured in its Vienna plant to be used as the raw material in the production of our AAT product. Baxalta is obligated to make available to us yearly minimum quantity of fraction IV. 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 Baxalta, Baxalta is obligated to provide us, upon our request, with fraction IV in the amount equivalent to the previous year's total amount of fraction IV sold to us in addition to the fraction IV to be sold during the last year of the agreement.

We have relationships with suppliers in addition to Baxalta, and we are currently in negotiations with an additional FDA and EMA - approved fraction IV suppliers to reduce our dependence on Baxalta.

Hyper-immune Plasma

We have a number of suppliers in the United States and Europe 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 additional long-term supply agreements for hyper-immune plasma.

Research and Development

Our research and development activity in the Proprietary Products segment is focused on developing new orphan plasma-derived therapeutic products, registering new products, including conducting clinical trials, improving existing products and processes and engaging in development work at the request of regulatory authorities and strategic partners. We are continuing to pursue further growth by diversifying our product pipeline through the discovery and development of additional plasma-derived protein therapeutic products for high-value indications. We incurred approximately $16.5 million, $16.0 million and $12.7 million research and development expenses in the years ended December 31, 2015, 2014 and 2013, 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 Baxalta and to other distributors.

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 with 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. While we occasionally receive direct orders for our Distribution segment products, we primarily sell our Distribution segment products through offers to participate in public tenders, which occur on an annual basis. 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, 2015, sales to Baxalta and Kupat Holim Clalit, an Israeli healthcare provider, accounted for 37% and 15%, respectively, of our total revenues. For the year ended December 31, 2014, sales to Baxalta and Kupat Holim Clalit, an Israeli healthcare provider, accounted for 36% and 17%, respectively, of our total revenues. For the year ended December 31, 2013, sales to Baxalta and Kupat Holim Clalit accounted for 40% and 12%, respectively, of our total revenues. No other sole customer accounted for greater than 10% of our total revenues in the years ended December 31, 2015, 2014 and 2013.

Baxalta 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.

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, Kedrion, and Cangene Corporation (acquired by Emergent BioSolutions). We have not seen significant changes in the activities of our competitors in recent years. Additionally, our strategic alliance with Baxalta 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 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 50% market share in the U.S. and more than 70% of sales worldwide, and until 2015 it was the only such product that is approved for sale in both – key European countries and the United States. 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. We expect CSL to launch the product in few selected EU markets during 2016. Apart from its sales of the past Talecris product, Grifols is also a local producer of a separate AAT product, Trypsone, which is marketed in Spain and in some Latin American countries, including Brazil. While Baxalta is our strategic partner for sales of Glassia, it also serves existing patients in the United States with its own product, Aralast. As far as we know Baxalta proactively markets 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. 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 approximately 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 horse 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 following its acquisition of the Anti-Rh product line of Ortho-Clinical Diagnostics, Inc., which was formerly our main competitor for this product. We estimate that Kedrion's product accounts for approximately 50% of 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 suppliers of competitive products in this market: Cangene, 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. These manufacturers include Grifols, Baxalta, CSL, Octapharma AG, Omrix Biopharmaceuticals Ltd. (a Johnson & Johnson company) and Cangene as well as 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 companionate use 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 refusal to approve applications, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, fines and/or criminal prosecution.

The steps required before a biologic 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 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. We cannot assure you 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 $2,000,000, 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 ("ACA"), Public Law No. 111-148, under the subtitle of Biologics Price Competition and Innovation Act of 2009 ("BPCI"), 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 BPCI, 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. The implementation of an abbreviated approval pathway for biological products is under the direction of the FDA and is currently being developed. In February 2012, the FDA published draft guidance documents on biosimilar product development. Since then, biosimilar product registration in the U.S. has been materialized by few other guidelines and acts, such as the draft guidance for formal meetings related to biosimilar product development (November 2015-"Final Guidance Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants Guidance for Industry") and the Biosimilar User Fee Act (BsUFA). 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 proposed 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.

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, enforcement letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties. Such enforcement may also lead to scrutiny and enforcement by other government and regulatory bodies. 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 NDA, 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 Black Box Warning (e.g., a specific warning in the label to address a specific risk), which has marketing restrictions, and post-marketing testing, or Phase IV testing, as well as risk minimization action plans and surveillance to monitor the effects of an approved product or place conditions on an approval that could otherwise restrict the distribution or use of the product.

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 United States Department of Justice and individual United States Attorney offices within the Department of Justice, state attorney generals 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. Recent legislative changes purport 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.

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 ACA 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.

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, the President of the United States signed into law the Patient Protection and Affordable Care Act and the Healthcare and Education Reconciliation Act of 2010 (collectively referred to as the "ACA"). The ACA 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 ACA promote the development of new payment and healthcare delivery systems, such as the Medicare Shared Savings Program, bundled payment initiatives and the Medicare pay for performance initiatives.

The ACA 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 ACA directly address drugs. For example, the ACA:

- 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 January 21, 2016, the Centers for Medicare and Medicaid Services issued final regulations to implement the changes to the Medicaid Drug Rebate Program under the healthcare reform law. These regulations become effective on April 1, 2016. We are evaluating the potential impact of these regulations on our business and operations.

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, 2015, we owned for use within our field of business five families of patents, which are registered or applied for in the United States and also in the European Union, Russia, Turkey, Israel, certain Latin American countries and other countries. At present, our two patents protecting our manufacturing process are considered to be material to the operation of our business as a whole. One such material patent is issued in the United States and expires in 2018. The other material 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. We are currently focusing mainly on seeking patent protection in Israel, the United States and Europe.

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. 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, 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 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, 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, service providers and our business partners to execute confidentiality agreements in connection with their employment relationships during the term of the commercial relationship with us and thereafter, and 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, and 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.

In addition, we lease from a third party approximately 1,398 square meters of a building located in the Kiryat Weizmann Science Park in Ness Ziona, Israel, under a lease agreement that terminates on March 31, 2017. The premises house our head office and research and development laboratory.

Environmental

We believe that our operations comply in all 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 100 percent owned 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

In January 2012, we were issued a tax payment order from the Israeli tax authorities for the 2004 to 2006 tax years in the amount of NIS 17 million (or approximately $4.4 million) (including accumulated interest and linkage differentials). We have appealed this assessment in court. In the opinion of our management, after consultation with our legal advisors, an additional provision was not needed beyond that included in our financial statements.

In addition to the above 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, other than those described above, 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, 2015, 2014, and 2013 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 an orphan drug focused, plasma-derived protein therapeutics company with an existing marketed product portfolio and a robust 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 and only liquid, ready-to-use, intravenous plasma-derived AAT product approved by the FDA. We market Glassia through a strategic partnership with Baxalta in the United States. Additionally, we have a product line consisting of ten other injectable pharmaceutical products which are marketed, in addition to Glassia, in more than 15 countries, including Israel, Russia, Brazil, India and other countries in Latin America and Asia. We currently have six plasma-derived protein products in our development pipeline, including Inhaled AAT for AATD, for which we completed a pivotal Phase II/III clinical trial in Europe and are expecting to file the MAA with the EMA in the first quarter of 2016. See "Item 4. Information on the Company—Our Product Pipeline and Development Program—Inhaled Formulations of AAT—AATD." We are also conducting a Phase II clinical trial with our Inhaled AAT for AATD in the United States, for which we have completed the enrollment of patients. In addition, we have completed a pivotal Phase II/III US clinical trial for anti-rabies immunoglobulin as a post-exposure prophylaxis and met the trial's primary endpoint of non-inferiority when measured against an IgG reference product. In addition to our propriety products we leverage our expertise and presence in the plasma-derived protein therapeutics market by distributing 14 complementary products in Israel that are manufactured by third parties.

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 drugs mainly for critical use 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, 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. For the year ended December 31, 2014, we derived $44.4 million of revenues from our Proprietary Products segment, or 62% of total revenues, and $26.7 million of revenues from our Distribution segment, or 38% of total revenues. For the year ended December 31, 2013, we derived $50.7 million of revenues from our Proprietary Products segment, or 72% of total revenues, and $20.0 million of revenues from our Distribution segment, or 28% of total revenues.

Factors Affecting Our Results of Operations

Growing Demand

Over the past few years, we have seen an increase in demand for products in our Proprietary Products segment. In particular, in 2014 and 2015, the number of patients treated by Glassia increased by more than 25% each year, and we expect the number of patients to continue to grow over the medium term as diagnostics improve and disease awareness increases. We expect that our revenues from the Proprietary Products segment will grow by approximately 75%, allowing us to achieve our midterm revenue goal of $100 million by 2017 through increased sales of our existing products in the Proprietary Products segment, mainly driven from sales of Glassia world-wide. The AAT augmentation market for AATD in the U.S., which is the primary market for Glassia has grown by approximately 10% annually in the last few years, and we expect that the overall market for Glassia will continue to increase due to new patient identification. Technological improvements and increased awareness permit innovations in the diagnosis of the illnesses and symptoms. In addition, demand in certain emerging markets such as Russia, Brazil and India for plasma-derived products have grown and are expected to continue to grow. This demand is driven by enhanced socioeconomic conditions and more informed patients who are demanding better quality medical care, as well as increasing government healthcare spending on plasma derivative products in some of these markets. More informed patients are demanding the use of drugs based on human antibodies obtained from human plasma rather than antibodies obtained from animal blood, which generally have a lower standard of quality and safety.

Additionally, 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 2-3% of all potential cases of AATD are treated in the United States and Europe, respectively, with an aggregate of up to an estimated 200,000 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. In addition, our product pipeline is focused on products for indications that will address markets in which we believe have a significant market opportunity, such as indications for the treatment of newly diagnosed Type-1 diabetes, lung-transplant rejection and GvHD.

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 had experience significant growth of sales in the recent years since 2010 and it may continue to grow if we will be able to increase our product portfolio.

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 strategic arrangement with 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 Baxalta 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 Baxalta in September 2010. From the inception of the strategic arrangement through December 31, 2015, we have received $34.5 million from Baxalta 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, 2015 from Baxalta in the amount of $146.6 million. We currently generate revenues from sales of Glassia to Baxalta, and incur cost of revenues to produce it. In accordance with the latest amendment to the manufacturing and distribution agreement, Baxalta has the right to begin producing Glassia itself, which is expected to occur not before 2019 at the earliest, and pay us royalties. As Baxalta transitions to producing Glassia in its own facilities, our capacity will become available to produce inhaled formulations of AAT, AAT products for sale in other geographies and indications, or other plasma-derived products. We would generate higher margins from royalties from Baxalta under this arrangement, as we would not incur cost of revenues, but we may receive lower revenues. We expect to replace those lower revenues by producing and selling other products, including inhaled formulations of AAT, if approved, in Europe, Glassia worldwide through local distributors and, if approved by the competent authorities, anti-rabies product in the United States. Our expectations with respect to Glassia assume the continuation of our strategic partnership with Baxalta. 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 August 2012, we also entered into a strategic agreement with Chiesi, pursuant to which Chiesi will be an exclusive distributor of Inhaled AAT for AATD in Europe. Chiesi will be responsible for, among other things, product marketing, patient screening and obtaining reimbursement approvals for the Inhaled AAT for AATD product. As part of the agreement, we are entitled to receive payments of up to $60.0 million, contingent on meeting regulatory and sales milestones. In addition, Chiesi has committed to purchase Inhaled AAT for AATD in minimum quantities following the second anniversary of obtaining certain regulatory and reimbursement approvals.

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 KamRAB, our vaccine against rabies in humans. Kedrion markets its products in Europe, the United States and in approximately 40 other countries worldwide. We have not yet started to generate revenues under this agreement as Kedrion has just completed the Phase III clinical trials in the United States, which, as stated above, met the trial’s primary endpoint.

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 clinical trials to obtain regulatory approvals, regulatory expenses, costs for materials for development, external consulting 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, we seek to share development costs with strategic partners, such as Baxalta for the clinical trials for Glassia in the United States and Kedrion for the clinical trials for KamRAB in the United States. See “Item 4. Information on the Company — Strategic Partnerships — Baxalta (Glassia)” and “Business — Strategic Partnerships — Kedrion (KamRAB).”

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, 2015, 2014 and 2013, 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. 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 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, and the increase of strengthening of the remaining competitors, mainly for specific immunoglobulin products.

While there are additional producers of AAT products in Europe and the United States, including Baxalta, we have not seen significant changes in these producers' activities in the market. Additionally, our strategic alliance with Baxalta 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 Baxalta. 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 our Distribution segment, in recent periods, we benefitted from the temporary suspension in sales in Israel of two of our competitors' IVIG products. These competing IVIG products returned to the market at the end of 2012. As a result, we experienced increased competition for our Distribution segment products in 2015, 2014 and 2013. Such competition may further increase in the future.

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.

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) 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 and the licensing of our technology to strategic partners. 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. In the years ended December 31, 2015, 2014 and 2013, we derived a significant portion of our total revenues from sales of Glassia to Baxalta. Sales to Baxalta accounted for approximately 37%, 36% and 40% of our total revenues in the years ended December 31, 2015, 2014 and 2013, respectively. Revenue from all sales of Glassia comprised approximately 43%, 43% and 49% of our total revenues for the years ended December 31, 2015, 2014 and 2013, respectively. We expect revenues attributable to the sale of Glassia to Baxalta will grow in the next three years, in line with the expected continued increase in the number of patients treated by Glassia and pursuant to the fourth amendment to the Manufacturing, Supply and Distribution Agreement, until Baxalta begins production of Glassia, at which time our sales to Baxalta will be reduced as they are replaced by royalties from Baxalta.

In our Distribution segment, we generate revenues from the sale in Israel of products produced by third parties. In 2013, such revenues were affected by the return of one of our competitor's IVIG products to the Israeli market after a temporary reduction during the prior year. In 2014, sales of IVIG increased again due to our successful marketing efforts and increased demand in the market. In 2015 sales of IVIG moderately increased. However, due to exchange rate differences and changes in the market conditions, revenues have moderately decreased. Sales of IVIG accounted for approximately 24%, 26% and 18% of our total revenues for the years ended December 31, 2015, 2014 and 2013, 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 launch of new AAT products currently in different development phases and the launch of our anti-rabies specific immunoglobulin in the United States.

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 Baxalta and successful penetration to the U.S. market, we have focused during the years ended December 31, 2015, 2014 and 2013 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 Baxalta 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. In 2012, we submitted a supplement to the FDA with respect to Glassia production improvements. In March 2013, we received a request from the FDA to submit additional data and explanations prior to its approval of our new production processes, and we received FDA approval in July 2014. During the second quarter of 2014, inventory in the amount of $3.0 million, produced using the improved manufacturing process, was written off due to a short shelf life of the inventory and our reevaluation of the fair value of such inventory.

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. Such increase halted in 2014 and 2015, when our gross profitability decreased in 2014 compared to that for 2013, primarily due to (i) revenues that were $4.5 million lower than the milestone achieved in 2013, (ii) revenues from upfront payments related to collaborative agreements that were $1.8 million lower than that of the prior year, (iii) a onetime $3.0 million inventory write-off in the second quarter of 2014, (iv) a $1.0 million increase of cost of vials sold due to excess capacity and (v) a $1.1 million increase in costs due to a one-time sales incentive. In 2015, our gross profit increased compared to 2014 primarily due to lower profitability in the Proprietary Products segment, and a small reduction in total revenues in 2015, due to increased cost of revenues attributable to our Proprietary Products segment, which offset the effect of the one-time $3.0 million inventory write-off in the second quarter of 2014.

Our gross margins are generally higher in our Proprietary Products segment (29%, 27%, and 46.5% for the years ended December 31, 2015, 2014 and 2013, respectively), reflecting higher margins on our proprietary products than in our Distribution segment (12.3%, 12.2%, and 14.3% for the years ended December 31, 2015, 2014 and 2013). In 2015, the gross margin in the Proprietary Products segment was higher than that of 2014 as a result of the effect of the lack of the one-time $3.0 million inventory write-off in the second quarter of 2014, which offset mainly lower profits resulting from our change in the mix of our product sold. Our gross margins in 2014 were lower than 2013 mainly as a result of a $4.5 million milestone received in 2013, which was not received in 2014. 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) increase as these products have higher gross margins than our immunoglobulin proprietary products.

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 Proprietary Products segment.

We expect our research and development expenses to remain stable annually over the next couple of years to reflect our plan to fund certain additional clinical trials for AAT for certain additional indications. 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 team development. 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 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 discount on convertible debentures.

Taxes on Income

We have not been required to pay income taxes since 1997 other than tax withheld in a foreign jurisdiction in 2012, which were not incurred in 2013, 2014 and 2015.

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 will expire 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 2021. 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, 2015, we have net operating loss carryfowards of approximately $85.5 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,		
	2015	**2014**	**2013**
	(in thousands, except per share data)		
Revenues from Proprietary Products	$ 42,952	$ 44,389	$ 50,658
Revenues from Distribution	26,954	26,676	19,965
Total revenues	69,906	71,065	70,623
Cost of revenues from Proprietary Products	30,468	32,617	27,104
Cost of revenues from Distribution	23,640	23,406	17,112
Total cost of revenues	54,108	56,023	44,216
Gross profit	15,798	15,042	26,407
Research and development expenses	16,530	16,030	12,745
Selling and marketing expenses	3,652	2,898	2,100
General and administrative expenses	7,040	7,593	7,862
Operating income (loss)	(11,424)	(11,479)	3,700
Financial income	463	404	278
Income (expense) in respect of currency exchange differences and derivatives instruments	625	—	(369)
Financial expense	(934)	(2,086)	(3,142)
Income (loss) before taxes on income	(11,270)	(13,161)	467
Taxes on income	-	52	24
Net income (loss)	$ (11,270)	$ (13,213)	$ 443

Year Ended December 31, 2015 Compared to Year Ended December 31, 2014

Segment Results

	Year Ended December 31,		Change 2015 vs. 2014	
	2015	2014	Amount	Percent
	(in thousands)			
Revenues:				
Proprietary Products	$ 42,952	$ 44,389	$ (1,437)	(3.2)%
Distribution	26,954	26,676	278	1.0%
Total	$ 69,906	$ 71,065	$ (1,159)	(1.6)%
Cost of Revenues:				
Proprietary Products	$ 30,468	$ 32,617	$ (2,149)	(6.6)%
Distribution	23,640	23,406	234	1.0%
Total	$ 54,108	$ 56,023	$ (1,915)	(3.4)%
Gross Profit:				
Proprietary Products	$ 12,484	$ 11,772	$ 712	(6.0)%
Distribution	3,314	3,270	44	1.3%
Total	$ 15,798	$ 15,042	$ 756	5.0%

Revenues

In the year ended December 31, 2015, we generated $69.9 million of total revenues, compared to $71.1 million in the year ended December 31, 2014, a decrease of $1.2 million, or approximately 0.2%. This decrease was primarily due to a $1.4 million decrease in our Proprietary Products segment revenues, mainly due to decrease in sales volume, partially offset by an increase of $0.3 million in our Distribution segment mainly attributable to increased demand and marketing efforts.

Cost of Revenues

In the year ended December 31, 2015, we incurred $54.1 million of cost of revenues, compared to $56.0 million in the year ended December 31, 2014, a decrease of $1.9 million, or approximately 3%. The cost of revenues in our Proprietary Products segment decreased by $2.1 million, which was primarily due to a $3.0 million onetime inventory write-off in the second quarter of 2014, as there was no corresponding write-off in 2015, and lower stock-based compensation of $0.6 million, partially offset by an increase of $1.3 million of materials purchase and change in inventory. The cost of revenues in our Distribution segment increased by $0.2 million, which was primarily due to an increase in volume of sales.

Gross profit in our Proprietary Products segment increased by $0.7 million in 2015, primarily due to a $2.1 million decrease in cost of revenue, which was mainly attributable to the lack of the $3.0 million inventory write-off in the second quarter of 2014, partially offset by an insignificant decrease in sales volume. Gross profit in our Distribution segment remained stable. As a percentage of total revenues, gross margin was 22.6% and 21.2% for the years ended December 31, 2015 and 2014, respectively. Gross margin for the Proprietary Products segment, as a percentage of revenues from that segment, was 29.1% and 26.5% for the years ended December 31, 2015 and 2014, respectively. Gross margin for the Distribution segment, as a percentage of revenues from that segment, was 12.3% for the years ended December 31, 2015 and 2014. The increase in gross profit margin was primarily driven by the decrease in the Proprietary Products segment revenues, the effect of which was offset by a decrease in Proprietary Products segment costs.

Research and Development Expenses

In the year ended December 31, 2015, we incurred $16.5 million of research and development expenses, compared to $16.0 million in the year ended December 31, 2014, an increase of $0.5 million, or approximately 3%. This increase was primarily due to a $2.1 million increase in facility costs allocated to research and development partially offset by a $1.6 million decrease in expense for clinical trials. Research and development expenses accounted for approximately 23.6% and 22.6% of total revenues for the years ended December 31, 2015 and 2014, respectively.

Set forth below are the research and development expenses associated with our major development programs in the years ended December 31, 2015 and 2014:

	Year ended December 31,	
	2015	2014
	(in thousands)	
Inhaled AAT	$ 4,939	$ 6,326
AAT for newly diagnosed Type-1 Diabetes	1,753	1,959
Unallocated salary	4,566	4,514
Unallocated facility cost allocated to research and development	4,569	2,409
Unallocated other expenses	703	822
Total research and development expenses	$ 16,530	$ 16,030

Research and development expenses for Inhaled AAT for AATD decreased by $1.4 million due to the completion of the clinical trial and preparation for registration in the European Union. Research and development expenses for Type-1 Diabetes decreased by $0.2 million. Unallocated expenses are expenses that are not managed by projects and are allocated between various tasks that are not always related to a major project. In the years ended December 31, 2015 and 2014, we incurred $4.5 million each year, of unallocated salary expenses, $4.6 million and $2.4 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 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 — Risks Related to Our Business and Industry — We may not be able to commercialize our product candidates in development for numerous reasons."

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, 2015, we incurred $3.7 million of selling and marketing expenses, compared to $2.9 million in the year ended December 31, 2014, an increase of $0.8 million, or approximately 26%. This increase was primarily due to a $0.3 million increase in marketing support to distributors , $0.2 million increase in wages and $0.2 million increase in marketing expenses. Selling and marketing expenses accounted for approximately 5.2% and 4.0% of total revenues for the years ended December 31, 2015 and 2014, respectively.

General and Administrative Expenses

In the year ended December 31, 2015, we incurred $7.0 million of general and administrative expenses, compared to $7.6 million in the year ended December 31, 2014, a decrease of $0.6 million, or approximately -7.2%. This decrease was primarily due to a decrease in share base payment expenses. General and administrative expenses accounted for approximately 10.1% and 10.7% of total revenues for the years ended December 31, 2015 and 2014, respectively.

Financial Income

In the year ended December 31, 2015, we generated $0.5 million of financial income, compared to $0.4 million in the year ended December 31, 2014, an increase of $0.1 million, or approximately 15%.

Expense in respect of currency exchange differences and derivatives instruments

In the year ended December 31, 2015, we incurred income of $0.6 million in respect of currency exchange differences on balances in other currencies versus the U.S. dollar. In the year ended December 31, 2014 there was no impact from that line item.

Financial Expenses

In the year ended December 31, 2015, we incurred $0.9 million of financial expenses, compared to $2.1 million in the year ended December 31, 2014, a decrease of $1.2 million, or approximately 55% associated with a decrease in financial expenses for our convertible debt which was partially repaid at the end of 2014 and paid in full at the end of 2015.

Taxes on Income

In the year ended December 31, 2015, we had no taxes on income, compared to $52,000 incurred from deferred tax assets in the year ended December 31, 2014.

Year Ended December 31, 2014 Compared to Year Ended December 31, 2013

Segment Results

	Year Ended December 31,		Change 2014 vs. 2013	
	2014	2013	Amount	Percent
	(in thousands)			
Revenues:				
Proprietary Products	$ 44,389	$ 50,658	$ (6,269)	(12.3)%
Distribution	26,676	19,965	6,711	33.6%
Total	$ 71,065	$ 70,623	$ (442)	1%
Cost of Revenues:				
Proprietary Products	$ 32,617	$ 27,104	$ 5,513	20.3%
Distribution	23,406	17,112	6,294	36.7%
Total	$ 56,023	$ 44,216	$ 11,807	26.7%
Gross Profit:				
Proprietary Products	$ 11,772	$ 23,554	$ (11,782)	(50.0)%
Distribution	3,270	2,853	417	14.6%
Total	$ 15,042	$ 26,407	$ (11,365)	(43.0)%

Revenues

In the year ended December 31, 2014, we generated $71.1 million of total revenues, compared to $70.6 million in the year ended December 31, 2013, an increase of $0.4 million, or approximately 0.6%. This increase was primarily due to a $6.7 million increase in our Distribution segment revenues, mainly attributable to increased demand and marketing efforts partially offset by decrease of $6.3 million in our Proprietary Products segment mainly due to a $4.5 million milestone payment in the second quarter of 2013, a $1.8 million decrease in revenues recognized from our collaborative agreements and $1.1 million one-time sale incentive.

Cost of Revenues

In the year ended December 31, 2014, we incurred $56.0 million of cost of revenues, compared to $44.2 million in the year ended December 31, 2013, an increase of $11.8 million, or approximately 27%. The cost of revenues in our Proprietary Products segment increased by $5.5 million, which was primarily due to a $3.0 million inventory write-off in the second quarter of 2014, increase of cost of vials sold due to excess capacity and higher stock-based compensation of $0.7 million. The cost of revenues in our Distribution segment increased by $6 million, which was primarily due to an increase in volume of sales.

Gross profit in our Proprietary Products segment decreased by $11.8 million, primarily due to a $4.5 million milestone payment we received from Baxalta for the achievement of a development-based milestone related to the transfer of technology to Baxalta in 2013, a $3.0 million inventory write-off in the second quarter of 2014 and increase of cost of vials sold due to excess capacity and one time sales incentive. Gross profit in our Distribution segment increased by $0.4 million, which was primarily due to an increase in sales volume. As a percentage of total revenues, gross margin was 21.2% and 37.4% for the years ended December 31, 2014 and 2013, respectively. Gross margin for the Proprietary Products segment, as a percentage of revenues from that segment, was 26.5% and 46.5% for the years ended December 31, 2014 and 2013, respectively. Gross margin for the Distribution segment, as a percentage of revenues from that segment, was 12.3% and 14.3% for the years ended December 31, 2014 and 2013, respectively. The decrease in gross profit margin was primarily driven by the decrease in the Proprietary Products segment revenues and an increase in Proprietary Products segment costs.

Research and Development Expenses

In the year ended December 31, 2014, we incurred $16.0 million of research and development expenses, compared to $12.7 million in the year ended December 31, 2013, an increase of $3.3 million, or approximately 26%. This increase was primarily due to a $ 1.7 million increase in facility cost allocated to research and development, a $0.8 million increase in wages and $ 0.5 million increase in consultant expenses. Research and development expenses accounted for approximately 22.3% and 18.1% of total revenues for the years ended December 31, 2014 and 2013, respectively.

Set forth below are the research and development expenses associated with our major development programs in the years ended December 31, 2014 and 2013:

	Year ended December 31,	
	2014	2013
	(in thousands)	
Inhaled AAT	$ 6,326	$ 7,619
AAT for newly diagnosed Type-1 Diabetes	1,959	238
Unallocated salary	4,514	3,847
Unallocated facility cost allocated to research and development	2,409	223
Unallocated other expenses	822	818
Total research and development expenses	$ 16,030	$ 12,745

Research and development expenses for Inhaled AAT for AATD decreased by $1.3 million due to the completion of the clinical trial. Research and development expenses for Type-1 Diabetes increased by $1.7 million due to the launch of the Phase II/III clinical trial in the first quarter of 2014. Unallocated expenses are expenses that are not managed by projects and are allocated between various tasks that are not always related to a major project. In the years ended December 31, 2014 and 2013, we incurred $4.5 million and $3.8 million, respectively, of unallocated salary expenses, an increase of $0.7 million due to increased wages, $2.4 million and $0.2 million, respectively, of facility costs allocated to improvements in processes and $0.8 million, of unallocated other expenses in both years.

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 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 — Risks Related to Our Business and Industry — We may not be able to commercialize our product candidates in development for numerous reasons.”

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, 2014, we incurred $2.9 million of selling and marketing expenses, compared to $2.1 million in the year ended December 31, 2013, an increase of $0.8 million, or approximately 38%. This increase was primarily due to a $0.5 million increase in wages and $0.3 million increase in marketing and consulting expenses. Selling and marketing expenses accounted for approximately 4.0% and 3.0% of total revenues for the years ended December 31, 2014 and 2013, respectively.

General and Administrative Expenses

In the year ended December 31, 2014, we incurred $7.6 million of general and administrative expenses, compared to $7.9 million in the year ended December 31, 2013, a decrease of $0.3 million, or approximately -3.0%. This decrease was primarily due to a write-off of receivables from India for doubtful debt in 2013. General and administrative expenses accounted for approximately 10.7% and 11.1% of total revenues for the years ended December 31, 2014 and 2013, respectively

Financial Income

In the year ended December 31, 2014, we generated $0.4 million of financial income, compared to $0.3 million in the year ended December 31, 2013, an increase of $0.1 million, or approximately 45%. This increase was primarily due to an increase of short-term investments.

Expense in respect of currency exchange differences and derivatives instruments

In the year ended December 31, 2014, we incurred no expenses in respect of currency exchange differences compared to $0.4 million of income in respect currency exchange differences and derivatives in the year ended December 31, 2013.

Financial Expenses

In the year ended December 31, 2014, we incurred $2.1 million of financial expenses, compared to $3.1 million in the year ended December 31, 2013, a decrease of $1.0 million, or approximately 34%.

Taxes on Income

In the year ended December 31, 2014, we incurred $52,000 of taxes on income from deferred tax assets, compared to $24,000 incurred in the year ended December 31, 2013.

Quarterly Results of Operations

The following tables set forth unaudited quarterly consolidated statements of operations data for the four quarters of fiscal years 2015 and 2014. 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, 2015	September 30, 2015	June 30, 2015	March 31, 2015	December 31, 2014	September 30, 2014	June 30, 2014	March 31, 2014
	(in thousands)							
Revenues from Proprietary Products	$ 17,525	$ 9,553	$ 12,708	$ 3,173	$ 19,104	$ 9,143	$ 8,721	$ 7,421
Revenues from Distribution	8,143	6,516	6,538	5,757	5,827	8,007	7,076	5,766
Total revenues	25,668	16,069	19,246	8,930	24,931	17,150	15,797	13,187
Cost of revenues from Proprietary Products	10,649	6,889	9,635	3,295	12,172	5,739	9,703	5,003
Cost of revenues from Distribution	6,954	5,472	5,971	5,243	5,288	7,036	6,160	4,922
Total cost of revenues	17,603	12,361	15,606	8,538	17,460	12,775	15,863	9,925
Gross profit	8,065	3,708	3,640	392	7,471	4,375	(66)	3,262
Research and development expenses	4,425	5,047	3,415	3,643	3,417	4,180	5,068	3,365
Selling and marketing expenses	966	950	944	799	857	675	719	647
General and administrative expenses	1,881	1,722	1,737	1,700	1,582	2,017	2,037	1,957
Operating income (loss)	793	(4,011)	(2,456)	(5,750)	1,615	(2,497)	(7,890)	(2,707)
Financial income	100	63	114	186	43	199	26	136
Income (expense) in respect of currency exchange differences and derivatives, net	205	(341)	248	513	(92)	(44)	97	39
					—	—	—	—
Financial expense	(110)	(333)	(248)	(243)	(416)	(519)	(584)	(567)
Income (loss) before taxes on income	988	(4,622)	(2,342)	(5,294)	1,150	(2,861)	(8,351)	(3,099)
Taxes on income	-	-	-	-	(18)	36	11	23
Net income (loss)	$ 988	$ (4,622)	$ (2,342)	$ (5,294)	$ 1,168	$ (2,897)	$ (8,362)	$ (3,122)

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, payments received in connection with strategic partnerships and the issuance of convertible debentures, warrants to purchase our ordinary shares and other equity securities. The balance of cash and cash equivalents and short-term investments as of December 31, 2015, 2014 and 2013 totaled $28.3 million, $51.9 million and $74.1 million, respectively.

We have certain strategic partnership and distribution agreements under which we receive payments for the achievement of certain milestones. As of December 31, 2015, we received an aggregate of$40.5 million in payments under these agreements, and there are $64.5 million in payments under these agreements that we could potentially receive if we achieve the milestones set forth in such agreements. See “Item 4. Information on the Company— Strategic Partnerships — Chiesi (Inhaled AAT for AATD product)” and “Item 4. Information on the Company— Strategic Partnerships — Baxalta (Glassia).”

On October 15, 2009, we issued NIS 100 million (or approximately $25.6 million based on the exchange rate reported by the Bank of Israel on December 31, 2015) in aggregate principal amount of convertible debentures on the TASE. The convertible debentures matured on December 1, 2015, with three annual payments starting on December 1, 2013, with 20% of principal due and paid on December 1, 2013 and 40% on each of December 1, 2014 and 2015. The interest rate on the convertible debentures was variable, and was indexed to the rate borne by the Israeli Government Bonds — Series 817, plus a margin of 6.10%. The interest rate on the Series 817 bonds reset every quarter. The convertible debentures were convertible into our ordinary shares at a rate of NIS 37.12 par value of debentures per ordinary share, subject to customary anti-dilution adjustments. Holders of the convertible debentures had the right to convert to our ordinary shares on each business day until November 15, 2015, except for between November 16 and December 1 of each of 2013 and 2014. During 2014 and 2013, debentures in the aggregate principal amount of approximately $ 7,000 and $6.5 million, respectively, were converted to ordinary shares. During the fourth quarter of 2014, we repaid NIS 30.2 million (approximately $7.7 million) according to the terms above. The remaining balance of our convertible debt (approximately $7.8 million as of December 1, 2015) was fully paid on December 1, 2015.

Our capital expenditures for the years ended December 31, 2015, 2014 and 2013 were $2.7 million, $3.1 million and $5.6 million, respectively. Our capital expenditures currently relate primarily to the maintenance and improvements of our facilities. We expect our capital expenditures to increase in the near term as we expand our manufacturing capacity to meet increasing demand to our products.

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

Cash Flows from Operating Activities

Net cash 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.

Net cash used in operating activities was $9.9 million for the year ended December 31, 2014. This net cash used in operating activities reflects a net loss of $13.2 million and non-cash expenses of $8.2 million offset by an increase in inventories of $3.5 million and a decrease in deferred revenues of $4.0 million reflecting revenues that were collected in advance of 2014.Net cash used in operating activities was $3.8 million for the year ended December 31, 2013. This net cash used in operating activities reflects a net income of $0.5 million and non-cash expenses of $7.8 million offset by an increase in trade receivables of $3.5 million due to sales made at the end of 2013, which payment was collected in 2014, and a decrease in deferred revenues of $6.3 million reflecting revenues that were collected in advance of 2013.

Cash Flows from Investing Activities

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, as partially offset by investment in property, plant and equipment of $2.7 million.

Net cash used in investing activities was $26.8 million for the year ended December 31, 2014. This net use of cash reflects investment in property, plant and equipment of $3.1 million (including capital investment in the new logistic facility) and $23.7 million net cash invested in short term investments.

Net cash used in investing activities was $3.9 million for the year ended December 31, 2013. This net use of cash reflects investment in property, plant and equipment of $5.6 million partially offset by the net proceeds from sale of short-term investments of $1.7 million.

Cash Flows from Financing Activities

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.

Net cash used by financing activities was $7.6 million for the year ended December 31, 2014. This net cash used by financing activities reflects a $7.7 million repayment of convertible debentures partially offset by $0.1 million proceeds from the exercise of warrants.Net cash provided by financing activities was $49.2 million for the year ended December 31, 2013. This net cash provided by financing activities reflects $52.9 million proceeds from our initial public offering in the United States offset by a $4.3 million repayment of convertible debentures.

Contractual Obligations and Commitments

The following is a summary of our contractual obligations and commitments as of December 31, 2015 (in thousands):

	Total	Less than 1 Year	1 – 3 Years	4-5 Years
Purchase commitments	$ 33,294	-	-	-
Long-term debt obligations (1)	204	43	86	75
Operating lease obligations	1,044	754	290	-
Total	$ 34,542	$ 721	$ 376	$ 75

(1) Includes interest payments on our long term loan which bears annually fixed interest rate of 3.45%.

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 17 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 first and fourth quarters and weaker in our second and third quarters.

Off-Balance Sheet Arrangements

As of December 31, 2015, 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.

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 to determine whether the net realizable value is lower than cost. 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 did not recognize any impairment of non-financial assets for any of the periods presented.

Share-based Payment Transactions

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

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.

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 17 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 and Available for Sale (“AFS”) financial investments that include equity investments and debt securities. Equity investments classified as AFS are those that are classified as neither held for trading nor designated as fair value through profit or loss. Debt securities in this category 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 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 February 25, 2016.

Name	Age	Position
Executive Officers:		
Amir London	47	Chief Executive Officer
Gil Efron	50	Deputy Chief Executive Officer and Chief Financial Officer
Liliana Bar, PhD	61	Vice President, Research and Development
Barak Bashari	51	Senior Vice President, Operations
Yael Brenner	53	Vice President, Quality
Shani Dotan	43	Vice President, Human Resources
Orit Pinchuk	51	Vice President, Regulatory Affairs
Dr. Eran Schenker	53	Vice President, Medical Director
Pnina Strauss	41	Vice President, Inhalation Programs & IP
Ruth Wolfson, PhD	69	Senior Vice President, Scientific Affaires
Directors:		
Leon Recanati	67	Chairman
David Tsur	65	Director, Active Deputy Chairman
Reuven Behar	61	Director
Dr. Michael Berelowitz*	71	Director
Dr. Estery Giloz-Ran **	42	External Director
Jonathan Hahn	33	Director
Dr. Abraham Havron**	68	External Director, Chairman of Audit Committee and Chairman of Compensation Committee
Ziv Kop*	44	Director
Tuvia Shoham**	71	Director

* Independent director under the Nasdaq listing requirements.

** Independent director under the Israeli Companies Law, 5759-7999 (the “Companies Law”) and 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.

Gil Efron has served as our Deputy Chief Executive Officer and Chief Financial Officer since July 2015. Prior to that, Mr. Efron served as our Chief Financial Officer from September 2011. Mr. Efron has over 20 years of experience in various finance management positions. Mr. Efron is also currently the owner and Chief Executive Officer of GEO Consulting Ltd., which he founded in February 2011 and provides financial management services. From February 2006 until 2011, Mr. Efron served as Chief Financial Officer of RRsat Global Communications Ltd. (Nasdaq: RRST), a provider of distribution and content management services for television and radio broadcasting networks. Prior to that, Mr. Efron served in various finance positions, including as Chief Financial Officer of Proficiency Ltd., as Chief Financial Officer of IP Planet Network Ltd. and as a senior auditor with the Israeli member firm of PricewaterhouseCoopers. Mr. Efron also served as a director of Poalim Ventures I Ltd. Mr. Efron is a certified public accountant in Israel and holds a BA degree in Economics and Accounting and an MA degree in Business Administration from the Hebrew University of Jerusalem.

Dr. Liliana Bar has served as our Vice President, Research and Development 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.

Barak Bashari has served as our Vice President, Operations and Plant Manager since September 2012. Mr. Bashari has 17 years of experience in pharmaceuticals operations in various positions. Prior to joining us, from October 2004 to August 2012, Mr. Bashari was the Executive Director of Teva Pharmaceutical Industry Ltd.'s three sterile plants in Israel. Mr. Bashari holds a B.Sc. degree in Mechanical Engineering from the Technion-Israeli Institute of Technology (Haifa) and an MSM degree from the New York Polytechnic University.

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.

Orit Pinchuk has served as our Vice President, Regulatory Affairs 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. Eran Schenker has served as our Medical Director since March 2015. Dr. Schenker has 20 years of experience in international medical affairs and business development for biotechnology and pharmaceutical companies. Prior to joining us, from 2007 to 2014, Dr. Schenker worked at Neurim pharmaceuticals, where he initially served as the medical director and business development and later as vice president and completed the launch of the company's flag CNS product in more than 40 countries. Earlier in his career, from 2005 to 2006, Dr. Schenker served as the CEO and Medical Director of Collplant Ltd. (TASE:CLPT) preparing the company, who developed plant driven recombinant genetically modified biomaterials technology for produces with human collagen, for an IPO. From 1995 to 2005, Dr. Schenker served as the CEO and Medical Director in Medic Touch Ltd., mainly involved in designing and implementing the clinical plan, customer care and medical affairs systems. Dr. Schenker graduated B. Med. Sc. and holds a Medical Doctor (M.D.) degree from the School of Medicine at Ben Gurion University.

Pnina Strauss has served as our Vice President, Clinical Development & IP since August 2012. Prior to that, Ms. Strauss had served as our Senior Director, Clinical Development & IP since 2010 and our Manager, Clinical Development & IP since 2007. Ms. Strauss has over 10 years of experience in the pharmaceutical industry, fulfilling key positions that cover, among others, disciplines of regulatory affairs and business development. Ms. Strauss holds a BSc degree in Biochemistry and Food Sciences from the Hebrew University of Jerusalem and an MBA degree from the University of Derby.

Dr. Ruth Wolfson has served as our Senior Vice President, Scientific Affairs since January 2015. Prior to that, Ms. Wolfson served as our Senior Vice President, Quality and Regulatory Affairs from 2010 through 2014 and as our Vice President, Regulatory Affairs from 2004 to 2010. Ms. Wolfson has more than 15 years of experience in regulatory affairs, including submissions to the FDA, EMA and the Health Protection Branch in Canada. From 1989 to 2004, she served as Head of Regulatory Affairs at InterPharm Laboratories Ltd., a biopharmaceutical corporation. Ms. Wolfson holds a B.Sc. degree in Agriculture and an M.Sc. degree in Biochemical Agriculture, both with distinction, from the Hebrew University of Jerusalem, as well as a PhD from the Weizmann Institute’s Department of Biochemistry.

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 the 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 was Chief Executive Officer of Arad Systems and RAD Chemicals Inc. 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.

Reuven Behar has served on our board of directors since April 2013. Mr. Behar has been a partner with Fischer Behar Chen Well Orion & Co., our Israeli counsel, since 1999. Mr. Behar leads the firm's Litigation and Antitrust Departments and also serves as a mediator and arbitrator in commercial, intellectual property and family matters, as well as an executor in probate cases. Mr. Behar serves on the board of directors of several private companies and served as the Chairman of the board of directors of Netafim Ltd. Mr. Behar is a Lieutenant Colonel in the Israel Defense Forces. Mr. Behar holds an LL.B. degree from the Hebrew University of Jerusalem and an M.M. degree from J.L. Kellogg Graduate School of Management, Northwestern University.

Dr. Estery Giloz-Ran has served on our board of directors since January 2014 and is an external director within the meaning of the Companies Law. During 2013, Dr. Giloz-Ran was a Visiting Scholar at the New York University in the Department of Accounting, as well as a Visiting Assistant Professor of Finance in the Sy Syms School of Business at the Yeshiva University in New York City. From 2010 to 2015, Dr. Giloz-Ran was also the Head of Accountancy at the Peres Academic Center in the Accounting and Business Administration Department and a lecturer at Ben-Gurion University, teaching courses in finance, taxes and accounting. From 2008 to 2010, Dr. Giloz-Ran was a tax consultant and tax capital investment law adviser at Intel Corporation in Israel. Dr. Giloz-Ran holds a PhD in tax and accounting and an M.B.A. degree, both from Ben Gurion University, and a B.A. degree in Business Management from the Open University. Dr. Giloz-Ran completed her Post-Doctorate as Visiting Scholar at New York University in the Leonard N. Stern School of Business in 2014. Dr. Giloz-Ran is a certified public accountant (Israel).

Jonathan Hahn has served on our board of directors since March 2010. Mr. Hahn is currently the President and a director of Tuteur where he has been since 2010. Previous to that, Mr. Hahn 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 and is an external director within the meaning of the Companies Law. From 2005 to 2014, Dr. Havron has 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.

Ziv Kop has served on our board of directors since May 2005. Since March 2014, Mr. Kop has served as the Chief Operating Officer and Active Board Member of Outbrain Inc., where he has served as a board member since 2006. From October 2003 to August 2013, Mr. Kop served as Managing Partner at GlenRock Israel Ltd., a private equity investment firm, where he managed a portfolio of growth companies in the fields of advanced technologies and healthcare, including Evogene Ltd. (NYSE:EVGN), (TASE:EVGN), Mobileye N.V. (Nasdaq: MBLY), Quigo Technologies Inc., Outbrain Inc., Rainbow Medical Ltd. From 2003 to 2012, Mr. Kop served as Chief Executive Officer of Roei Medical Technologies Ltd. Mr. Kop currently serves on the board of directors of Evogene Ltd., a plant genomics company listed on the TASE and New York Stock Exchange, and he previously served on the board of Mobilemax Ltd., a company listed on the TASE, from 2007 to 2013. Mr. Kop has also served on the boards of the following private companies: Outbrain Inc. since 2006, TOOT Trading Technologies Ltd. since 2010, Rainbow Medical from 2007 to 2013, Lifebond Ltd. from 2007 to 2013, Gmul Investments Ltd. from 2008 to 2012 and Gmul Nadlan Ltd. from 2008 to 2012. Prior to joining GlenRock, Mr. Kop served as Chief Executive Officer of POC Management Consulting, Ltd., a leading Israeli consultancy in the field of strategic planning, from 2002 to 2003. Mr. Kop holds a L.L.B. degree and an MA degree in Law and Business Administration, both from Tel Aviv University, and he is a graduate of INSEAD's Young Managers Program.

Tuvia Shoham has served on our board of directors since May 2007 and is an independent director within the meaning of the Companies Law and the Nasdaq listing requirements. Mr. Shoham is a member of the board of directors of Shachak & Co., a private real estate company. Mr. Shoham has extensive experience as a financial consultant for companies in various industry sectors, including managing a wide range of financial arrangements and advising businesses on recovery and privatization plans. Mr. Shoham was previously a partner with the Israeli member firm of PricewaterhouseCoopers, and served as Kamada's accountant for many years. He is a certified public accountant in Israel and also holds a B.A. and an M.B.A. degree from the Hebrew University in Jerusalem.

Dr. Michael Berelowitz has served on our board of directors since August 2015, and is an independent director within the meaning of the Nasdaq listing requirements. 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 was a member of the board of directors of Endocrine Fellows Foundation and currently serves as the chair of the corporate governance and nominations committee and is a member of the audit comment of Recro Pharma, Inc. He is also currently a member of the compensation committee of Oramed Pharmaceuticals Inc. where he has served on the board since May 2010. 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.

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

Our current board of directors consists of nine directors, including two external directors in accordance with the requirements of the Companies Law. See "— External Directors." Our external directors also qualify as "independent directors" under the corporate governance standards of the Nasdaq listing requirements and the independence requirements of Rule 10A-3 of the Exchange Act. Additionally, our board has determined that each of Mr. Ziv Kop, Tuvia Shoham and Dr. Michael Berelowitz is an "independent director" under the Nasdaq listing requirements. Under our articles of association, the number of directors on our board of directors will be no less than five and no more than 11, and must include at least two external directors.

Other than external directors, who are subject to special election requirements under the Companies Law, under our articles of association, our directors will be elected by the vote of a majority of the ordinary shares present, in person or by proxy, and voting at a shareholders' meeting. Each director (other than external directors) 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 be filled by a vote of a simple majority of the directors then in office. See "— External Directors — Election and Dismissal of External Directors" for a description of the procedure for the election of external directors.

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 (except for external directors, who may be dismissed only as set forth under the Companies Law), provided that the director being removed from office is given a reasonable opportunity to present his or her case before the general meeting. See "— External Directors — Election and Dismissal of External Directors."

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. An external director may not appoint an alternate director unless such alternate director is eligible to be an external director and has either "financial and accounting expertise" or "professional expertise," depending on the qualifications of the external director he or she is replacing. See "— External Directors." 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

Qualifications of 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. Dr. Abraham Havron and Dr. Estery Giloz-Ran currently serve as external directors. Dr. Abraham Havron was first elected as an external director in March 2011 and was reelected in January 2014. His current term will end on March 13, 2017. Dr. Estery Giloz-Ran was elected as an external director in January 2014 and her initial term will end on January 27, 2017. Alicia Rotbard, who served as an external director from November 2005 and the former chairperson of our audit committee and compensation committee, passed away in November 2015.

A person may not serve as an external director if the person is a relative of a controlling shareholder. The Companies Law defines "relative" as a spouse, sibling, parent, grandparent, descendant, or spouse's descendant, sibling or parent, and the spouse of each of the foregoing. The Companies Law provides that a person may not serve as an external director if, on the date of the person's appointment or within the preceding two years, the person or his or her relatives, partners, employers or anyone to whom that person is subordinate, whether directly or indirectly, or entities under the person's control have or had any affiliation with the company, any controlling shareholder of the company or relative of a controlling shareholder, or any entity that, as of the appointment date is, or at any time during the two years preceding that date was, controlled by the company or by the company's controlling shareholder (each an "Affiliated Party"). If there is no controlling shareholder or any shareholder holding 25% or more of our voting rights, a person may not serve as an external director if the person has any affiliation to the chairman of the board of directors, the chief executive officer, any shareholder holding 5% or more of the company's shares or voting rights or the most senior financial officer as of the date of the person's appointment.

The term affiliation includes (subject to certain exceptions):

- an employment relationship;
- a business or professional relationship, even if not maintained on a regular basis (excluding insignificant relationships);
- control; and
- service as an office holder (excluding service as a director in a private company prior to the first offering of its shares to the public if such director was appointed as a director of the private company in order to serve as an external director following the initial public offering).

The Companies Law defines “office holder” as a general manager, chief business manager, deputy general manager, vice general manager, any other person assuming the responsibilities of any of the foregoing positions, without regard to such person’s title, a director and any other manager directly subordinate to the general manager.

Additionally, any person who has received, during his or her tenure as an external director, direct or indirect compensation from the company for his or her role as a director, other than compensation permitted under the Companies Law and the regulations promulgated thereunder (including indemnification or exculpation, the company’s commitment to indemnify or exculpate such person and insurance coverage), may not continue to serve as an external director.

No person may serve as an external director if the person’s positions or other affairs create, or may create, a conflict of interest with that person’s responsibilities as a director, or may otherwise interfere with such person’s ability to serve as a director, or if the person is an employee of the Israel Securities Authority or of an Israeli stock exchange. If at the time an external director is appointed all current members of the board of directors, who are not controlling shareholders or relatives of controlling shareholders, are of the same gender, then the external director to be appointed must be of the other gender. In addition, a person who is a director of a company may not be elected as an external director of another company if, at that time, a director of the other company is acting as an external director of the first company.

The Companies Law and the regulations promulgated thereunder provide that an external director must meet certain professional qualifications or have financial and accounting expertise. At least one external director must have financial and accounting expertise. However, if at least one of our other directors (1) meets the independence requirements under applicable U.S. laws and the Nasdaq listing requirements for membership on the audit committee and (2) has financial and accounting expertise as defined in the Companies Law and applicable regulations, then none of our external directors is required to possess financial and accounting expertise as long as they possess the requisite professional qualifications. The board of directors determines whether a director possesses financial and accounting expertise. A director with financial and accounting expertise is a director who by virtue of his or her education, professional experience and skills, has a high level of proficiency in and understanding of business accounting matters and financial statements so that he or she is able to understand in depth our financial statements and initiate debate regarding the manner in which the financial information is presented. Our board of directors has determined that Alicia Rotbard and Dr. Estery Giloz-Ran possess the requisite financial and accounting expertise.

Similarly, the board of directors also determines whether a director possesses the requisite professional qualifications. The regulations promulgated under the Companies Law define an external director with requisite professional qualifications as a director who satisfies one of the following requirements: (1) the director holds an academic degree in either economics, business administration, accounting, law or public administration; (2) the director either holds an academic degree or has completed another form of higher education in the company’s primary field of business or in an area which is relevant to his or her office as an external director in the company; or (3) the director has at least five years of experience serving in one of the following capacities, or at least five years of cumulative experience serving in two or more of the following capacities: (a) a senior business management position in a company with a substantial volume of business; (b) a senior position in the company’s primary field of business; or (c) a senior position in public administration or service.

Until the lapse of a two-year period from the date that an external director has ceased to act as an external director, (1) neither a company, nor its controlling shareholders, including any corporations controlled by a controlling shareholder, may grant such former external director or his or her spouse or children any benefits (directly or indirectly), (2) such person may not be engaged to serve as an office holder at the company or any corporation controlled by a controlling shareholder, and (3) such person may not be employed or receive professional services for payment from a controlling shareholder, directly or indirectly, including through a corporation controlled by a controlling shareholder. Additionally, until the lapse of a one-year period from the date that an external director has ceased to act as an external director, any relative of the former external director who is not his or her spouse or children is subject to these prohibitions.

Election and Dismissal of External Directors

Under Israeli law, external directors are elected by a majority vote at a shareholders' meeting, provided that either:

- the shares that are voted at the meeting in favor of the election of the external director, excluding abstentions, include at least a majority of the votes of shareholders who are not controlling shareholders and shareholders who do not have a personal interest in the appointment (excluding a personal interest that did not result from the shareholder's relationship with the controlling shareholder); or

- the total number of shares held by non-controlling shareholders and shareholders who do not have a personal interest in the appointment (excluding a personal interest that did not result from the shareholder's relationship with the controlling shareholder) that are voted against the election of the external director does not exceed 2% of the aggregate voting rights in the company.

Under Israeli law, the initial term of an external director of an Israeli public company is three years. The external director may be reelected, subject to certain circumstances and conditions, to two additional terms of three years provided that either:

- his or her service for each such additional term is recommended by one or more shareholders holding at least 1% of the company's voting rights and is approved at a shareholders meeting by a disinterested majority, where the total number of shares held by non-controlling, disinterested shareholders voting for such reelection exceeds 2% of the aggregate voting rights in the company, and provided further that the external director is not an affiliated or competing shareholder, as defined in the Companies Law, or a relative of such a shareholder at the time of the appointment, and is not affiliated with such a shareholder at the time of appointment or within the two years preceding the date of appointment;

- his or her service for each such additional term is recommended by the board of directors and is approved at a shareholders meeting by the same majority required for the initial election of an external director (as described above); or

- such external director nominates himself or herself for each such additional term and his or her election is approved at a shareholders meeting by the same disinterested majority as required for the election of an external director nominated by a 1% or more shareholder (as described above).

However, the term of office for external directors for Israeli companies traded on certain foreign stock exchanges, including the NASDAQ Global Select Market, may be extended indefinitely in increments of additional three-year terms, in each case provided that the audit committee and the board of directors of the company confirm that, in light of the external director's expertise and special contribution to the work of the board of directors and its committees, the reelection for such additional period(s) is beneficial to the company, and provided that the external director is reelected subject to the same shareholder vote requirements as if elected for an additional term (as described above). Prior to the approval of the reelection of the external director at a general shareholders meeting, the company's shareholders must be informed of the term previously served by him or her and of the reasons why the board of directors and audit committee recommended the extension of his or her term.

An external director may be removed at a special general meeting of shareholders called by the board of directors by the same special majority of the shareholders required for his or her election if he or she ceases to meet the statutory qualifications for appointment or if he or she violates his or her duty of loyalty to the company. An external director may also be removed by order of an Israeli court if the court finds that the external director is permanently unable to exercise his or her duties, has ceased to meet the statutory qualifications for his or her appointment or has violated his or her duty of loyalty to the company.

If the vacancy of an external directorship causes a company to have fewer than two external directors, the company's board of directors is required under the Companies Law to call a special general meeting of the company's shareholders as soon as possible to appoint such number of new external directors so that the company thereafter has two external directors.

Additional Provisions

Under the Companies Law, each committee authorized to exercise any of the powers of the board of directors is required to include at least one external director, and both the audit committee and compensation committee are required to include all of the external directors.

An external director is entitled to compensation and reimbursement of expenses in accordance with regulations promulgated under the Companies Law and is otherwise prohibited from receiving any other compensation, directly or indirectly, in connection with serving as a director except for certain exculpation, indemnification and insurance provided by the company, as specifically allowed by the Companies Law.

Audit Committee

Audit Committee Role

We have an audit committee consisting of Tuvia Shoham, an independent director under the Israeli Companies Law, and Nasdaq listing rules, and our external directors, Dr. Abraham Havron and Dr. Estery Giloz-Ran. Dr. Havron serves as the chairman of the audit committee. 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:

- retaining and terminating our independent auditors, subject to ratification of the board of directors;
- 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 working plan of the internal auditor, examining such working 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.

Companies Law Requirements

Under the Companies Law, the audit committee and compensation committee may not include:

- the chairman of the board of directors;
- any director employed by the company or who provides services to the company on a regular basis (other than as a member of the board of directors);
- a controlling shareholder or a relative of a controlling shareholder (as defined below); and
- any director employed by the company's controlling shareholder or by an entity controlled by the controlling shareholder, a director who regularly provides services to its controlling shareholder or to an entity controlled by the controlling shareholder, or any director who derives most of his or her income from the controlling shareholder.

The audit committee must include all of the external directors and a majority of its members must be independent directors, as defined in the Companies Law. The chairman of the audit committee must be an external director. In general, an independent director under the Companies Law is an external director or a director who is appointed or classified as such and who is eligible to serve as an external director (other than the professional qualifications or accounting and financial expertise requirement), whom the audit committee has certified as meeting these requirements, and who has not served as a director of the company for more than nine consecutive years. A director who qualifies as an independent director under applicable U.S. laws and the Nasdaq listing requirements may be deemed to be an independent director under the Companies Law, so long as he or she meets the independence requirements as to relationships with the controlling shareholder (and any entity controlled by the controlling shareholder, other than the company and other entities controlled by the company) and the nine-year requirement described above. Following the nine-year period, a director of an Israeli company traded on Nasdaq may continue to be considered an independent director under the Companies Law for unlimited additional periods of three years each, provided the audit committee and the board of directors of the company confirm that, in view of the director's expertise and special contribution to the work of the board of directors and its committees, the reelection for each such additional period is beneficial to the company.

Listing Requirements

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 each of Tuvia Shoham and Dr. Estery Giloz-Ran qualify 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.

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. 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 Mr. Tuvia Shoham and our external directors, Dr. Abraham Havron and Dr. Estery Giloz-Ran. Dr. Havron serves as the chairman of the compensation committee. Under Nasdaq listing requirements, we are required to maintain a compensation committee consisting of at least two members, each of whom is an "independent director" under the Nasdaq listing requirements. Our board of directors has affirmatively determined that each member of our compensation committee qualifies as an "independent director" under the Nasdaq listing requirements. Pursuant to the Companies Law, a compensation committee must be comprised of no fewer than three members and, subject to certain exceptions, must include all of the external directors, whom will form a majority of its members. The Companies Law also provides restrictions as to who may serve on the compensation committee. See "— Audit Committee — Companies Law 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 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). Our finance committee currently consists of Mr. David Tsur, Mr. Tuvia Shoham, an independent director under the Companies Law and the Nasdaq listing requirements and Mr. Jonathan Hahn. Mr. Tsur serves as the chairman of the finance committee.

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.

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 management and consulting services provided by a controlling shareholder or his or her relative, 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, directly or indirectly (including through a corporation controlled by a controlling shareholder), 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. Under these regulations, a shareholder holding at least 1% of the issued share capital of the company may require, within 14 days of the publication or announcement of such determinations, that despite such determinations by the audit committee and the board of directors, such transaction will require shareholder approval under the same majority requirements that would otherwise apply to such transactions.

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 compensation policy, which was approved by our shareholders on January 28, 2014 and amended by our shareholders on June 30, 2015, 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

Our external directors are entitled to remuneration subject to the provisions and limitations set forth in regulations promulgated under the Companies Law. As of the date of this Annual Report, we apply the same provisions and limitations applied to our external directors to the compensation of our independent director, Tuvia Shoham, under the Companies Law. We currently pay our external directors who are financial experts under the Companies Law, Dr. Estery Giloz-Ran, an annual fee of NIS 114,755 (approximately $29,409), as well as a fee of NIS 4,415 (approximately $1,131) for each board or committee meeting attended in person, NIS 2,649 (approximately $679) for each board or committee meeting attended via telephone or videoconference and NIS 2,208 (approximately $566) for participation by written consent. We currently pay our other external director, Dr. Avraham Havron, and our independent director under the Companies Law, Mr. Tuvia Shoham, an annual fee of NIS 86,154 (approximately $22,080), as well as a fee of NIS 3,318 (approximately $850) for each board or committee meeting attended in person, NIS 1,991 (approximately $510) for each board or committee meeting attended via telephone or videoconference and NIS 1,660 (approximately $425) for participation by written consent.

We currently pay each of our other directors an annual fee of NIS 69,556 (approximately $17,826), as well as a fee of NIS 2,589 (approximately $664) for each board or committee meeting attended in person, NIS 1,553 (approximately $398) for each board or committee meeting attended via telephone or videoconference and NIS 1,292 (approximately $331) 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 $11,658), in addition to the cash consideration paid to our other directors who are not external directors or independent directors. Mr. Tsur is entitled to annual leave in accordance with Israeli law and is entitled to use vacation days accumulated in his capacity as Chief Executive Officer during the term of his service as Active Deputy Chairman. In addition, commencing on July 1, 2017, 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 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.

From time to time, we grant options to directors. Most recently, in accordance with our shareholders' approval, on June 30, 2015, we granted each of our directors (other than the external directors and Mr. David Tsur) options to purchase 5,000 ordinary shares. The options shall be exercisable on a cashless basis based on an exercise price of NIS 18.74 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.

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.

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. If the compensation of our directors is inconsistent with our stated compensation policy, then the approval of the company's shareholders 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, including share-based compensation, for the year ended December 31, 2015, was approximately $2 million. This amount includes approximately $108,250 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 foregoing amounts include compensation incurred and set aside or accrued for Mr. David Tsur, who served as our Chief Executive Officer until his resignation from such position effective as of July 1, 2015, and Mr. Amir London, who has served as our Chief Executive Officer effective as of July 1, 2015.

The following table presents information regarding compensation accrued in our financial statements for our five most highly compensated office holders, namely our Active Deputy Chairman of the Board (our former Chief Executive Officer), our Chief Executive Officer, Deputy Chief Executive Officer and Chief Financial Officer, Vice President, Operations and Plant Manager and Vice President, Regulatory Affairs , as of December 31, 2015.

Name and Position	Salary	Bonus[1]	Value of Options Granted[2]	Other(3)	Total
			(in thousands)		
David Tsur *Active Deputy Chairman of the Board*	$ 331	$ -	$ 311	$ 31	$ 673
Amir London *Chief Executive Officer*	$ 237	$ 15	$ 90	$ 19	$ 361
Gil Efron *Deputy Chief Executive Officer and Chief Financial Officer*	$ 222	$ 23	$ 79	$ 25	$ 349
Barak Bashari *Vice President, Operations and Plant Manager*	$ 201	$ 15	$ 37	$ 22	$ 275
Orit Pinchuk *Vice President Regulatory Affairs*	$ 162	$ 12	$ 45	$ 19	$ 238

(1) The annual bonus is subject to the fulfillment of certain targets determined for each year by the board of directors (for our Chief Executive Officer) and by our Chief Executive Officer (for our other executive officers).

(2) The value of options is the expense recorded in our financial statements for the period ended December 31, 2015 with respect to all options granted to such executive officer.

(3) Cost of use of company car.

Pursuant to the Companies Law, the compensation (including insurance, indemnification and exculpation) of a public company's office holders (other than directors, described above, and the chief executive officer, described below) is to be approved first by the compensation committee; second by the company's board of directors; and third, if such compensation arrangement is inconsistent with the company's stated compensation policy, the company's shareholders provided 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 of non-controlling shareholders and shareholders who do not have a personal interest in such matter voting against the compensation package does not exceed 2% of the aggregate voting rights in the company.

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, a majority of the company's shareholders provided 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 of non-controlling shareholders and shareholders who do not have a personal interest in such matter voting against the compensation package does not exceed 2% of the aggregate voting rights in the company.

Under the Companies Law, if the shareholders of the company do not approve the compensation arrangement with an office holder who is not a director, including the chief executive officer, the compensation committee and board of directors may override the shareholders' decision, subject to certain conditions. 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.

In the event that an existing compensation arrangement with an office holder who is not a director, including the chief executive officer, is amended, only the approval of the compensation committee is required so long as the compensation committee determines that the amendment is not material in relation to the existing compensation arrangement.

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, pursuant to an amendment to our Articles of Association approved by our shareholders on June 30, 2015, 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). The company may not exculpate in advance a director from liability arising out of a prohibited dividend or distribution to shareholders.

Under the Companies Law, a company may indemnify an office holder 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 indemnification agreements, the maximum aggregate amount of indemnification that we may pay to all of our office holders together is 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.

We have entered into an indemnification agreement with each of our office holders who joined the company after April 2013, with substantially similar terms to the agreement we have entered into with each of our other office holders, except that the maximum aggregate amount of indemnification that we may pay them under their indemnification agreements, together with all of our office holders, is 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, 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 Chirman, such office holders are entitled to an annual bonus subject to the fulfillment of certain targets determined for each year by the 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.

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.

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, Deputy Chief Executive Officer and Chief Financial Officer. Mr. Efron has served as our Deputy Chief Executive since July 2015, along with his position of our Chief Financial Officer. Effective as of September 1, 2011, we entered into an employment agreement with Gil Efron with respect to his employment as our chief financial officer. Either party may terminate the agreement at any time upon three months' prior written notice to the other party, and we may terminate the agreement immediately for cause in accordance with Israeli law.

Barak Bashari, Vice President, Operations and Plant Manager. Effective as of September 2, 2012, we entered into an employment agreement with Barak Bashari with respect to his employment as our Vice President, Operations and Plant Manager. 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.

Orit Pinchuk, Vice President, Regulatory Affairs. Effective as of January 1, 2014, we entered into an employment agreement with Orit Pinchuk, who was appointed as our Vice President, Regulatory on October, 2014. 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.

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

Employees

As of December 31, 2015, we employed 319 full-time employees, including 159 in Operations, 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, 2014, we employed 302 full-time employees, including 161 in Operations, 69 in Quality, 18 in Research and Development, 17 in Regulation, 12 in Business Development, 12 in Human Resources and 13 in Finance. As of December 31, 2013, we employed 289 full-time employees, including 157 in Operations, 62 in Quality, 22 in Research and Development, 12 in Regulation, 10 in Business Development, 15 in Human Resources and 11 in Finance. As of December 31, 2015, 2014 and 2013, 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 in December 2013. Approximately 60% of our employees currently work under the collective bargaining agreement signed in December 2013. All of them work in our Beit Kama facility. 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 believe our employee relations are good.

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 Israeli Ministry of Economy (formerly named the Ministry of Industry, Trade and Labor) apply to us and affect matters such as cost of living adjustments to payroll, length of working hours and week, recuperation pay, travel expenses, and pension rights.

Share Ownership

The following table sets forth information with respect to the beneficial ownership of our ordinary shares by each of our directors and executive officers and all of current directors and executive officers as a group.

The percentage of beneficial ownership of our ordinary shares is based on 36,418,741 ordinary shares outstanding as of February 25, 2016. 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)	15,469	*
Gil Efron (2)	104,719	*
Dr. Liliana Bar (3)	26,250	*
Barak Bashari (4)	32,969	*
Shani Dotan (5)	14,063	*
Orit Pinchuk (6)	13,125	*
Dr. Eran Schenker (7)	26,203	*
Pnina Strauss (8)	30,563	*
Dr. Ruth Wolfson (9)	30,696	*
Leon Recanati (10)	3,995,623	10.97%
David Tsur (11)	1,030,662	2.83%
Reuven Behar (12)	71,920	*
Dr. Estery Giloz-Ran (13)	11,250	*
Jonathan Hahn (14)	3,653,401	10.03%
Dr. Abraham Havron (15)	12,992	*
Ziv Kop (16)	33,820	*
Tuvia Shoham (17)	61,404	*
Directors and Executive Officers as a group	9,165,127	25.17%

* Less than 1% of our ordinary shares.

(1) Does not include unvested options to purchase 132,031 ordinary shares that are not exercisable within 60 days of this Annual Report.

(2) Includes options to purchase 6,250 ordinary shares exercisable within 60 days of the date of this Annual Report, at a weighted average exercise price of NIS 34.80 (or $8.92) per share, which expire between June 13, 2018 and October 27, 2021. Does not include unvested options to purchase 40,781 ordinary shares that are not exercisable within 60 days of this Annual Report.

(3) Includes options to purchase 2,813 ordinary shares exercisable within 60 days of the date of this Annual Report, at a weighted average exercise price of NIS 39.51 (or $10.13) per share, which expire between February 28, 2019 and October 27, 2021. Does not include unvested options to purchase 16,250 ordinary shares that are not exercisable within 60 days of this Annual Report.

(4) Includes options to purchase 1,250 ordinary shares exercisable within 60 days of the date of this Annual Report, at a weighted average exercise price of NIS 39.65 (or $10.16) per share, which expire between February 28, 2019 and October 27, 2021. Does not include unvested options to purchase 25,156 ordinary shares that are not exercisable within 60 days of this Annual Report.

(5) Does not include unvested options to purchase 18,438 ordinary shares that are not exercisable within 60 days of this Annual Report.

(6) Includes options to purchase 3,125 ordinary shares exercisable within 60 days of the date of this Annual Report, at an exercise price of NIS 49.55 (or $12.70) per share, which expire on July 13, 2020. Does not include unvested options to purchase 14,375 ordinary shares that are not exercisable within 60 days of this Annual Report.

(7) Mr. Schenker holds 26,203 shares. Does not include unvested options to purchase 25,000 ordinary shares that are not exercisable within 60 days of this Annual Report.

(8) Includes options to purchase 250 ordinary shares exercisable within 60 days of the date of this Annual Report, at an exercise price of NIS 21.18 (or $5.43) per share. Does not include unvested options to purchase 17,938 ordinary shares that are not exercisable within 60 days of this Annual Report.

(9) Dr. Wolfson holds 2,727 ordinary shares . Does not include unvested options to purchase 17,031 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. Does not include unvested options to purchase 22,500 ordinary shares that are not exercisable within 60 days of this Annual Report.

(11) Mr. Tsur holds1,021,287shares, includes options to purchase 9,375 ordinary shares exercisable within 60 days of the date of this Annual Report, at a weighted average exercise price of NIS 41.58 (or $10.66) per share, which expire between June 8, 2018 and May 14, 2020. Does not include unvested options to purchase 112,500 ordinary shares that are not exercisable within 60 days of this Annual Report.

(12) Mr. Behar holds 60,670 ordinary shares directly. Does not include unvested options to purchase 13,750 ordinary shares that are not exercisable within 60 days of this Annual Report.

(13) Does not include unvested options to purchase 8,750 ordinary shares that are not exercisable within 60 days of this Annual Report.

(14) Mr. Jonathan Hahn holds directly 313,841 ordinary shares. 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 of the Kamada's shares. We were informed that additional 50% of the shares of Sinara are held by Mr. Hahn's siblings, who also direcly hold an aggragate 576,649 ordibnary shares.. Does not include unvested options to purchase 13,750 ordinary shares that are not exercisable within 60 days of this Annual Report.

(15) Includes 1,742 shares owned by Operon Consultants Ltd., which is wholly-owned by Dr. Havron. Does not include unvested options to purchase 8,750 ordinary shares that are not exercisable within 60 days of this Annual Report.

(16) Mr. Kop holds 22,570 ordinary shares .Does not include unvested options to purchase 13,750 ordinary shares that are not exercisable within 60 days of this Annual Report.

(17) Mr. Shoham holds 50,154 ordinary shares .Does not include unvested options to purchase 13,750 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 (the "2011 Plan"), under which we are authorized to grant options 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 was 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 some of the options granted 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 may be exercised for cash, or at the discretion of our board of directors, by way of cashless exercise. In the event of a cashless exercise, 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.

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, unexercised options shall be substituted for options of the surviving or acquiring entity, subject to an appropriate adjustment to the exercise price. The board or the compensation committee may determine that the terms of certain option grants 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 options are not assumed or substituted by the successor company.

Options 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 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 of the options. 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 shares. As of December 31, 2015, an aggregate of 193,612ordinary shares were reserved for future issuance under the 2011 Plan (subject to certain adjustments specified in the 2011 Plan) and options to purchase 2,281,493 ordinary shares were outstanding under the 2011 Plan. Any options that expire prior to exercise or issuance under the 2011 Plan will become again available for grant 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 36,418,741ordinary shares outstanding as of February 25, 2016. 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
Hahn Family (1)	3,642,151	10.00%
Leon Recanati (2)	3,973,123	10.91%
D.S Apex Holdings group (3)	2,648,376	7.27%
The Phoenix Holding Ltd. (4)	2,849,826	7.83%
Yelin Lepidot (5)	1,983,714	5.45%

(1) Mr. Jonathan Hahn holds directly 313,841 ordinary shares. 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 of the Kamada’s shares. We were informed that additional 50% of the shares of Sinara are held by Mr. Hahn’s siblings, who also direcly hold an aggragate 576,649 ordibnary shares.

(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.

(3) Based solely upon, and qualified in its entirety with reference to, a notice dated January 06, 2016 submitted to our company. To the best of our knowledge, BRM Group Ltd. and Mr. Zvi Stepak are the joint controlling shareholders of DS Apex Holdings Ltd. ("DS Apex"). BRM Group Ltd. is a private investment company beneficially owned by Messrs. Eli Barkat, Nir Barkat, and Yuval Rakavy.

(4) Based solely upon, and qualified in its entirety with reference to, a notice dated January 06, 2016 . submitted to our company. 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.

(5) Based solely upon, and qualified in its entirety with reference to, a notice dated January 04, 2016 . submitted to our company.

To our knowledge, based on information provided to us by our transfer agent in the United States, as of February 19, 2016, we had one shareholder of record who was registered with an address in the United States, holding approximately 6,420,031 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, 2013 to January 1, 2016, the ownership percentage of Mr. Jonathan Hahn and Hahn family decreased by 6.76% from 16.76% to 10.00%. Mr. Leon Recanati's ownership percentage decreased by 1.03% from 11.94% to 10.91%. The Phoenix Holdings Group ownership percentage decreased by 3.35% from 11.18% to 7.83%. The Yelin Lepidot group's ownership percentage increased from less than 5% to 5.45% during such period. The DS Apex group's ownership percentage increased to 7.27% from less than 5% of our outstanding shares and Meitav group's ownership percentage decreased to less than 5% of our outstanding shares from 5.62% during such period. To the best of our knowledge, those changes are a result of a merger between the DS Apex group and Meitav group.

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 controlled by Mr. Ralf Hahn, the former Chairman of our board of directors. Mr. Jonathan Hahn, our 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, Uruguay 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. Tuteur is entitled to a one-time success bonus based on achieving certain targets in 2015. Tuteur shall cease to have exclusivity if it fails to comply with the minimum purchase requirement in each of the counties, 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 after the date that Tuteur commences sales of a product in Bolivia. We are entitled to terminate the agreement upon 30 days' notice if a third party acquires more than 50% of the common stock or voting rights of Tuteur or Tuteur fails to receive the relevant regulatory approvals within the required time. Either party can terminate the agreement upon bankruptcy of the other party, a material breach of the agreement by the other party after a 30-day cure period and non-performance as a result of force majeure for more than two months. Our board of directors and audit committee approved the agreement and the amendments thereto and determined that each was not an "extraordinary transaction" within the meaning of the Companies Law.

Khairi S.A.

On July 26, 2015 and on July 29, 2015, our Audit Committee and Board of Directors, respectively, approved the engagement of Khairi S.A. ("Khairi") as a distributor 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 will be an arm's length transaction based on the terms of the distribution agreement signed with Tuteur and is currently under negotiation. Mr. Leon Recanati (the Chairman of our board of directors), Mr. Jonathan Hahn (a director) and his siblings and Mr. Reuven Behar (a director) are shareholders of Khairi. Mr. Reuven Behar serves as the chairman of the board of directors of Khairi. In 2015, Khari distributed our AAT product in Cuba at a non-material amount.

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 has served as director since April 2013, 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 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), 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.

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, will be 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.

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. After we become eligible under applicable securities laws to file a registration statement on Form F-3, we will 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.

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 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.

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:		
2015	$ 5.15	$ 3.09
2014	$ 17.95	$ 3.02
2013	$ 17.07	$ 9.60
Quarterly:		
Fourth Quarter 2015	$ 4.47	$ 3.24
Third Quarter 2015	$ 4.12	$ 3.09
Second Quarter 2015	$ 5.15	$ 3.75
First Quarter 2015	$ 4.83	$ 3.79
Fourth Quarter 2014	$ 17.07	$ 13.40
Third Quarter 2014	$ 15.48	$ 11.55
Second Quarter 2014	$ 14.87	$ 9.60
First Quarter 2014	$ 17.95	$ 14.04
Most Recent Six Months:		
February 2016 (through February 23, 2016)	$ 4.03	$ 3.28
January 2016	$ 4.44	$ 3.61
December 2015	$ 4.47	$ 4.00
November 2015	$ 4.26	$ 3.74
October 2015	$ 4.11	$ 3.24
September 2015	$ 3.57	$ 3.37

On February 23, 2016, the last reported sale price of our ordinary shares on the Nasdaq Global Select Market was $3.68 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 3.91, the exchange rate published by the Bank of Israel as of February 19, 2016.

	NIS		$	
	Price Per Ordinary Share		Price Per Ordinary Share	
	High	Low	High	Low
Annual:				
2015	19.45	12.09	4.97	3.09
2014	62.00	11.60	15.85	2.97
2013	60.77	33.80	15.54	8.64
2012	35.95	19.02	9.19	4.86
2011	33.00	17.65	8.44	4.51
Quarterly:				
First Quarter 2016 (through February 23, 2016)	17.70	13.10	4.53	3.35
Fourth Quarter 2015	17.48	13.03	4.47	3.33
Third Quarter 2015	15.77	12.09	4.03	3.09
Second Quarter 2015	19.45	14.11	4.97	3.61
First Quarter 2015	19.33	14.70	4.94	3.76
Fourth Quarter 2014	17.07	11.60	4.36	2.97
Third Quarter 2014	25.96	16.22	6.64	4.15
Second Quarter 2014	54.75	23.85	14.00	6.10
First Quarter 2014	62.00	49.71	15.85	12.71
Most Recent Six Months:				
February 2016 (through February 23, 2016)	16.12	13.10	4.13	3.35
January 2016	17.70	14.33	4.53	3.66
December 2015	17.48	15.50	4.47	3.96
November 2015	16.88	14.85	4.32	3.80
October 2015	15.78	13.03	4.03	3.33
September 2015	14.10	13.24	3.61	3.39

On February 23, 2016, the last reported sale price of our ordinary shares on the TASE was NIS 13.76 per share, or $3.52 per share (based on the exchange rate reported by the Bank of Israel on such date, which was NIS 3.907 = $1.00).

Item 10. Additional Information

A. Share Capital

Not applicable.

B. Memorandum and Articles of Association

Ordinary Shares

Voting

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

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

Transfer of Shares

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

Election of Directors

Our ordinary shares do not have cumulative voting rights for the election of directors. Rather, under our articles of association, our directors (other than external directors) are elected by the holders of a simple majority of our ordinary shares at a general shareholder meeting (excluding abstentions). See "Item 6. Directors, Senior Management and Employees — Board of Directors." As a result, the holders of our ordinary shares that represent more than 50% of the voting power represented at a shareholder meeting and voting thereon (excluding abstentions) have the power to elect any or all of our directors whose positions are being filled at that meeting, subject to the special approval requirements for external directors described under "Item 6. Directors, Senior Management and Employees — External Directors." In addition, under our articles of association, vacancies on our board of directors, including vacancies resulting from there being fewer than the maximum number of directors permitted by our articles of association, may be filled by a vote of a simple majority of the directors then in office.

Dividend and Liquidation Rights

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

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

Shareholder Meetings

Under Israeli law, we are required to convene an annual general meeting of our shareholders at least once every calendar year and within a period of not more than 15 months following the preceding annual general meeting. Our board of directors may convene a special general meeting of our shareholders whenever it sees fit and is required to do so upon the written request of two directors or one quarter of the serving members of our board of directors, or one or more holders of 5% or more of our outstanding share capital and 1% of our voting power, or the holder or holders of 5% or more of our voting power.

The Companies Law requires that resolutions regarding the following matters (among others) be approved by our shareholders at a general meeting: amendments to our articles of association; appointment, terms of service and termination of service of our auditors; election of external directors; approval of certain related party transactions; increases or reductions of our authorized share capital; mergers; and the exercise of our board of director's powers by a general meeting, if our board of directors is unable to exercise its powers and the exercise of any of its powers is essential for our proper management.

The chairman of our board of directors presides over our general meetings. However, if at any general meeting the chairman is not present within 15 minutes after the appointed time, or is unwilling to act as chairman of such meeting, then the shareholders present will choose any other person present to be chairman of the meeting. Subject to the provisions of the Companies Law and the regulations promulgated thereunder, shareholders entitled to participate and vote at general meetings are the shareholders of record on a date to be decided by the board of directors, which, as company listed also on an exchange outside of Israel, may be between four and 40 days prior to the date of the meeting.

The Companies Law requires that a notice of any annual general meeting or special general meeting be provided to shareholders at least 21 days prior to the meeting and if the agenda of the meeting includes, among other things, the appointment or removal of directors, the approval of transactions with office holders or interested or related parties, an approval of a merger or the approval of the compensation policy, notice must be provided at least 35 days prior to the meeting.

Quorum

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

Resolutions

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

Access to Corporate Records

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

Acquisitions Under Israeli Law

Full Tender Offer

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

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

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

Special Tender Offer

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

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

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

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

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

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

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

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

Merger

The Companies Law permits merger transactions if approved by each party's board of directors and, unless certain requirements described under the Companies Law are met, a majority of each party's shareholders. Under our articles of association, a merger shall require the approval of 66% of the voting rights represented at a meeting of our shareholders and voting on the matter, in person or by proxy, and any amendment to such provision shall require the approval of 60% of the voting rights represented at a meeting of our shareholders and voting on the matter, in person or by proxy.

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

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

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

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

Under the Companies Law, each merging company must send a copy of the proposed merger plan to its secured creditors. Unsecured creditors are entitled to receive notice of the merger, as provided by the regulations promulgated under the Companies Law. Upon the request of a creditor of either party to the proposed merger, the court may delay or prevent the merger if it concludes that there exists a reasonable concern that, as a result of the merger, the surviving company will be unable to satisfy the obligations of the target company. The court may also give instructions in order to secure the rights of creditors.

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

Anti-takeover Measures

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

Tax Law

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

Modification of Class Rights

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

Establishment

We were incorporated under the laws of the State of Israel on December 13, 1990 under the name Kamada Ltd. We are registered with the Israeli Registrar of Companies in Jerusalem. Our registration number is 51-152460-5. Our purpose as set forth in our amended and restated articles of association is to engage in any lawful business.

Transfer Agent and Registrar

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

C. Material Contracts

We have not entered into any material contracts other than in the ordinary course of business and other than those described in “Item 4. Information on the Company” or elsewhere in this Annual Report.

D. Exchange Controls

Non-residents of Israel who hold our ordinary shares are able to receive any dividends, and any amounts payable upon the dissolution, liquidation and winding up of our affairs, freely repatriable in non-Israeli currency at the rate of exchange prevailing at the time of conversion. However, Israeli income tax is required to have been paid or withheld on these amounts. In addition, the statutory framework for the potential imposition of exchange controls has not been eliminated, and may be restored at any time by administrative action.

E. Taxation

The following description is not intended to constitute a complete analysis of all tax consequences relating to the acquisition, ownership and disposition of our ordinary shares. You should consult your own tax advisor concerning the tax consequences of your particular situation, as well as any tax consequences that may arise under the laws of any state, local, foreign or other taxing jurisdiction.

Israeli Tax Considerations and Government Programs

The following is a brief summary of the material Israeli tax laws applicable to us, and certain Israeli Government programs benefiting us. This section also contains a discussion of material Israeli tax consequences concerning the ownership of and disposition of our ordinary shares. This summary does not discuss all aspects of Israeli tax law that may be relevant to a particular investor in light of his or her personal investment circumstances or to some types of investors, such as traders in securities, who are subject to special treatment under Israeli law. The discussion below is subject to amendment under Israeli law or changes to the applicable judicial or administrative interpretations of Israeli law, which could affect the tax consequences described below.

The discussion below does not cover all possible tax considerations. Potential investors are urged to consult their own tax advisors as to the Israeli or other tax consequences of the purchase, ownership and disposition of our ordinary shares, including in particular, the effect of any foreign, state or local taxes.

General Corporate Tax Structure in Israel

Israeli companies are generally subject to corporate tax, at a rate of 26.5% in 2014 and 2015 and 25% in 2016. However, the effective corporate tax rate payable by a company that derives income from an Approved Enterprise, a Privileged Enterprise or a Preferred Enterprise (as discussed below) may be considerably less. Capital gains generated by an Israeli company are generally subject to tax at the corporate tax rate.

Law for the Encouragement of Industry (Taxes), 1969

The Law for the Encouragement of Industry (Taxes), 1969 (the "Encouragement of Industry Law"), provides several tax benefits to "Industrial Companies." Pursuant to the Encouragement of Industry Law, a company qualifies as an Industrial Company if it is a resident of Israel and at least 90% of its income in any tax year (exclusive of income from certain defense loans) is generated from an "Industrial Enterprise" that it owns. An Industrial Enterprise is defined as an enterprise whose principal activity, in a given tax year, is industrial activity.

An Industrial Company is entitled to certain tax benefits, including: (i) a deduction of the cost of purchases of patents and know-how and the right to use patents and know-how used for the development or promotion of the Industrial Enterprise in equal amounts over a period of eight years, beginning from the year in which such rights were first used, (ii) the right to elect to file consolidated tax returns, under certain conditions, with additional Israeli Industrial Companies controlled by it, and (iii) the right to deduct expenses related to public offerings in equal amounts over a period of three years beginning from the year of the offering.

Eligibility for benefits under the Encouragement of Industry Law is not contingent upon the approval of any governmental authority.

There is no assurance that we qualify or will continue to qualify as an Industrial Company or that the benefits described above will be available in the future.

Law for the Encouragement of Capital Investments, 1959

Our facilities in Israel have been granted Approved Enterprise status under the Law for the Encouragement of Capital Investments, 1959, commonly referred to as the "Investment Law". The Investment Law provides that a capital investment in eligible production facilities (or other eligible assets) may, upon application to the Investment Center, be designated as an "Approved Enterprise." Each certificate of approval for an Approved Enterprise relates to a specific investment program delineated both by its financial scope, including its sources of capital, and by its physical characteristics, for example, the equipment to be purchased and utilized pursuant to the program. The tax benefits generated from any such certificate of approval relate only to taxable income attributable to the specific Approved Enterprise.

In recent years the Investment Law has undergone major reforms and several amendments which were intended to provide expanded tax benefits and to simplify the bureaucratic process relating to the approval of investments qualifying under the Investment Law. The different benefits under the Investment Law depend on the specific year in which the enterprise received approval from the Investment Center or the year it was eligible for Approved/Privileged Enterprise status under the Investment Law, and the benefits available at that time. Below is a short description of the different benefits available to us under the Investment Law:

Approved Enterprise

One of our facilities has Approved Enterprise status granted by the Investment Center, which made us eligible for a grant and certain tax benefits under the "Grant Track." The approved investment program provided us with a grant in the amount of 24% of our approved investments, in addition to certain tax benefits, which will apply to our turnover resulting from the operation of such investment program, for a period of up to ten consecutive years from the first year in which we generated taxable income. The tax benefits under the Grant Track include accelerated depreciation and amortization for tax purposes as well as a tax exemption for the first two years of the benefit period and the taxation of income generated from an Approved Enterprise at a reduced corporate tax rate of 10%-25%, for a certain period of time. The benefit period is ordinarily seven to ten years commencing with the year in which the Approved Enterprise first generates taxable income. The benefit period is limited to 12 years from the earlier of the operational year as determined by the Investment Center or 14 years from the date of approval of the Approved Enterprise. The tax benefits under the Approved Enterprise status will expire at the end of 2017.

Privileged Enterprise

We 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 to tax benefits as a Privileged Enterprise under the "Tax Benefit Track," which will apply to the turnover attributed to such enterprise, for a period of up to ten years from the first year in which we generated taxable income.

On April 1, 2005, an amendment to the Investment Law came into effect (the "2005 Amendment"), which revised the criteria for investments qualified to receive tax benefits. An eligible investment program under the 2005 Amendment will qualify for benefits as a "Privileged Enterprise" (rather than the previous terminology of Approved Enterprise). Pursuant to the 2005 Amendment, a company whose facilities meet certain criteria set forth in the 2005 Amendment may claim certain tax benefits offered by the Investment Law (as further described below) directly in its tax returns, without the need to obtain prior approval. In order to receive the tax benefits, the company must make an investment in the Privileged Enterprise which meets all of the conditions, including exceeding a certain percentage or a minimum amount, specified in the Investment Law. Such investment must be made over a period of no more than three years ending at the end of the year in which the company requested to have the tax benefits apply to the Privileged Enterprise (the "Year of Election"). According to the tax ruling mentioned above, our Year of Election is 2009. We also elected 2012 as a Year of Election. The duration of tax benefits is subject to a limitation of the earlier of seven to ten years from the first year in which the company generated taxable income (at or after the Year of Election), or 12 years from the first day of the Year of Election. Therefore, the tax benefits under our Privileged Enterprise are scheduled to expire at the end of 2023.

The term "Privileged Enterprise" means an industrial enterprise which is "competitive" and contributes to the gross domestic product, and for which a minimum entitling investment was made in order to establish it (as explained above). For this purpose, an industrial enterprise is deemed to be competitive and contributing to the gross domestic product if it meets one of the following conditions: (1) its main activity is in the field of biotechnology or nanotechnology, as certified by the Director of the Industrial Research and Development Administration before the project was approved; or (2) its income during a tax year from sales to a certain market does not exceed 75% of its total income from sales in that tax year; or (3) 25% or more of its total income from sales in the tax year is from sales to a certain market with at least 14,000,000 inhabitants.

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

The tax benefits available to Privileged Enterprises under the "Tax Benefits Track" are as follows: An exemption from corporate tax may be available on undistributed income for a period of two to ten years, depending on the location of the Privileged Enterprise within Israel, as well as a reduced corporate tax rate of 10% to 25% for the remainder of the benefit period, depending on the level of foreign investment in each year.

However, a company that pays a dividend out of income generated during the tax exemption period from the Privileged/Approved Enterprise is subject to deferred corporate tax with respect to the otherwise exempt income (grossed-up to reflect the pre-tax income that we would have had to earn in order to distribute the dividend) at the corporate tax rate which would have applied if the company had not enjoyed the exemption (i.e. at a reduced tax rate between 10% and 25%, depending on the level of foreign investment). A company is generally required to withhold tax on such distribution at a rate of 20% effective as of January 1, 2014 (or a reduced rate under an applicable double tax treaty, subject to the approval by the Israeli Tax Authority).

Preferred Enterprise

An amendment to the Investment Law that became effective on January 1, 2011 ("Amendment No. 68") changed the benefit alternatives available to companies under the Investment Law and introduced new benefits to "Preferred Enterprises." The tax benefits granted to a Preferred Enterprise are determined depending on the location of the Preferred Enterprise within Israel. Amendment No. 68 imposes a reduced flat corporate tax rate which is not program-dependent and applies to the industrial enterprise's entire "preferred income" which is generated by its Preferred Enterprise.

According to the Investment Law, a uniform corporate tax rate will apply to all qualifying income of the Preferred Enterprise. The uniform corporate tax rate is 9% in areas in Israel designated as Development Zone A and 16% elsewhere in Israel, effective as of January 01, 2014.

The tax benefits under Amendment No. 68 also include accelerated depreciation and amortization for tax purposes during the first five-year period for productive assets that the Preferred Enterprise uses pursuant to the rates prescribed in the Investment Law. Preferred Enterprises located in specific locations within Israel (Zone A) are eligible for grants and/or loans approved by the Israeli Investment Center, as well as tax benefits. Our facility in Beit-Kama, Israel, is located in zone A.

A dividend distributed from income which is attributed to a Preferred Enterprise/Special Preferred Enterprise will be subject to withholding tax at source at the following rates: (i) Israeli resident corporation – 0%, (ii) Israeli resident individual – 20% as of 2014 (iii) non-Israeli resident – 20% as of 2014 subject to a reduced tax rate under the provisions of an applicable double tax treaty.

The provisions of Amendment No. 68 do not apply to existing Privileged Enterprises or Approved Enterprises, which will continue to be entitled to the tax benefits under the Investment Law as in effect prior to Amendment No. 68. Nevertheless, a company owning such enterprises may choose to apply Amendment No. 68 to its existing enterprises while waiving benefits provided under the Investment Law as in effect prior to Amendment No. 68. A company owning a Privileged Enterprise or an Approved Enterprise that makes such election by July 30, 2015, will be entitled to distribute income generated by the Approved/Privileged Enterprise to its Israeli corporate shareholders tax free. Once a company elects to be classified as a Preferred Enterprise under the provisions of Amendment No. 68, the election cannot be rescinded and such company will no longer enjoy the tax benefits of its Approved/Privileged Enterprises.

To date, we have not elected to be classified as a Preferred Enterprise under Amendment No. 68.

There can be no assurance that we will comply with the conditions required to remain eligible for benefits under the Investment Law in the future, including under our certificate of approval with respect to our Approved Enterprise and our tax ruling with respect to our Privileged Enterprise, or that we will be entitled to any additional benefits thereunder. If we do not fulfill these conditions in whole or in part, the benefits can be canceled and we may be required to refund the amount of the benefits, linked to the Israeli consumer price index, with interest.

The Encouragement of Industrial Research and Development Law, 5744-1984

Under the Encouragement of Industrial and Development Law, 5744-1984 (the “Research Law”), research and development programs which meet specified criteria and are approved by a committee of the Office of the Chief Scientist of the Israeli Ministry of Economy (formerly named the Ministry of Industry, Trade and Labor) are eligible for grants. The grants awarded are typically up to 50% of the project’s expenditures, as determined by the research committee. The grantee is required to pay royalties to the State of Israel from the sale of products developed under the program. Regulations under the Research Law generally provide for the payment of royalties of 3% to 6% on sales of products and services based on technology developed using grants, until 100% of the grant is repaid, with interest. The terms of the Israeli government participation also require that products developed with government grants be manufactured in Israel and that the technology developed thereunder may not be transferred outside of Israel, unless approval is received from the Office of the Chief Scientist and additional payments are made to the State of Israel. However, this does not restrict the export of products that incorporate the funded technology. The royalty repayment ceiling can reach up to three times the amount of the grant received if manufacturing is moved outside of Israel, and substantial payments may be required if the technology itself is transferred outside of Israel.

We have previously received grants from the Office of the Chief Scientist for development of our anti-Rh product, Kam Rho (D) IM or IV, and our anti-rabies product, KamRAB. In 2006, we completed our obligations to pay royalties for these developments. We have a balance of royalty payments for inactive projects that we estimate to amount to approximately $469 as of December 31, 2015. In April 2008, we filed a request to close these inactive files, which was partially rejected by the Office of the Chief Scientist in September 2010, alleging that we were making use of the know-how accumulated in these files and are therefore required to pay royalties for certain products. According to the final assessment of the Office of the Chief Scientist, during 2015 we paid an amount of $92,000 to the Office of the Chief Scientist, but we were not yet granted the approval on closure for these inactive files.

Taxation of Our Shareholders

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

Capital gains

Under present Israeli tax legislation, the tax rate applicable to real capital gain derived by Israeli resident corporations from the sale of shares of an Israeli company is the general corporate tax rate (26.5% in 2014 and 2015 and 25% in 2016).

Generally, as of January 1, 2006, the tax rate applicable to real capital gain derived by Israeli individuals from the sale of shares which had been purchased on or after January 1, 2003, whether or not listed on a stock exchange, is 25%, unless such shareholder claims a deduction for interest and linkage differences expenses in connection with the purchase and holding of such shares. Additionally, if such a shareholder is considered a "Substantial Shareholder" (*i.e.*, a person who holds, directly or indirectly, alone or together with another, 10% or more of any of the company's "means of control" (including, among other things, the right to receive profits of the company, voting rights, the right to receive the company's liquidation proceeds and the right to appoint a director)) at the time of sale or at any time during the preceding 12-month period, such gain will be taxed at the rate of 30%. Individual shareholders dealing in securities in Israel are taxed at their marginal tax rates applicable to business income (up to 48%).

Furthermore, beginning on January 1, 2013, an additional tax liability at the rate of 2% was added to the applicable tax rate on the annual taxable income of individuals (whether any such individual is an Israeli resident or non-Israeli resident) exceeding NIS 811,560 in 2014, NIS 810,720 in 2015 and NIS 803,520 in 2016.

Notwithstanding the foregoing, capital gains generated from the sale of shares by a non-Israeli shareholder may be exempt from Israeli taxes provided that, in general, both the following conditions are met: (i) the seller of the shares does not have a permanent establishment in Israel to which the generated capital gain is attributed and (ii) if the seller is a corporation, less than 25% of its means of control are held, directly and indirectly, by Israeli residents or Israeli residents that are the beneficiaries or are eligible to less than 25% of the seller's income or profits from the sale. In addition, the sale of the shares may be exempt from Israeli capital gain tax under the provisions of an applicable tax treaty. For example, the Convention between the Government of the United States of America and the Government of Israel with respect to Taxes on Income, or the "Israel-U.S.A. Double Tax Treaty," generally exempts U.S. residents from Israeli capital gains tax in connection with such sale, provided that (i) the U.S. resident owned, directly or indirectly, less than 10% of the Israeli resident company's voting power at any time within the 12-month period preceding such sale; (ii) the seller, if an individual, has been present in Israel for less than 183 days (in the aggregate) during the taxable year; and (iii) the capital gain from the sale was not generated through a permanent establishment of the U.S. resident in Israel.

The purchaser of the shares, the stockbrokers who effected the transaction or the financial institution holding the shares through which payment to the seller is made are obligated, subject to the above-referenced exemptions if certain conditions are met, to withhold tax on the Real Capital Gain resulting from a sale of shares at the rate of 25%.

A detailed return, including a computation of the tax due, must be filed and an advance payment must be paid on January 31 and July 31 of each tax year for sales of shares traded on a stock exchange made within the six months preceding the month of the report. However, if the seller is exempt from tax or all tax due was withheld at the source according to applicable provisions of the Israeli Income Tax Ordinance and the regulations promulgated thereunder, the return does not need to be filed and an advance payment does not need to be made. Taxable capital gains are also reportable on an annual income tax return if applicable.

Dividends

Our company is obligated to withhold tax, at the rate of 20% effective as of January 1, 2014, upon the distribution of a dividend attributed to an Approved/Privileged Enterprise's income, subject to a reduced tax rate under the provisions of an applicable double tax treaty, provided that a certificate from the Israeli Tax Authorities allowing for a reduced withholding tax rate is obtained in advance. If the dividend is distributed from income not attributed to an Approved/Privileged Enterprise, the following withholding tax rates will apply: (i) Israeli resident corporations — 0%, (ii) Israeli resident individuals — 25% and (iii) non-Israeli residents (whether an individual or a corporation) — 25%, subject to a reduced tax rate under the provisions of an applicable double tax treaty, provided that a certificate from the Israeli Tax Authorities allowing for a reduced withholding tax rate is obtained in advance. Generally, the withholding rate will not be reduced under the Israel-U.S.A. Double Tax Treaty.

Estate and gift tax

Israeli law presently does not impose estate or gift taxes.

United States Federal Income Taxation

The following is a description of the material U.S. federal income tax consequences to a U.S. Holder (as defined below) of the acquisition, ownership and disposition of our ordinary shares. This description addresses only the U.S. federal income tax consequences to holders of our ordinary shares in the United States that will hold our ordinary shares as capital assets for U.S. federal income tax purposes. This description does not address many of the tax considerations applicable to holders that may be subject to special tax rules, including, without limitation:

- banks, certain financial institutions or insurance companies;
- real estate investment trusts, regulated investment companies or grantor trusts;
- dealers or traders in securities, commodities or currencies;
- tax-exempt entities;
- certain former citizens or long-term residents of the United States;
- persons that received our shares as compensation for the performance of services;
- persons that will hold our shares as part of a “hedging,” “integrated” or “conversion” transaction or as a position in a “straddle” for U.S. federal income tax purposes;
- partnerships (including entities classified as partnerships for U.S. federal income tax purposes) or other pass-through entities, or holders that will hold our shares through such an entity;
- S-corporations;
- persons whose “functional currency” is not the U.S. Dollar;
- persons that own directly, indirectly or through attribution 10% or more of the voting power or value of our shares; or

- persons holding our ordinary shares in connection with a trade or business conducted outside the United States.

Moreover, this description does not address the U.S. federal estate, gift or alternative minimum tax consequences, or any state, local or foreign tax consequences, of the acquisition, ownership and disposition of our ordinary shares.

This description is based on the U.S. Internal Revenue Code of 1986, as amended, (the "Code"), existing, proposed and temporary U.S. Treasury Regulations and judicial and administrative interpretations thereof, in each case as available on the date hereof. All of the foregoing is subject to change, which change could apply retroactively and could affect the tax consequences described below. There can be no assurance that the U.S. Internal Revenue Service ("IRS") will not take a different position concerning the tax consequences of the acquisition, ownership and disposition of our ordinary shares or that the IRS's position would not be sustained.

For purposes of this description, a "U.S. Holder" is a beneficial owner of our ordinary shares that, for U.S. federal income tax purposes, is:

- a citizen or resident of the United States;
- a corporation (or other entity treated as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the United States or any jurisdiction thereof; or
- a trust or estate the income of which is subject to United States federal income taxation regardless of its source.

Holders should consult their tax advisors with respect to the U.S. federal, state, local and foreign tax consequences of acquiring, owning and disposing of our ordinary shares.

Distributions

Subject to the discussion below under "Passive Foreign Investment Company Considerations," the gross amount of any distribution made to a U.S. Holder with respect to our ordinary shares before reduction for any Israeli taxes withheld therefrom, other than certain pro rata distributions of our ordinary shares to all our shareholders, generally will be includible in the U.S. Holder's income as dividend income to the extent the distribution is paid out of our current or accumulated earnings and profits as determined under U.S. federal income tax principles. Subject to the discussion below under "Passive Foreign Investment Company Considerations," non-corporate U.S. Holders may qualify for the lower rates of taxation with respect to dividends on ordinary shares applicable to long-term capital gains (i.e., gains from the sale of capital assets held for more than one year) provided that certain conditions are met, including certain holding period requirements and the absence of certain risk reduction transactions. However, dividends on our ordinary shares will not be eligible for the dividends received deduction generally allowed to corporate U.S. Holders. Subject to the discussion below under "Passive Foreign Investment Company Considerations," to the extent that the amount of any distribution by us exceeds our current and accumulated earnings and profits as determined under U.S. federal income tax principles, it will be treated first as a tax-free return of tax basis in our ordinary shares and thereafter as capital gain. We do not expect to maintain calculations of our earnings and profits under U.S. federal income tax principles and, therefore, U.S. Holders should expect that the entire amount of any distribution generally will be reported as dividend income.

Dividends paid to U.S. Holders with respect to our ordinary shares will be treated as foreign source income, which may be relevant in calculating a U.S. Holder's foreign tax credit limitation. Subject to certain conditions and limitations, Israeli tax withheld on dividends may be deducted from taxable income or credited against U.S. federal income tax liability. An election to deduct foreign taxes instead of claiming foreign tax credits applies to all foreign taxes paid or accrued in the taxable year. The limitation on foreign taxes eligible for credit is calculated separately with respect to specific classes of income. For this purpose, dividends that we distribute generally should constitute "passive category income," or, in the case of certain U.S. Holders, "general category income." A foreign tax credit for foreign taxes imposed on distributions may be denied if certain minimum holding period requirements are not satisfied. The rules relating to the determination of the foreign tax credit are complex, and U.S. Holders should consult their tax advisors to determine whether and to what extent they will be entitled to this credit.

Sale, Exchange or Other Disposition of Ordinary Shares

Subject to the discussion below under "Passive Foreign Investment Company Considerations," U.S. Holders generally will recognize gain or loss on the sale, exchange or other disposition of our ordinary shares equal to the difference between the amount realized on the sale, exchange or other disposition and the holder's tax basis in our ordinary shares, and any gain or loss will be capital gain or loss. The tax basis in an ordinary share generally will be equal to the cost of the ordinary share. For non-corporate U.S. Holders, capital gain from the sale, exchange or other disposition of ordinary shares is generally eligible for a preferential rate of taxation in the case of long-term capital gain. The deductibility of capital losses for U.S. federal income tax purposes is subject to limitations under the Code. Any gain or loss that a U.S. Holder recognizes generally will be treated as U.S. source income or loss for foreign tax credit limitation purposes.

Passive Foreign Investment Company Considerations

If we were to be classified as a "passive foreign investment company," ("PFIC"), in any taxable year, a U.S. Holder would be subject to special rules generally intended to reduce or eliminate any benefits from the deferral of U.S. federal income tax that a U.S. Holder could derive from investing in a non-U.S. company that does not distribute all of its earnings on a current basis.

A non-U.S. corporation will be classified as a PFIC for U.S. federal income tax purposes in any taxable year in which, after applying certain look-through rules, either

- at least 75% of its gross income is “passive income”, or
- at least 50% of the average quarterly value of its gross assets is attributable to assets that produce passive income or are held for the production of passive income.

Passive income for this purpose generally includes dividends, interest, royalties, rents, gains from commodities and securities transactions, the excess of gains over losses from the disposition of assets which produce passive income and amounts derived by reason of the temporary investment of funds raised in offerings of our ordinary shares. If a non-U.S. corporation owns at least 25% by value of the stock of another corporation, the non-U.S. corporation is treated for purposes of the PFIC tests as owning its proportionate share of the assets of the other corporation and as directly receiving its proportionate share of the other corporation’s income. If we are classified as a PFIC in any year with respect to which a U.S. Holder owns our ordinary shares, we generally will continue to be treated as a PFIC with respect to that U.S. Holder in all succeeding years during which the U.S. Holder owns our ordinary shares, regardless of whether we continue to meet the tests described above.

However, our PFIC status for each taxable year may be determined only after the end of such year and will depend on the composition of our income and assets, our activities and the value of our assets (which may be determined in large part by reference to the market value of our ordinary shares, which may be volatile) from time to time. If we are a PFIC then unless a U.S. Holder makes one of the elections described below, a special tax regime will apply to both (i) any “excess distribution” by us to that U.S. Holder (generally, the U.S. Holder’s ratable portion of distributions in any year which are greater than 125% of the average annual distribution received by the holder in the shorter of the three preceding years or its holding period for our ordinary shares) and (ii) any gain realized on the sale or other disposition of the ordinary shares.

Under this regime, any excess distribution and realized gain will be treated as ordinary income and will be subject to tax as if (i) the excess distribution or gain had been realized ratably over the U.S. Holder’s holding period, (ii) the amount deemed realized in each year had been subject to tax in each year of that holding period at the highest marginal rate for that year (other than income allocated to the current period or any taxable period before we became a PFIC, which will be subject to tax at the U.S. Holder’s regular ordinary income rate for the current year and will not be subject to the interest charge discussed below), and (iii) the interest charge generally applicable to underpayments of tax had been imposed on the taxes deemed to have been payable in those years. In addition, dividend distributions made to a U.S. Holder will not qualify for the lower rates of taxation applicable to long-term capital gains discussed above under “Distributions.” Certain elections may be available that would result in an alternative treatment (such as mark-to-market treatment) of our ordinary shares. We do not intend to provide the information necessary for U.S. Holders to make qualified electing fund elections if we are classified as a PFIC. U.S. Holders should consult their tax advisors to determine whether any of these elections would be available and if so, what the consequences of the alternative treatments would be in their particular circumstances.

If we are determined to be a PFIC, the general tax treatment for U.S. Holders described in this paragraph would apply to indirect distributions and gains deemed to be realized by U.S. Holders in respect of any of our subsidiaries that also may be determined to be PFICs.

In addition, all U.S. Holders may be required to file tax returns (including on IRS Form 8621) containing such information as the U.S. Treasury may require. For example, if a U.S. Holder owns ordinary shares during any year in which we are classified as a PFIC and the U.S. Holder recognizes gain on a disposition of our ordinary shares or receives distributions with respect to our ordinary shares, the U.S. Holder generally will be required to file an IRS Form 8621 with respect to the company, generally with the U.S. Holder's federal income tax return for that year. The failure to file this form when required could result in substantial penalties.

Based on the financial information currently available to us and the nature of our business, we do not expect that we will be classified as a PFIC for the taxable year ending December 31, 2015. However, this determination could be subject to change. If, contrary to our expectations, we were to be classified as a PFIC, U.S. Holders of ordinary shares may be required to file form 8621 with respect to their ownership of our ordinary shares in the year in which we were a PFIC. U.S. Holders of our ordinary shares should consult their tax advisors in this regard.

Backup Withholding and Information Reporting Requirements

U.S. backup withholding and information reporting requirements may apply to payments to holders of our ordinary shares. Information reporting generally will apply to payments of dividends on, and to proceeds from the sale of, our ordinary shares made within the United States, or by a U.S. payor or U.S. middleman, to a holder of our ordinary shares, other than an exempt recipient (including a corporation). A payor may be required to backup withhold from payments of dividends on, or the proceeds from the sale or redemption of, ordinary shares within the United States, or by a U.S. payor or U.S. middleman, to a holder, other than an exempt recipient, if the holder fails to furnish its correct taxpayer identification number or otherwise fails to comply with, or establish an exemption from, the backup withholding tax requirements. Any amounts withheld under the backup withholding rules generally should be allowed as a credit against the beneficial owner's U.S. federal income tax liability, if any, and any excess amounts withheld under the backup withholding rules may be refunded, provided that the required information is timely furnished to the IRS.

Additional Medicare Tax

Certain U.S. Holders who are individuals, estates or trusts may be required to pay an additional 3.8% Medicare tax on, among other things, dividends and capital gains from the sale or other disposition of shares of common stock for taxable years beginning after December 31, 2012. For individuals, the additional Medicare tax applies to the lesser of (i) "net investment income" or (ii) the excess of "modified adjusted gross income" over $200,000 ($250,000 if married and filing jointly or $125,000 if married and filing separately). "Net investment income" generally equals the taxpayer's gross investment income reduced by the deductions that are allocable to such income. U.S. Holders will likely not be able to credit foreign taxes against the 3.8% Medicare tax.

Foreign Asset Reporting

Certain U.S. Holders who are individuals (and under proposed regulations, certain entities) may be required to report information relating to an interest in our ordinary shares, subject to certain exceptions (including an exception for shares held in accounts maintained by U.S. financial institutions). U.S. Holders are urged to consult their tax advisors regarding their information reporting obligations, if any, with respect to their ownership and disposition of our ordinary shares.

The above description is not intended to constitute a complete analysis of all tax consequences relating to acquisition, ownership and disposition of our ordinary shares. Holders should consult their tax advisors concerning the tax consequences of their particular situations.

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

You may inspect our securities filings, including this Annual Report and the exhibits and schedules thereto, without charge at the offices of the SEC at 100 F Street, N.E., Washington, D.C. 20549. You may obtain copies of all or any part of the Annual Report from the Public Reference Section of the SEC, 100 F Street, NE, Washington, D.C. 20549 upon the payment of the prescribed fees. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains a website at www.sec.gov that contains reports, proxy and information statements and other information regarding registrants like us that file electronically with the SEC. You can also inspect the Annual Report on this website.

A copy of each document (or a translation thereof to the extent not in English) concerning our company that is referred to in this Annual Report is available for public view (subject to confidential treatment of certain agreements pursuant to applicable law) at our principal executive offices.

I. Subsidiary Information

Not applicable.

Item 11. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

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

Foreign Currency Risk

Fluctuations in exchange rates, especially the NIS against the U.S. dollar, may affect our results, as part of our assets is linked to NIS, as are part of our liabilities. Changes in exchange rates may also affect the prices of products purchased by us and designated for marketing in Israel in cases where these product prices are not linked to the U.S. dollar and during the period after these products are sold to our customers in NIS. In addition, the fluctuation in the NIS exchange rate against the U.S. dollar may impact our results, as a portion of our manufacturing cost is NIS denominated.

In 2009, we signed an agreement with a contract research organization for the management of clinical trials in Europe. Total payments to the contract research organization under the agreement are denominated in U.S. dollars. In addition, payments to trial sites will go through the contract research organization, linked to the Euro to U.S. dollar exchange rate. As such, a weakening of the Euro against the U.S. dollar would lower trial costs in U.S. dollars, and vice versa. Our purchases in other currencies are not material, and therefore the impact of fluctuations in exchange rates for these currencies are not material for our results.

For the years ended December 31, 2015, 2014 and 2013, we have witnessed high volatility in the U.S. dollar exchange rate. This fact impacts our revenues from the Distribution segment, where prices are denominated in or linked to the NIS upon delivery of product while our expenses for the purchase of raw materials and imported goods in the Distribution segment are in U.S. dollars and part of our development and marketing expenses are paid in NIS.

We attempt to mitigate our currency exposure by matching assets denominated in NIS currency with liabilities denominated in NIS. In the Distribution segment, we attempt to mitigate foreign currency exposure by matching Euro denominated expenses with Euro denominated revenues. Additionally, we used, and from time to time, will continue to use, currency hedging transactions using financial derivatives, collars and forward currency contracts. We attempt to enter into forward currency contracts with critical terms that match those of the underlying exposure. As of December 31, 2015, we had open transactions in derivatives in the amount of approximately $23.2 million. We regularly monitor and review the need for currency hedging transactions in accordance with trend analysis.

The following table presents information about the changes in the exchange rates of the NIS against the U.S. dollar:

Period	Change in Average Exchange Rate of the NIS against the U.S. Dollar (%)
Year ended December 31, 2013	(6.4)
Year ended December 31, 2014	12.0
Year ended December 31, 2015	8.6

As of December 31, 2015, we had excess assets over liabilities denominated in NIS in the amount of $6.0 million. When the U.S. dollar appreciates against the NIS, we recognize financial expenses with respect to exchange rate differences. When the U.S. dollar devalues against the NIS, we recognize financial revenues.

As of December 31, 2015, we had foreign currency exposures to currencies other than U.S. dollars amounting to $3.0 million in excess liabilities over assets. Most of this exposure is to the Euro.

A 10% increase (decrease) in the value of the NIS against the U.S. dollar would have decreased (increased) our financial assets by $0.6 million, $0.5 million and $0.3 million as of December 31, 2015, 2014 and 2013, respectively.

Item 12. Description of Securities Other Than Equity Securities

Not applicable.

PART II

Item 13. Defaults, Dividend Arrearages and Delinquencies

Not applicable.

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

Initial Public Offering

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

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

As of December 31, 2015, we have used a large portion of the net proceeds of our initial public offering. We intend to use the remaining net proceeds we received from our initial public offering as disclosed in our Registration Statement on Form F-1.

Item 15. Controls and Procedures

(a) *Disclosure Controls and Procedures.* Our management, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2015, pursuant to Rule 13a-15 under the Exchange Act. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer (the principal executive and principal financial officer, respectively) have concluded that our disclosure controls and procedure are effective to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure, and is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms.

(b) *Report* of *Management on Internal Control over Financial Reporting*. Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our management has assessed the effectiveness of internal control over financial reporting based on the Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this assessment, our management has concluded that our internal control over financial reporting as of December 31, 2015 was effective.

(c) *Attestation Report of the Registered Public Accounting Firm*. This annual report does not include an attestation report of the company's registered public accounting firm because we qualify as an emerging growth company and, as such, are exempt from such attestation.

(d) *Changes in Internal Control over Financial Reporting*. During the period covered by this report, we have not made any changes to our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 16A. Audit committee financial expert

Our board of directors has determined that Tuvia Shoham and Dr. Estery Giloz-Ran, each an "independent" director for purposes of serving on an audit committee under the Exchange Act and Nasdaq listing requirements, qualify as "audit committee financial experts," as defined in Item 407(d)(5) of Regulation S-K.

Item 16B. Code of Ethics

In November 2011, we adopted a Code of Ethics, which applies to our directors, officers and employees, including our Chief Executive Officer, Chief Financial Officer, principal accounting officer or controller, and persons performing similar functions. The Code of Ethics is posted on our website, www.kamada.com.

Item 16C. Principal Accountant Fees and Services

During the years ended December 31, 2015 and 2014, we were billed the following aggregate fees for the professional services rendered by Kost Forer Gabbay and Kasierer, a member of Ernst & Young Global, independent registered public accounting firm:

	Year Ended December 31,	
	2015	**2014**
Audit Fees(1)	$ 180,000	$ 160,000
Audit-Related Fees(2)	--	--
Tax Fees(3)	5,942	12,000
Total	$ 185,942	$ 172,000

(1) Audit fees are aggregate fees for audit services for each of the years shown in this table, including fees associated with the annual audit and reviews of our quarterly financial results submitted on Form 6-K, consultations on various accounting issues and audit services provided in connection with other statutory or regulatory filings.

(2) Audit-related fees are for services rendered by our auditors in connection with our registration statements, including our Registration Statement on Form F-1 related to our initial public offering,

(3) Tax services rendered by our auditors were for tax compliance and for tax consulting associated with international transfer pricing.

Our audit committee has adopted a policy for pre-approval of audit and non-audit services provided by our independent auditor. Under the policy, such services must require the specific pre-approval of our audit committee followed by ratification of our full board of directors. Any proposed services exceeding the pre-approval amounts for all services to be provided by our independent auditor require an additional specific pre-approval by our audit committee.

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

Not applicable.

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

In the year ended December 31, 2015, neither the company nor any affiliated purchaser (as defined in the Exchange Act) purchased any of the company's ordinary shares.

Item 16F. Change in Registrant's Certifying Accountant

None.

Item 16G. Corporate Governance

As a foreign private issuer whose shares are listed on the Nasdaq Global Select Market, we have the option to follow Israeli corporate governance practices rather than certain of those of Nasdaq, except to the extent that such laws would be contrary to U.S. securities laws and provided that we disclose the practices we are not following and describe the home country practices we follow instead. We rely on this "foreign private issuer exemption" with respect to the following Nasdaq requirements:

- *Shareholder approval requirements for equity issuances and equity-based compensation plans.* Under the Companies Law, the adoption of, and material changes to, equity-based compensation plans generally require the approval of the board of directors (for approval of equity based arrangements, see "Item 6. Directors, Senior Management and Employees — Fiduciary Duties and Approval of Specified Related Party Transactions under Israeli Law — Disclosure of Personal Interests of a Controlling Shareholder and Approval of Certain Transactions," "Item 6. Directors, Senior Management and Employees — Compensation of Directors" and "Item 6. Directors, Senior Management and Employees — Compensation of Executive Officers"). Similarly, the approval of the board of directors is generally sufficient for a private placement unless the private placement is deemed a "significant private placement" (see "Item 6. Directors, Senior Management and Employees — Approval of Significant Private Placements"), in which case shareholder approval is also required, or an office holder or a controlling shareholder or their relative has a personal interest in the private placement, in which case, audit committee approval is required prior to the board approval and, for a private placement in which a controlling shareholder or its relative has a personal interest, shareholder approval is also required (see "Item 6. Directors, Senior Management and Employees — Fiduciary Duties and Approval of Specified Related Party Transactions under Israeli Law").

- *Requirement for independent oversight on our director nominations process and to adopt a formal written charter or board resolution addressing the nominations process.* In accordance with Israeli law and practice, directors are recommended by our board of directors for election by our shareholders. The Damar Group and Recananti Group have entered into a shareholders' agreement which includes an agreement about voting in the election of nominees appointed by the other party (see "Item 7. Major Shareholders and Related Party Transactions — Related Party Transactions — Shareholders' Agreement").

- *Quorum requirement*. Under our articles of association and as permitted under the Companies Law, a quorum for any meeting of shareholders shall be the presence of at least two shareholders present in person, by proxy or by a voting instrument, who hold at least 25% of the voting power of our shares instead of 33 1/3% of the issued share capital required under Nasdaq requirements. At an adjourned meeting, any number of shareholders shall constitute a quorum.

- *Compensation Committee Charter*. As permitted under the Companies Law, we do not have a formal charter for our compensation committee.

Except as stated above, we comply with the rules generally applicable to U.S. domestic companies listed on Nasdaq subject to certain exemptions the JOBS Act provides to emerging growth companies. We may in the future decide to use other foreign private issuer exemptions with respect to some or all of the other Nasdaq listing requirements. Following our home country governance practices, as opposed to the requirements that would otherwise apply to a company listed on Nasdaq, may provide less protection than is accorded to investors under Nasdaq listing requirements applicable to domestic issuers. For more information, see "Item 3. Key Information —D. Risk Factors — We are an 'emerging growth company' with reduced reporting requirements that may make our ordinary shares less attractive to investors" and "Item 3. Key Information —D. Risk Factors — As we are a 'foreign private issuer' and intend to follow certain home country corporate governance practices, our shareholders may not have the same protections afforded to shareholders of companies that are subject to all Nasdaq corporate governance requirements." We will also be required to comply with Israeli corporate governance requirements under the Companies Law applicable to Israeli public companies such as us whose shares are also listed for trade on an exchange outside Israel.

Item 16H. Mine Safety Disclosure

Not applicable.

PART III

Item 17. Financial Statements

Consolidated Financial Statements are set forth under Item 18.

Item 18. Financial Statements

Our Consolidated Financial Statements beginning on pages F-1 through F-61, as set forth in the following index, are hereby incorporated herein by reference. These Consolidated Financial Statements are filed as part of this Annual Report.

Item 19. Exhibits

Exhibit No.	Description
1.1	Articles of Association of the Registrant (as translated from Hebrew) (incorporated by reference to Exhibit 3.1 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on May 15, 2013).
1.2	Amendment to Articles of Association of the Registrant (as translated from Hebrew) (incorporated by reference to Appendix A1 of the Proxy filed as Exhibit 99.1 to Form 6-K filed with the Securities and Exchange Commission on May 22, 2015).
1.3	Memorandum of Association of the Registrant, as currently in effect (as translated from Hebrew) (incorporated by reference to Exhibit 3.1 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on May 15, 2013).
2.1	Form of Certificate for Ordinary Shares (incorporated by reference to Exhibit 4.1 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on May 15, 2013).
4.1†	Exclusive Manufacturing, Supply and Distribution Agreement, dated as of August 23, 2010, by and between Kamada Ltd. and Baxter Healthcare Corporation (incorporated by reference to Exhibit 10.1 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on May 15, 2013).

4.2†	Technology License Agreement, dated as of August 23, 2010, by and between Kamada Ltd. and Baxter Healthcare S.A. (incorporated by reference to Exhibit 10.2 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on May 15, 2013).
4.3†	Amended and Restated Fraction IV-1 Paste Supply Agreement, dated as of August 23, 2010, by and between Kamada Ltd. and Baxter Healthcare Corporation (incorporated by reference to Exhibit 10.3 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on April 11, 2013).
4.4†	First Amendment to the Amended and Restated Fraction IV-1 Paste Supply Agreement, dated as of May 10, 2011, by and between Kamada Ltd. and Baxter Healthcare Corporation (incorporated by reference to Exhibit 10.4 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on April 11, 2013).
4.5†	Second Amendment to the Amended and Restated Fraction IV-1 Paste Supply Agreement, dated as of June 22, 2011, by and between Kamada Ltd. and Baxter Healthcare Corporation (incorporated by reference to Exhibit 10.5 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on April 11, 2013).
4.6†	Exclusive Distribution Agreement, dated as of August 2, 2012, by and between Kamada Ltd. and Chiesi Farmaceutici S.p.A. (incorporated by reference to Exhibit 10.6 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on May 15, 2013).
4.7†	License Agreement, dated as of November 16, 2006, by and between PARI GmbH and Kamada Ltd. (incorporated by reference to Exhibit 10.7 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on April 11, 2013).
4.8†	Amendment No. 1 to License Agreement, dated as of August 9, 2007, by and between PARI GmbH and Kamada Ltd. (incorporated by reference to Exhibit 10.8 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on April 11, 2013).
4.9†	Addendum No. 1 to License Agreement, dated as of February 21, 2008, by and between PARI GmbH and Kamada Ltd. (incorporated by reference to Exhibit 10.9 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on April 11, 2013).
4.10†	Supply and Distribution Agreement, dated as of July 18, 2011, by and between Kamada Ltd. and Kedrion S.p.A. (incorporated by reference to Exhibit 10.10 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on April 11, 2013).
4.11†	Distribution Agreement, dated as of August 2, 2011, by and between Kamada Ltd. and TUTEUR S.A.C.I.F.I.A. (incorporated by reference to Exhibit 10.11 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on April 11, 2013).

4.12	English summary of the material terms of the convertible debentures (incorporated by reference to Exhibit 10.12 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on May 15, 2013).
4.13	Kamada Ltd. 2011 Israeli Share Option Plan (incorporated by reference to Exhibit 10.13 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on April 11, 2013).
4.14	Kamada Ltd. 2005 Israeli Share Option Plan (incorporated by reference to Exhibit 10.14 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on April 11, 2013).
4.15	English translation of form of Indemnification Agreement with the Registrant's directors and officers (incorporated by reference to Exhibit 10.15 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on May 15, 2013).
4.16	English translation of amendment to form of Indemnification Agreement with the Registrant's directors and officers (incorporated by reference to Appendixes A3 and A4 of the Proxy filed as Exhibit 99.1 to Form 6-K filed with the Securities and Exchange Commission on May 22, 2015).
4.17	English summary of two lease agreements dated June 20, 2002, by and between the Israel Lands Administration and Kamada Nehasim (2001) Ltd., as such agreements were amended by lease agreement dated January 30, 2011, by and between the Israel Lands Administration and Kamada Nehasim (2001) Ltd. (incorporated by reference to Exhibit 10.16 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on April 11, 2013).
4.18	English summary of a lease agreement dated December 2, 1984, by and between Africa-Israel Holdings Ltd. and RAD Chemicals Ltd., as amended by a supplement to the lease agreement dated October 7, 1999, by and between Africa-Israel Holdings Ltd., RAD Chemicals Ltd. and Kamada Ltd., as further amended by supplements to the lease agreement dated November 27, 2005; December 6, 2005; June 27, 2006; September 29, 2009; May 30, 2011; and August 13, 2012, by and between Africa-Israel Holdings Ltd. and Kamada Ltd. (incorporated by reference to Exhibit 10.17 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on April 11, 2013).
4.19†	Fraction IV-1 Paste Supply Agreement, dated December 3, 2012, by and between Baxter Healthcare S.A. and Kamada Ltd. (incorporated by reference to Exhibit 10.18 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on April 11, 2013).
4.20	Registration Rights Agreement, dated as of April 14, 2013, by and among Kamada Ltd. and the individuals and entities identified therein (incorporated by reference to Exhibit 10.19 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on May 15, 2013).
4.21	Side Letter Agreement, dated as of March 23, 2011, by and between Kamada Ltd. and Baxter Healthcare Corporation (incorporated by reference to Exhibit 10.20 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on May 15, 2013).

4.22	First Amendment to the Exclusive Manufacturing Supply and Distribution Agreement, dated as of September 6, 2012, between Kamada Ltd. and Baxter Healthcare Corporation (incorporated by reference to Exhibit 10.21 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on May 15, 2013).
4.23†	Second Amendment to the Exclusive Manufacturing, Supply and Distribution Agreement, dated as of May 14, 2013, by and between Kamada Ltd. and Baxter Healthcare Corporation (incorporated by reference to Exhibit 10.22 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on May 15, 2013).
4.24†	First Amendment to the Technology License Agreement, dated as of May 14, 2013, by and between Kamada Ltd. and Baxter Healthcare Corporation (incorporated by reference to Exhibit 10.23 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on May 28, 2013).
4.25	Compensation Policy approved by the shareholders of the Registrant on January 28, 2014 (incorporated by reference to Exhibit A to the Proxy Statement dated December 19, 2013 filed as Exhibit 99.1 to Form 6-K filed with the Securities and Exchange Commission on December 24, 2013).
4.26	Amendment to Compensation Policy approved by the shareholders of the Registrant on June 30, 2015 (incorporated by reference to Appendix A2 of the Proxy Statement filed as Exhibit 99.1 to Form 6-K filed with the Securities and Exchange Commission on May 22, 2015).
4.27†	Third Amendment to the Exclusive Manufacturing, Supply and Distribution Agreement, dated as of September, 2014, by and between Kamada Ltd. and Baxter Healthcare Corporation (incorporated by reference to Exhibit 4.25 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on April 28, 2015).
4.28†	First Amendment to the Distribution Agreement, dated as of August 19, 2014, by and between Kamada Ltd. and TUTEUR S.A.C.I.F.I.A (incorporated by reference to Exhibit 4.26 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on April 28, 2015).
4.29†	Third Amendment to the Amended and Restated Fraction IV-1 Paste Supply Agreement executed on June 19, 2015 by and between Kamada Ltd. and Baxalta US Inc.
4.30†	Fourth Amendment to the Exclusive Manufacturing, Supply and Distribution Agreement, dated as of October, 2015, by and between Kamada Ltd. and Baxalta US Inc.
4.31†	Second Amendment to the Technology License Agreement, dated as of August 25, 2015, by and between Kamada Ltd. and Baxalta GmbH.
8.1	Subsidiaries of the Registrant.
12.1	Certification of Chief Executive Officer Pursuant to Rule 13a-14(a)/15d-14(a).
12.2	Certification of Chief Financial Officer Pursuant to Rule 13a-14(a)/15d-14(a).
13.1	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
15.1	Consent of Ernst & Young Global, independent registered public accounting firm.

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

SIGNATURES

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

KAMADA LTD.

By: /s/ Gil Efron
Gil Efron
Deputy Chief Executive Officer and
Chief Financial Officer

Date: February 25, 2016

Kamada Ltd.

Consolidated Financial Statements as of December 31, 2015

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Report of Independent Registered Public Accounting Firm
The Board of Directors and Shareholders of Kamada Ltd.

We have audited the accompanying consolidated balance sheets of Kamada Ltd. ("the Company") as of December 31, 2015 and 2014 and the related consolidated statements of comprehensive Income, changes in equity and cash flows for each of the three years ended December 31, 2015. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, based on our audits, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2015 and 2014 and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2015, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

Tel-Aviv, Israel
February 25, 2016

/S/ Kost Forer Gabbay & Kasierer
A member of Ernst & Young Global

Consolidated Balance Sheets

	Note	As of December 31, 2015	2014
		In thousands	
Current Assets			
Cash and cash equivalents	5	$ 5,047	$ 14,546
Short-term investments	6	23,259	37,350
Trade receivables, net	7	23,071	17,514
Other accounts receivables	8	2,881	2,359
Inventories	9	26,336	25,423
		80,594	97,192
Property, plant and equipment, net	10	21,309	21,769
Other long term assets	11	89	179
		21,398	21,948
		101,992	119,140
Current Liabilities			
Current maturities of loans and convertible debentures	12,15	37	7,492
Trade payables	13	16,917	16,530
Other accounts payables	14	4,064	4,045
Deferred revenues	18a,b	1,921	2,919
		22,939	30,986
Non-Current Liabilities			
Loans	15	151	-
Employee benefit liabilities, net	17	787	722
Deferred revenues	18a,b	5,608	7,015
		6,546	7,737
Shareholder's Equity	20		
Ordinary shares of NIS 1 par value:			
Authorized - 60,000,000 ordinary shares; Issued and outstanding – 36,418,741 and 35,988,563 shares at December 31, 2015 and 2014, respectively		9,320	9,208
Additional paid in capital		162,238	158,417
Conversion option in convertible debentures		-	1,147
Capital reserve due to translation to presentation currency		(3,490)	(3,490)
Capital reserve from hedges		(1)	(116)
Capital reserve from available for sale financial assets		73	10
Capital reserve from share-based payments		9,157	8,783
Capital reserve from employee benefits		(59)	(81)
Accumulated deficit		(104,731)	(93,461)
		72,507	80,417
		$ 101,992	$ 119,140

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

Consolidated Statements of Comprehensive income (Loss)

	Note	For the Year Ended December 31, 2015	2014	2013
		In thousands, except for share and per share data		
Revenues from proprietary products		$ 42,952	$ 44,389	$ 50,658
Revenues from distribution		26,954	26,676	19,965
Total revenues	23a	69,906	71,065	70,623
Cost of revenues from proprietary products		30,468	32,617	27,104
Cost of revenues from distribution		23,640	23,406	17,112
Total cost of revenues	23b	54,108	56,023	44,216
Gross profit		15,798	15,042	26,407
Research and development expenses	23c	16,530	16,030	12,745
Selling and marketing expenses	23d	3,652	2,898	2,100
General and administrative expenses	23e	7,040	7,593	7,862
Operating income (loss)		(11,424)	(11,479)	3,700
Financial income	23f	463	*404	*278
Expense in respect of currency exchange differences and derivatives instruments, net		625	-	(369)
Financial expense	23f	(934)	*(2,086)	*(3,142)
Income (loss) before taxes on income		(11,270)	(13,161)	467
Taxes on income		-	52	24
Net Income (loss)		(11,270)	(13,213)	443
Other Comprehensive Income (loss):				
Items that may be reclassified to profit or loss in subsequent periods:				
Gain (loss) on available for sale financial assets		63	37	(27)
Gain (loss) on cash flow hedges		71	(162)	303
Net amounts transferred to the statement of profit or loss for cash flow hedges		44	(110)	(376)
Items that will not be reclassified to profit or loss in subsequent periods:				
Actuarial gain from defined benefit plans		22	48	12
Total comprehensive income (loss)		$ (11,070)	$ (13,400)	$ 355
Income (loss) per share attributable to equity holders of the Company:	24			
Basic income (loss) per share		$ (0.31)	$ (0.37)	$ 0.01
Diluted income (loss) per share		$ (0.31)	$ (0.37)	$ 0.01

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

Consolidated Statements of Changes in Equity

	Share capital	Share premium	Conversion option in convertible debentures	Capital reserve from Available for sale financial assets	Capital reserve due to translation to presentation currency	Capital reserve from hedges	Capital reserve from share-based payments	Capital reserve from employee benefits	Accumulated deficit	Total equity
	In thousands									
Balance as of December 31, 2012	$ 7,204	$ 96,874	$ 3,794	$ -	$ (3,490)	$ 229	$ 4,614	$ (141)	$ (80,691)	$ 28,393
Net income	-	-	-	-	-	-	-	-	443	443
Other comprehensive income (loss)	-	-	-	(27)	-	(73)	-	12	-	(88)
Total comprehensive income	-	-	-	(27)	-	(73)	-	12	443	355
Exercise of options into shares	62	1,275	-	-	-	-	(752)	-	-	585
Issuance of ordinary shares, net of issuance costs	1,749	51,053	-	-	-	-	-	-	-	52,802
Conversion of convertible debentures into shares	186	7,294	(972)	-	-	-	-	-	-	6,508
Expiration of conversion option on convertible debentures	-	604	(604)	-	-	-	-	-	-	-
Cost of share-based payment	-	-	-	-	-	-	1,327	-	-	1,327
Balance as of December 31, 2013	$ 9,201	$ 157,100	$ 2,218	$ (27)	$ (3,490)	$ 156	$ 5,189	$ (129)	$ (80,248)	$ 89,970
Net loss	-	-	-	-	-	-	-	-	(13,213)	(13,213)
Other comprehensive income (loss)	-	-	-	37	-	(272)	-	48	-	(187)
Total comprehensive income (loss)	-	-	-	37	-	(272)	-	48	(13,213)	(13,400)
Exercise of options into shares	7	238	-	-	-	-	(157)	-	-	88
Conversion of convertible debentures into shares	(*	9	(1)	-	-	-	-	-	-	8
Expiration of conversion option on convertible debentures	-	1,070	(1,070)	-	-	-	-	-	-	-
Cost of share-based payment	-	-	-	-	-	-	3,751	-	-	3,751
Balance as of December 31, 2014	$ 9,208	$ 158,417	$ 1,147	$ 10	$ (3,490)	$ (116)	$ 8,783	$ (81)	$ (93,461)	$ 80,417
Net loss	-	-	-	-	-	-	-	-	(11,270)	(11,270)
Other comprehensive income (loss)	-	-	-	63	-	115	-	22	-	200
Total comprehensive income (loss)	-	-	-	63	-	115	-	22	(11,270)	(11,070)
Exercise of options into shares	112	2,674	-	-	-	-	(1,533)	-	-	1,253
Expiration of conversion option on convertible debentures	-	1,147	(1,147)	-	-	-	-	-	-	-
Cost of share-based payment	-	-	-	-	-	-	1,907	-	-	1,907
Balance as of December 31, 2015	$ 9,320	$ 162,238	$ -	$ 73	$ (3,490)	$ (1)	$ 9,157	$ (59)	$ (104,731)	$ 72,507

(* Represent an amount lower than $1.
The accompanying notes are an integral part of the Consolidated Financial Statements

Consolidated Statements of Cash Flows

	Note	For the Year Ended December 31, 2015	2014	2013
		In thousands		
Cash Flows from Operating Activities				
Net Income (loss)		$ (11,270)	$ (13,213)	$ 443
Adjustments to reconcile net loss to net cash provided by operating activities:				
Adjustments to the profit or loss items:				
Depreciation and amortization	10, 11	3,227	2,788	3,001
Financial expenses (income), net		(154)	1,682	3,233
Cost of share-based payment	21	1,907	3,751	1,327
Income tax expense		-	52	24
Loss (gain) from sale of property and equipment		-	(2)	73
Change in employee benefit liabilities, net		87	(57)	121
		5,067	8,214	7,779
Changes in asset and liability items:				
Increase in trade receivables, net		(5,604)	(869)	(3,445)
Decrease (increase) in other accounts receivables		118	(50)	(444)
Increase in inventories		(913)	(3,490)	(1,182)
Decrease (increase) in deferred expenses		(565)	1,209	(1,231)
Increase in trade payables		887	3,261	1,579
Increase (decrease) in other accounts payables		94	(344)	264
Decrease in deferred revenues		(2,405)	(4,026)	(6,270)
		(8,388)	(4,309)	(10,729)
Cash received (paid) during the year for:				
Interest paid		(484)	(1,210)	(1,968)
Interest received		1,143	758	663
Withholding taxes paid		(47)	(158)	(42)
		612	(610)	(1,347)
Net cash used in operating activities		$ (13,979)	$ (9,918)	$ (3,854)

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

Consolidated Statements of Cash Flows

	Note	For the Year Ended December 31, 2015	2014	2013
		In thousands		
Cash Flows from Investing Activities				
Proceeds from sale of)investment in) short term investments, net		$ 13,971	$ (23,746)	$ 1,732
Purchase of property and equipment and intangible assets	10	(2,718)	(3,076)	(5,643)
Proceeds from sale of property and equipment		-	3	8
Net cash provided by (used in) investing activities		11,253	(26,819)	(3,903)
Cash Flows from Financing Activities				
Proceeds from exercise of warrants and options		1,254	88	562
Proceeds from issuance of ordinary shares, net		-	-	52,953
Receipt of long-term loans		197	-	-
Repayment of long-term loans		(9)	-	(12)
Repayment of convertible debentures	15	(7,797)	(7,728)	(4,295)
Net cash provided by (used in) financing activities		(6,355)	(7,640)	49,208
Exchange differences on balances of cash and cash equivalent		(418)	(187)	793
Increase (decrease) in cash and cash equivalents		(9,499)	(44,564)	42,244
Cash and cash equivalents at the beginning of the year		14,546	59,110	16,866
Cash and cash equivalents at the end of the year		$ 5,047	$ 14,546	$ 59,110
Significant non-cash transactions				
Issuance expenses accrued in other accounts payable		$ -	$ -	$ 151
Exercise of warrants presented as liability		$ -	$ -	$ 23
Exercise of convertible debentures into shares		$ -	$ 7	$ 6,508

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

NOTE 1: - GENERAL

a. General description of the Company and its activity

Kamada Ltd. ("the Company") is an orphan drug focused, plasma derived protein therapeutics Company with an existing marketed product portfolio. The Company develops and produces plasma-derived protein therapeutics and currently markets these products through strategic partners in the United States and Europe and through local distributors, in several emerging markets. The Company flagship product is "Glassia".

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

Proprietary Products	Development, manufacture and sale of plasma-derived therapeutics products.
Distribution	Distribution of drugs in Israel manufacture by other companies, most of which are produced from plasma or its derivatives products.

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

b. The Company has three fully-owned subsidiaries – Kamada Inc, Kamada Biopharma Limited and Bio-Kam Ltd which are not active. In addition the Company owns 74% of Kamada Assets Ltd. ("Kamada Assets").

c. Definitions

In these Financial Statements –

The Company	-	Kamada Ltd.
The Group	-	The Company and its subsidiaries.
Subsidiary	-	A company which the Company has a control over (as defined in IFRS 10) and whose financial statements are consolidated with the Company's Financial Statements.
Related parties	-	As defined in IAS 24.
USD/$	-	U.S. dollar.
NIS	-	New Israeli Shekel

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES

a. Basis of presentation of financial statements

1. These financial statements have been prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standard Board.

2. Measurement basis:

The Company's Financial Statements are prepared on a cost basis, except for financial instruments (including derivatives) at fair value through profit or loss such as available for sales financial assets, employee benefit assets and employee benefit liabilities.

The Company has elected to present profit or loss items using the "function of expense" method.

b. The Company's operating cycle is one year.

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

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

d. Functional currency, presentation currency and foreign currency

1. Functional currency and presentation currency

The consolidated financial statements are presented in U.S. dollars, which is the Company's functional and presentation currency.

2. Transactions, assets and liabilities in foreign currency

Transactions denominated in foreign currency are recorded on initial recognition at the exchange rate at the date of the transaction. After initial recognition, monetary assets and liabilities denominated in foreign currency are translated at the end of each reporting period into the functional currency at the exchange rate at that date. Exchange differences are recognized in profit or loss. Non-monetary assets and liabilities measured at cost in a foreign currency are translated at the exchange rate at the date of the transaction.

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

3. Index-linked monetary items

Monetary assets and liabilities linked to the changes in the Israeli Consumer Price Index ("Israeli CPI") are adjusted at the relevant index at the end of each reporting period according to the terms of the agreement.

e. Cash equivalents

Cash equivalents are considered as highly liquid investments, including unrestricted short-term bank deposits with an original maturity of three months or less from the date of purchase.

f. Short-term investments:

Short-term bank deposits with a maturity of more than three months from the deposit date but less than one year, available for sale financial investments (debentures) and financial assets held for trading at fair value through profit or loss (debentures and investment in equity).

g. Allowance for doubtful accounts

The allowance for doubtful accounts is determined in respect of specific debts whose collection, in the opinion of the Company's management, is doubtful. Impaired debts are derecognized when they are assessed as uncollectible. As of December 31, 2015 and 2014, the balance of allowance for doubtful accounts was $398 thousands and $433 respectively.

h. Inventory

Inventories are measured at the lower of cost and net realizable value. The cost of inventories comprises costs of purchase and costs incurred in bringing the inventories to their present location and condition. Net realizable value is the estimated selling price in the ordinary course of business less the estimated costs of completion and the estimated selling costs.

Cost of inventories is determined as follows:

Raw materials	-	At cost of purchase using the first-in, first-out method.
Work in process	-	At the average costs for the month of manufacturing including materials, labor and other direct and indirect manufacturing costs on the basis of each batch.
Finished products	-	At the average costs for month of manufacturing including materials, labor and other direct and indirect manufacturing costs on the basis of each batch.
Purchased products and goods	-	On a "first in – first out" basis.

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

The Company periodically evaluates the condition and age of inventories and makes provisions for inventories with a lower market value or which are slow moving.

i. 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 the Company and the costs incurred or to be incurred in respect of the transaction can be measured reliably. In cases where the Company operates as a principal supplier and it exposed to the risks and rewards associated with the transaction, revenues are presented on a gross basis. Revenues are measured at the fair value of the consideration received less any trade discounts, volume rebates and returns.

The specific criteria for revenue recognition for the following types of revenues are:

- 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.

- Agreements with multiple elements provide for varying consideration terms, such as upfront payments and milestone payments. Revenues from such agreements that do not contain a general right of return and that are composed of multiple elements such as distribution exclusivity, license and services are allocated to the different elements and are recognized in respect of each element separately. An element constitutes a separate accounting unit if and only if it has a separate value to the customer. Revenue from the different element is recognized when the criteria for revenue recognition have been met and only to the extent of the consideration that is not contingent upon completion or performance of future services in the contract.

- Revenue from milestone events stipulated in the agreements is recognized upon the occurrence of a substantive element specified in the agreement or as a measure of substantive progress towards completion. Amounts received for participation in research and development, are recognized as revenues on a straight line basis over the estimated development period.

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

Deferred revenues

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

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

j. Taxes on income

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

1. Current taxes:

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

2. Deferred taxes:

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

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

Deferred tax assets are reviewed at the end of each reporting period and reduced to the extent that it is not probable that they will be utilized. Temporary differences for which deferred tax assets had not been recognized are reviewed at the end of each reporting period and a respective deferred tax asset is recognized to the extent that their utilization is probable.

Deferred taxes are offset in the statement of financial position if there is a legally enforceable right to offset a current tax asset against a current tax liability and the deferred taxes relate to the same taxpayer and the same taxation authority.

k. Leases

The Group as lessee:

1. Finance lease

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

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

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

2. Operating lease

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

l. Property, plant and equipment

Property, plant and equipment are measured at cost, including directly attributable costs, less accumulated depreciation, accumulated impairment losses and any related investment grants and excluding day-to-day servicing expenses. Cost includes spare parts and auxiliary equipment that can be used only in connection with the plant and equipment.

The cost of self-constructed assets includes the cost of materials, direct labor costs as well as any costs directly attributable to bringing the asset to the location and condition necessary for it to operate in the manner intended by management.

Depreciation is calculated on a straight-line basis over the useful life of the assets at annual rates as follows:

	%	Mainly %
Buildings	4-2.5	4
Machinery and equipment	10-20	15
Vehicles	15	15
Computers, equipment and office furniture	6-33	33
Leasehold improvements	(*)	18

(*) Leasehold improvements are depreciated on a straight-line basis over the shorter of the lease term (including the extension option held by the Company and intended to be exercised) and the expected life of the improvement.

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

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

m. Intangible assets

Separately acquired intangible assets with finite useful life, are measured on initial recognition at cost. Intangible assets are amortized over their useful life using the straight-line method and reviewed for impairment whenever there is an indication that the asset may be impaired.

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

Research and development costs

Research expenditures are recognized in profit or loss when incurred. An intangible asset arising from a development project or from the development phase of an internal project is recognized if the Company can demonstrate the technical feasibility of completing the intangible asset so that it will be available for use or sale; the Company's intention to complete the intangible asset and use or sell it; the Company's ability to use or sell the intangible asset; how the intangible asset will generate future economic benefits; the availability of adequate technical, financial and other resources to complete the intangible asset; and the Company's ability to measure reliably the expenditure attributable to the intangible asset during its development. Since the Company development projects are often subject to regulatory approval procedures and other uncertainties, the conditions for the capitalization of costs incurred before receipt of approvals are not normally satisfied and therefore, development expenditures are recognized in profit or loss when incurred.

Software

The Company's assets include computer systems comprising hardware and software. Software forming an integral part of the hardware to the extent that the hardware cannot function without the programs installed on it is classified as property, plant and equipment. In contrast, software that adds functionality to the hardware is classified as an intangible asset.

The useful life of the aforementioned computer systems is five years.

n. Impairment of non-financial assets

The Company evaluates the need to record an impairment of the carrying amount of non-financial assets whenever events or changes in circumstances indicate that the carrying amount is not recoverable. If the carrying amount of non-financial assets exceeds their recoverable amount, the assets are reduced to their recoverable amount.

The recoverable amount is the higher of fair value less costs of sale and value in use. In measuring value in use, the expected future cash flows are discounted using a pre-tax discount rate that reflects the risks specific to the asset. The recoverable amount of an asset that does not generate independent cash flows is determined for the cash-generating unit to which the asset belongs.

An impairment loss of an asset, 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, shall not be increased above the lower of the carrying amount that would have been determined (net of depreciation or amortization) had no impairment loss been recognized for the asset in prior years and its recoverable amount.

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

o. Financial instruments

1. Financial assets

Financial assets within the scope of IAS 39 are initially recognized at fair value plus directly attributable transaction costs, except for financial assets measured at fair value through profit or loss.

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

a. Financial assets at fair value through profit or loss

Financial assets held for trading and derivative instruments that do not qualify for hedge accounting. Financial assets are classified as held for trading if they are acquired for the purpose of selling or repurchasing in the near term.

b. Loans and receivables

The Company has receivables that are financial assets with fixed or determinable payments that are not quoted in an active market. Loans are presented based on their terms, normally at face value plus direct transaction costs through the systematic amortization process and less incurred amortization.

c. Available for sale ("AFS") financial investments

AFS financial investments include debt securities. Debt securities in this category 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.

The Company has 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 it may sell these securities prior to maturity to meet liquidity needs or as part of risk versus reward objectives.

After initial measurement, AFS financial investments are subsequently measured at fair value with unrealized gains and losses recognized in other comprehensive income ("OCI") until the investment is derecognized or the investment is determined to be impaired. Interest earned whilst holding AFS financial investments is reported as financial income.

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

For AFS financial investments, the Company assesses at each reporting date whether there is objective evidence that an investment is impaired.

For debt instruments classified as AFS financial assets, objective evidence of impairment may arise as a result of one or more events that have a negative impact on the estimated future cash flows of the asset since the recognition of the asset. Where there is evidence of impairment, the cumulative loss - measured as the difference between the acquisition cost and the fair value - is reclassified from other comprehensive income and recognized as an impairment loss in profit or loss. In a subsequent period, the amount of the impairment loss is reversed if the increase in fair value can be related objectively to an event occurring after the impairment was recognized. The amount of the reversal, up to the amount of any previous impairment, is recorded in profit or loss.

2. Financial liabilities

Financial liabilities within the scope of IAS 39 are initially measured at fair value.

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

a. Financial liabilities measured at amortized cost

Loans, including debentures, are measured based on their terms at amortized cost using the effective interest method taking into account directly attributable transaction costs.

b. Financial liabilities measured at fair value through profit or loss

Derivatives, including separated embedded derivatives, are classified as held for trading unless they are designated as effective hedging instruments.

The group examines the existence of embedded derivative and the need to separate it on the date, the Company becoming side of the commitment. Revaluation of the need to separate the embedded derivative is done only when there is a change in the commitment, which impact significantly on the cash flow from the commitment.

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

3. Fair value

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

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

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

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

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

4. Offsetting financial instruments

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

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

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

5. Compound financial instruments

Convertible debentures which contain both an equity component and a liability component are separated into two components. This separation is performed by first determining the carrying amount of the liability component based on the fair value of an equivalent non-convertible liability. The carrying amount of the equity component is the residual amount. Direct transaction costs are apportioned between the equity component and the liability component based on the allocation of proceeds to the equity and liability components, as above. Conversion feature that is change in predetermined dates is accounted for as an equity component.

6. De-recognition of financial instruments

a. Financial assets

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

b. Financial liabilities

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

p. Derivative financial instruments designated as hedges

The Company enters into contracts for derivative financial instruments such as forward currency contracts and cylinder strategy in respect of foreign currency to hedge risks associated with foreign exchange rates fluctuations. Such derivative financial instruments are recognized at fair value.

At the inception of a hedge relationship, the Company formally designates and documents the hedge relationship to which the Company wishes to apply hedge accounting and the risk management objective and strategy for undertaking the hedge. The hedge effectiveness is assessed at the end of each reporting period.

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

Cash flow hedges

The effective portion of the gain or loss on the hedging instrument is recognized as other comprehensive income (loss), while any ineffective portion is recognized immediately in profit or loss.

Amounts recognized as other comprehensive income (loss) are reclassified to profit or loss when the hedged transaction affects profit or loss, such as when the hedged income or expense is recognized or when a forecast payment occurs.

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

q. Provisions

A provision in accordance with IAS 37 is recognized when the Group has a present (legal or constructive) obligation as a result of a past event, it is expected to require the use of economic resources to clear the obligation and a reliable estimate can be made of it.

r. Employee benefit liabilities

The Company has several employee benefit plans:

1. Short-term employee benefits

Short-term employee benefits include salaries, paid annual leave, paid sick leave, recreation and social security contributions and are recognized as expenses as the services are rendered. A liability in respect of a cash bonus or a profit-sharing plan is recognized when the Company has a legal or constructive obligation to make such payment as a result of past service rendered by an employee and a reliable estimate of the amount can be made.

2. Post-employment benefits

The plans are normally financed by contributions to insurance companies and classified as defined contribution plans or as defined benefit plans.

The Company has defined contribution plans pursuant to Section 14 to the Severance Pay Law under which the Group pays fixed contributions and will have no legal or constructive obligation to pay further contributions if the fund does not hold sufficient amounts to pay all employee benefits relating to employee service in the current and prior periods.

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

Contributions to the defined contribution plan in respect of severance or retirement pay are recognized as an expense when contributed concurrently with performance of the employee's services.

In addition the Company operates a defined benefit plan in respect of severance pay pursuant to the Severance Pay Law. According to the Law, employees are entitled to severance pay upon dismissal or retirement. The liability for termination of employment is measured using the projected unit credit method. The amounts are presented based on discounted expected future cash flows using a discount rate determined by reference to market yields at the reporting date on high quality corporate bonds that are linked to the Consumer Price Index with a term that is consistent with the estimated term of the severance pay obligation.

In respect of its severance pay obligation to certain of its employees, the Company makes current deposits in pension funds and insurance companies ("the plan assets"). Plan assets comprise assets held by a long-term employee benefit fund or qualifying insurance policies. Plan assets are not available to the Company's own creditors and cannot be returned directly to the Company.

The liability for employee benefits shown in the statement of financial position reflects the present value of the defined benefit obligation less the fair value of the plan assets.

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

s. Share-based payment transactions

The Company's employees and other service providers are entitled to remuneration in the form of equity-settled share-based payment transactions.

Equity-settled transactions

The cost of equity-settled transactions with employees is measured at the fair value of the equity instruments granted at grant date. The fair value is determined using a standard option pricing model.

As for other service providers, the cost of the transactions is measured at the fair value of the goods or services received as consideration for equity instruments. In cases where the fair value of the goods or services received as consideration of equity instruments cannot be measured, they are measured by reference to the fair value of the equity instruments granted.

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 entitled to the award ("the vesting period"). The cumulative expense recognized for equity-settled transactions at the end of each reporting period until the vesting date reflects the extent to which the vesting period has expired and the Company’s best estimate of the number of equity instruments that will ultimately vest.

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

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 the Company modifies 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.

t. Income (loss) per Share

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

u. Reclassification

During the year, the Company changed the classification of premium amortization on investment of corporate bonds in profit or loss from Financial expenses to Financial income (i.e. the amortization of premium will reduce the interest income from corporate bonds).

Comparative data in the amount of $1,207 thousands and $ 11 thousands in 2014 and 2013, respectively were reclassified from Financial expenses to Financial income.

NOTE 3: - SIGNIFICANT ACCOUNTING JUDGMENTS, ESTIMATES AND ASSUMPTIONS USED IN THE PREPARATION OF THE FINANCIAL STATEMENTS

Judgments

Revenue

The Company assesses the criteria for recognition of revenue related to up-front payments and multiple components as outlined by IAS 18, Revenue. Judgment is necessary to determine over which period the Company will satisfy its obligations related to up-front payments and when components can be recognized separately and the allocation of the related consideration to each component.

NOTE 3: - SIGNIFICANT ACCOUNTING JUDGMENTS, ESTIMATES AND ASSUMPTIONS USED IN THE PREPARATION OF THE FINANCIAL STATEMENTS(CONT.)

Estimates and assumptions

The key assumptions made in the financial statements concerning uncertainties at the end of the reporting period and the critical estimates computed by the Company that may result in a material adjustment to the carrying amounts of assets and liabilities within the next financial year are discussed below.

- Legal claims

  In estimating the likelihood of outcome of legal claims filed against the Company and its investees, the companies rely on the opinion of their legal counsel. These estimates are based on the legal counsel's best professional judgment, taking into account the stage of proceedings and historical legal precedents in respect of the different issues. Since the outcome of the claims will be determined in courts, the results could differ from these estimates.

- Pensions and other post-employment benefits

  The liability in respect of post-employment defined benefit plans is determined using actuarial valuations. The actuarial valuation involves making assumptions about, among others, discount rates, expected rates of return on assets, future salary increases and mortality rates. Due to the long-term nature of these plans, such estimates are subject to significant uncertainty.

- Determining the fair value of share-based payment transactions

  The fair value of share-based payment transactions is determined using an acceptable option pricing model.

  The assumptions used in the model include the share price, exercise price, expected volatility, exercise multiple, expected life, expected dividend and risk-free interest rate.

- Provisions for clinical trial and related expenses

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

- Inventory

  Inventory that is produced following a change in manufacturing process prior to final approval of regulatory authorities is subject to Company estimates as to the probability of receipt of such approval and its ability to sell such inventory with its remaining shelf life. The Company is periodically reassessing the probability of such approval and remaining shelf life of such inventory to determine whether the net realizable value is lower than cost. Once the regulatory approval is not granted the cost of this inventory will be charge to research and development expenses.

NOTE 4: - DISCLOSURE OF NEW IFRS IN THE PERIOD.

a. IFRS 15 – Revenues from contracts with customers

The standard outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. The core principle of the new standard is for companies to recognize revenue to depict the transfer of goods or services to customers in amounts that reflect the consideration (that is, payment) to which the Company expects to be entitled in exchange for those goods or services. The new standard also will result in enhanced disclosures about revenue, provide guidance for transactions that were not previously addressed comprehensively (for example, service revenue and contract modifications) and improve guidance for multiple-element arrangements.

IFRS 15 is to be applied retrospectively for annual periods beginning on or after January 1, 2018. Early adoption is permitted. IFRS 15 allows an entity to choose to apply a modified retrospective approach.

The Company is evaluating the possible impact of IFRS 15 but is presently unable to assess its effect, if any, on the financial statements.

b. IFRS 9 - Financial Instruments

In July 2014, the IASB completed the final element of its comprehensive response to the financial crisis by issuing IFRS 9Financial Instruments. The package of improvements introduced by IFRS 9 includes a logical model for classification and measurement, a single, forward-looking ‘expected loss’ impairment model and a substantially-reformed approach to hedge accounting.

IFRS 9 is to be applied for annual periods beginning on January 1, 2018. Early adoption is permitted.

The Company is evaluating the possible impact of IFRS 9 but is presently unable to assess its effect, if any, on the financial statements.

c. IFRS 16 – Leases

In January 2016, the IASB issued IFRS 16, Leases. IFRS 16, that replaces IAS 17, Leases, will only imply insignificant changes to the accounting for lessors. For lessees, the accounting will change significantly, as all leases (except short term leases and small asset leases) will be recognized on balance. Initially, the lease liability and the right-of-use asset is measured at the present value of future lease payments (defined as economically unavoidable payments). The right-of-use asset is subsequently depreciated in a similar way to other assets such as tangible assets, i.e. typically in a straight-line over the lease term. The new Standard is effective for annual periods beginning on or after January 1, 2019. Earlier application is permitted provided that IFRS 15, "Revenue from Contracts with Customers", is applied concurrently.

NOTE 4: - DISCLOSURE OF NEW IFRS IN THE PERIOD (CONT.)

The Company is evaluating the possible impact of IFRS 16 but is presently unable to assess its effect, if any, on the financial statements.

NOTE 5: - CASH AND CASH EQUIVALENTS

	December 31,	
	2015	2014
	In thousands	
Cash and deposits for immediate withdrawal	$ 4,957	$ 8,382
Cash equivalents in USD deposits	-	6,000
Cash equivalents in NIS deposits (1)	90	164
	$ 5,047	$ 14,546

(1) The deposits as of December 31, 2015 and 2014 bear interest set by period 0.01% per year, and 0.02%-0.12%, respectively.

NOTE 6: - SHORT-TERM INVESTMENTS

	December 31,	
	2015	2014
	In thousands	
Marketable securities (equity and debt) at fair value through profit or loss	$ 1,425	$ 8,820
Available for sale debt securities	21,834	28,530
	$ 23,259	$ 37,350

NOTE 7: - TRADE RECEIVABLES, NET

	December 31,	
	2015	2014
	In thousands	
Open accounts (1):		
In NIS	$ 10,294	$ 7,988
In USD	12,771	9,744
	23,065	17,732
Checks receivable	404	215
	23,469	17,947
Less allowance for doubtful accounts (2)	(398)	(433)
Trade receivables, net	$ 23,071	$ 17,514

(1) Customer debts do not bear interest. The average number of customer credit days is 80 days and 76 days as of December 31, 2015 and 2014, respectively.

(2) Allowance for doubtful accounts:

December 31, 2014	$ (433)
Deductions	35
December 31, 2015	$ (398)

An analysis of past due but not impaired trade receivables with reference to reporting date:

		Past due trade receivables with aging of					
	Neither past due nor impaired	Up to 30 Days	30-60 Days	60-90 Days	90-120 Days	Over 120 days	Total
	In thousands						
December 31, 2015	$ 20,022	$ 2,212	$ 376	$ 4	$ -	$ 53	$ 22,667
December 31, 2014	$ 15,133	$ 1,187	$ 662	$ 146	$ 23	$ 148	$ 17,299

NOTE 8: - OTHER ACCOUNTS RECEIVABLES

	December 31,	
	2015	2014
	In thousands	
Materials for clinical trials and inventory designated for R&D activities	$ 796	$ 231
Prepaid expenses	875	1,149
Government authorities	905	674
Receivables for unpaid interest	241	249
Financial derivatives, net	34	-
Other	30	56
	$ 2, 881	$ 2,359

NOTE 9: – INVENTORIES

	December 31,	
	2015	2014
	In thousands	
Finished products (1)	$ 10,583	$ 9,999
Purchased products	6,365	5,743
Work in progress	4,487	6,109
Raw materials	4,901	3,572
	$ 26,336	$ 25,423

(1) During the years 2015 and 2014, the Company recorded a write off at an amounted of $1,091 thousands and $3,952 thousands, respectively.

NOTE 10: – PROPERTY, PLANT AND EQUIPMENT

a. Composition and movement:

2015

	Land and Buildings(1)	Machinery and Equipment (1)	Vehicles	Computers, Equipment and Office Furniture	Leasehold Improvements	Total
	In thousands					
Cost						
Balance at January 1, 2015	$ 26,261	$ 22,273	$ 94	$ 4,159	$ 1,056	$ 58,843
Additions	440	1,838	-	417	23	2,718
Balance as of December 31, 2015	26,701	24,111	94	4,576	1,079	56,561
Accumulated Depreciation						
Balance as of January 1, 2015	9,828	17,929	78	3,235	1,004	32,074
Additions	1,409	1,381	5	375	8	3,178
Balance as of December 31, 2015	11,237	19,310	83	3,610	1,012	35,252
Depreciated cost as of December 31, 2015	$ 15,464	$ 4,801	$ 11	966	$ 67	$ 21,309

NOTE 10: – PROPERTY, PLANT AND EQUIPMENT (CONT.)

2014

	Land and Buildings(1)	Machinery and Equipment (1)	Vehicles	Computers, Equipment and Office Furniture	Leasehold Improvements	Total
	In thousands					
Cost						
Balance at January 1, 2014	$ 25,057	$ 20,859	$ 86	$ 3,791	$ 1,010	$ 50,803
Additions	1,204	1,417	8	372	46	3,047
Sale of property and equipment	-	(3)	-	(4)	-	(7)
Balance as of December 31, 2014	26,261	22,273	94	4,159	1,056	53,843
Accumulated Depreciation						
Balance as of January 1, 2014	8,511	16,912	73	2,864	1,000	29,360
Additions	1,317	1,020	5	374	4	2,720
Sale of property and equipment	-	(3)	-	(3)	-	(6)
Balance as of December 31, 2014	9,828	17,929	78	3,235	1,004	32,074
Depreciated cost as of December 31, 2014	$ 16,433	$ 4,344	$ 16	$ 924	$ 52	$ 21,769

(1) Including labor costs charged in 2015 and 2014 to the cost of facilities, machinery and equipment in the amount of $317 thousands and $609 thousands, respectively.

b. As for liens, refer to Note 19.

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

	December 31,	
	2015	2014
	In thousands	
Under finance lease	$ 1,040	$ 1,051

The Group has capitalized leasing rights from the Israel Land Administration for an area of 16,880 m² in Beit Kama containing the Group's structures. The sum attributed to capitalized rights is presented under property, plant and equipment and is depreciated over the leasing period, which includes the option period.

During 2010, the Company signed an agreement with the Israel Land Administration to consolidate its leasing rights and extend the lease period to 2058, including an extension option for additional 49 years.

NOTE 11: - OTHER LONG TERM ASSETS

	December 31,	
	2015	2014
	In thousands	
Long term leasing deposits	$ 35	$ 76
Intangibles assets, net	54	103
	$ 89	$ 179

Amortization expenses of intangible assets in the amount of $49 thousands and $68 thousands for 2015 and 2014, respectively, are classified under general and administrative expenses.

NOTE 12: – CURRENT MATURITIES OF LOANS AND CONVERTIBLE DEBENTURE

	Linked to NIS	
	December 31,	
	2015	2014
	In thousands	
Long term loan	37	-
Convertible debenture	-	7,492
	37	7,492

NOTE 13: - TRADE PAYABLES

	December 31,	
	2015	2014
	In thousands	
Open debts mainly in USD	$ 13,066	$ 13,075
Open debts in NIS	3,727	3,277
	16,793	16,352
Notes payable	124	178
	$ 16,917	$ 16,530

Supplier debts do not bear interest. The average number of supplier credit days is 66 days and 107days as of December 31, 2015 and 2014, respectively.

NOTE 14: – OTHER ACCOUNTS PAYABLES

	December 31,	
	2015	2014
	In thousands	
Employees and payroll accruals	$ 3,338	$ 3,045
Derivatives instruments	-	76
Accrued Expenses and Others	726	924
	$ 4,064	$ 4,045

NOTE 15: - LONG TERM LIABILITIES

a. Convertible debentures

The debentures are unlinked and bear variable yearly interest plus a yearly margin of 6.1% over the yearly interest rate born by "Israeli Government Bonds 817" throughout the interest period. The debentures are convertible on each business day, and each NIS 37.12 par value of debentures (Series C) shall be convertible to one ordinary share of NIS 1 par value.

On December 1, 2015 and 2014, the Company paid an amount of $ 7,797 thousands and $ 7,728 thousands, respectively, of the principal amount.

As of December 31, 2015, the Company had no par value outstanding.

b. Bank loan

On October 2015 the Company took a loan at an amount of NIS 770 thousands. The loan will be paid over 60 equal monthly installments. The loan bears fixed interest rate of 3.45%. As for pledges, refer to Note 19.

NOTE 16: - FINANCIAL INSTRUMENTS

a. Classification of financial assets and liabilities

The financial assets and financial liabilities in the balance sheet are classified by groups of financial instruments in pursuant to IAS 39:

	December 31,	
	2015	2014
	In thousands	
Financial assets		
Financial assets at fair value:		
Marketable securities (equity and debt) – through profit or loss	$ 1,425	$ 8,820
Financial assets at fair value through other comprehensive income:		
Available for sale debt securities	21,834	28,530
Derivative instruments	34	-
	$ 23,293	$ 37,350
Financial liabilities		
Financial liabilities at fair value through profit or loss:		
Derivatives instruments	$ -	$ 76
Financial liabilities measured at amortized cost:		
Bank loan	188	-
Convertible debentures	-	7,492
	$ 188	$ 7,492

NOTE 16: - FINANCIAL INSTRUMENTS (CONT.)

b. Financial risk factors

The Company's activities expose it to various financial risks, such as market risk (foreign currency risk, interest rate risk and price risk), credit risk and liquidity risk. The Company's comprehensive risk management plan focuses on activities that reduce to a minimum any possible adverse effects on the Company's financial performance. The Company utilized derivatives to hedge certain exposures to risk.

Risk management is the responsibility of the Company CEO and CFO, in accordance with the policy approved by the Board of Directors. The Board of Directors provides principles for the overall risk management.

1. Market risks

a) Foreign exchange risk

The Company operates in an international environment and is exposed to foreign exchange risk resulting from the exposure to different currencies, mainly the NIS. Foreign exchange risks arise from recognized assets and liabilities denominated in a foreign currency other than the functional currency, such as customers, suppliers and credit.

As of December 31, 2015, the Company has a position in derivatives intended to hedge decreases in the exchange rate of the USD vs. the NIS, over excess receipts in the NIS expected for 2015 (see also f. below).

b) Interest rate risk

The Company is exposed to risks of changes in the market interest rates on financial debenture assets with floating interest rates. The Company's interest rate risk mainly derives from financial debenture assets.

c) Price risk

As of December 31, 2015, the Company has financial instruments, shares and debentures, classified as financial assets measured at fair value through profit or loss and Available for sale financial investments, for which the Company is exposed to risk of fluctuations in the security price that is determined by reference to the quoted market price.

NOTE 16: - FINANCIAL INSTRUMENTS (CONT.)

2. Credit risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents, short-term bank deposits, marketable securities, trade receivables and foreign currency derivative contracts.

a) Trade receivables:

Average credit days for trade receivables are 80 days. The Company regularly monitors the credit extended to its customers and their general financial condition, and, when necessary, requires collateral as security for these debts such as letters of creditor and down payments. In addition, the Company partially insures its overseas sales with foreign trade risk insurance.

The Company keeps constant track of customer debt and the Financial Statements include an allowance for doubtful accounts that adequately reflects, in the Company's assessment, the loss embodied in the debts the collection of which is in doubt.

The Company maximum exposure to credit risk for the components of the statement of financial position as of December 31, 2015 and 2014 is the carrying amount of trade receivables.

b) Cash and cash equivalent and short term investments:

The Company holds cash, cash equivalents and other financial instruments at major financial institutions in Israel and in the U.S. In accordance with Company policy, evaluations of the relative strength of credit of the various financial institutions are made on an ongoing basis.

Short-term investments include short-term deposits with low risk for a period less than three months. The Company’s marketable securities consist of investment-grade corporate bonds, U.S and Israeli Governments bonds and equity investments. The Company’s investment policy, limits the amount the Company may invest in any one type of investment or issuer and the average maturities of the bond portfolio, thereby reducing credit risk concentrations.

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

c) Foreign currency derivative contracts:

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

NOTE 16: - FINANCIAL INSTRUMENTS (CONT.)

3. Liquidity risk

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

December 31, 2015

	Less than one year	1 to 2	2 to 3	3 to 5	Total
	In thousands				
Trade payables	$ 16,917	-	-	-	$ 16,917
Other accounts payables	4,064	-	-	-	4,064
Long term loan (including interest)	43	43	43	75	204
	$ 21,024	$ 43	$ 43	$ 75	$ 21,185

December 31, 2014

	Less than one year	1 to 2	2 to 3	3 to 5	Total
	In thousands				
Trade payables	$ 16,530	-	-	-	$ 16,530
Other accounts payables	4,045	-	-	-	4,045
Convertible debentures (including interest)	8,275	-	-	-	8,275
	$ 28,850	$ -	$ -	$ -	$ 28,850

c. Fair value

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

	Carrying Amount		Fair Value	
	December 31,		December 31,	
	2015	2014	2015	2014
	In thousands			
Financial liabilities				
Bank loan	$ 188	$ -	$ 185	$ -
Convertible debentures	$ -	$ 7,492	$ -	$ 8,065

The fair value of the bank loan was based on standard pricing valuation model such as DCF which considers the present value of future cash flows discounted at the interest rate that reflects market conditions (Level 3).

The fair value of the Convertible debenture was based on quoted prices in the Israeli Tel Aviv stock exchange (Level 1).

The carrying amount of cash and cash equivalents, trade and other receivables, trade and other payables approximates their fair value, due to the short term maturities of the instruments.

NOTE 16: - FINANCIAL INSTRUMENTS (CONT.)

d. Classification of financial instruments by fair value hierarchy

Financial assets measured at fair value:

	Level 1	Level 2
	In thousands	
December 31, 2015		
Marketable securities at fair value through profit or loss:		
Equity shares	$ 67	$ -
Mutual funds	365	-
Debt securities (corporate and government)	993	-
Derivatives instruments	-	34
Available for sale debt securities (corporate and government)	-	21,834
	$ 1,425	$ 21,868

	Level 1	Level 2
	In thousands	
December 31, 2014		
Marketable securities at fair value through profit or loss:		
Equity shares	$ 587	$ -
Mutual funds	577	-
Exchange traded notes	46	-
Debt securities (corporate and government)	7,610	-
Available for sale debt securities (corporate and government)	-	28,530
	$ 8,820	$ 28,530

Financial liabilities measured at fair value:

	Level 1	Level 2
	In thousands	
December 31, 2014		
Derivatives instruments qualified for hedging	$ -	$ 76

During 2015 there was no transfer due to the fair value measurement of any financial instrument from Level 1 to Level 2, and furthermore, there were no transfers to or from Level 3 due to the fair value measurement of any financial instrument.

NOTE 16: - FINANCIAL INSTRUMENTS (CONT.)

	December 31,	
	2015	2014
	In thousands	
Sensitivity test to changes in market price of listed Securities		
Gain (loss) from change:		
5% increase in market price	$ 1,163	$ 1,868
5% decrease in market price	$ (1,163)	$ (1,868)

Sensitivity test to changes in interest rates		
Gain (loss) from change:		
1% interest rate increase	$ -	$ (105)
1% interest rate decrease	$ -	$ 105

Sensitivity test to changes in foreign currency:		
Gain (loss) from change:		
5% increase in NIS	$ 300	$ 239
5% decrease in NIS	$ (300)	$ (239)
5% increase in Euro	$ (147)	$ (247)
5% decrease in Euro	$ 147	$ 247

Sensitivity tests and principal work assumptions

The selected changes in the relevant risk variables were determined based on management's estimate as to reasonable possible changes in these risk variables.

The Company has performed sensitivity tests of principal market risk factors that are liable to affect its reported operating results or financial position. The sensitivity tests present the profit or loss in respect of each financial instrument for the relevant risk variable chosen for that instrument as of each reporting date. The test of risk factors was determined based on the materiality of the exposure of the operating results or financial condition of each risk with reference to the functional currency and assuming that all the other variables are constant.

e. Linkage terms of financial liabilities by groups of financial instruments pursuant to IAS 39:

	December 31,	
	In thousands	
	2015	2014
In NIS:		
Bank loan measured at amortized cost	188	-
Convertible debenture measured at amortized cost	$ -	$ 7,492

NOTE 16: - FINANCIAL INSTRUMENTS (CONT.)

f. Derivatives and hedging:

Derivatives instruments not designated as hedging

The Company has foreign currency forward contracts designed to protect it from exposure to fluctuations in exchange rates in respect of its transactions. Foreign currency forward contracts are not designated as cash flow hedges, fair value or net investment in a foreign operation, and they are signed for identity for which the Company exposure to foreign currency for transactions. These derivatives are not considered in hedge accounting. As of December 31, 2015 the fair value of the derivative instruments not designated as hedging was an asset of $34.4 thousands. The open transactions for those derivatives were in an amount of $21.4 million.

Cash flow hedges:

As of December 31, 2015, the Company held NIS/USD hedging contracts (cylinder contracts) designated as hedges of expected future salaries expenses and for expected future purchases from Israeli suppliers.

The main terms of these positions were set to match the terms of the hedged items. As of December 31, 2015 the fair value of the derivative instruments designated as hedge accounting was a liability of $0.5 thousands. The open transactions for those derivatives were in an amount of $4.8 million.

Cash flow hedges of the expected salaries expenses in December 31, 2015 was estimated as highly effective and accordingly a net unrecognized loss was recorded in other comprehensive income (loss) in the amount of $ one thousand.

NOTE 17: - EMPLOYEE BENEFIT LIABILITIES, NET

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

a. Post-employment benefits:

According to the labor laws and Severance Pay Law in Israel, the Company is required to pay compensation to an employee upon dismissal or retirement or to make current contributions in defined contribution plans pursuant to Section 14 to the Severance Pay Law, as specified below. The Company's liability is accounted for as a post-employment benefit. The computation of the Company's employee benefit liability is made in accordance with a valid employment contract or a collective employees agreement based on the employee's salary and employment term which establish the entitlement to receive the compensation.

The post-employment employee benefits are normally financed by contributions classified as defined benefit plans, as detailed below:

1. Defined contribution deposit:

The Company’s agreements with part of its employees are in accordance with section 14 of the Israeli Severance Pay Law. Payments in accordance with Section 14 release the Company from any future severance liabilities in respect of those employees. Some of the employees are partly under Section 14 and partly under the defined benefit deposit. The expenses for the defined benefit deposit in 2015, 2014 and 2013 were $ 702 thousands, $ 453 thousands and $130 thousands, respectively.

NOTE 17: - EMPLOYEE BENEFIT LIABILITIES, NET (CONT.)

2. Defined benefit plans:

The Company accounts for the payment of compensation, as a defined benefit plan for which an employee benefit liability is recognized and for which the Company deposits amounts in central severance pay funds and in qualifying insurance policies.

3. Expenses recognized in comprehensive income (loss):

	Year Ended December 31,		
	2015	2014	2013
	In thousands		
Current service cost	$ 391	$ 455	$ 636
Interest expenses, net	18	23	24
Current service cost due to the transfer of real yield from the compensation component to the royalties component in executive insurance policies before 2004.	(10)	(9)	1
Total employee benefit expenses	$ 399	$ 469	$ 661
Actual (negative) return on plan assets	$ (12)	$ 295	$ 250

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

	Year Ended December 31,		
	2015	2014	2013
	In thousands		
Cost of revenues	$ 209	$ 244	$ 450
Research and development	90	101	118
Selling and marketing	18	14	17
General and administrative	82	110	76
	$ 399	$ 469	$ 661

NOTE 17: - EMPLOYEE BENEFIT LIABILITIES, NET (CONT.)

4. The plan assets (liabilities), net:

	December 31,	
	2015	2014
	In thousands	
Defined benefit obligation	$ (5,425)	$ (5,496)
Fair value of plan assets	4,638	4,774
Total liabilities, net	$ (787)	$ (722)

5. Changes in the present value of defined benefit obligation

	2015	2014
	In thousands	
Balance at January 1,	$ 5,496	$ 5,539
Interest costs	147	178
Current service cost	390	455
Benefits paid	(471)	(120)
Demographic assumptions	(7)	(5)
Financial assumptions	-	9
Currency Exchange	(130)	(560)
Balance at December 31,	$ 5,425	$ 5,496

6. Plan assets

a) Plan assets

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

NOTE 17: - EMPLOYEE BENEFIT LIABILITIES, NET (CONT.)

b) Changes in the fair value of plan assets

	2015	2014
	In thousands	
Balance at January 1,	$ 4,774	$ 4,712
Expected return	128	155
Contributions by employer	283	338
Benefits paid	(402)	(25)
Demographic assumptions	1	-
Financial assumptions	-	3
Current service cost due to the transfer of real yield from the compensation component to the royalties component in executive insurance policies before 2004.	10	9
Currency exchange	(156)	(418)
Balance at December 31,	$ 4,638	$ 4,774

7. The principal assumptions underlying the defined benefit plan

	2015	2014	2013
		%	
Discount rate of the plan liability	4.8	4	4.23
Future salary increases	4	4	4

The sensitivity analyses below have been determined based on reasonably possible changes of the principal assumptions underlying the defined benefit plan as mentioned above, occurring at the end of the reporting period.

If the discount rate would be one percent higher (lower), the defined benefit obligation would decrease (increase) by $198 thousands ($294 thousands) if all other assumptions were held constant.

If the expected salary growth would increase by 1% the defined benefit obligation would increase by $273 thousands.

In November 2014, the staff of the Israel Securities Authority issued Accounting Position Paper No. 21-1 regarding the existence in Israel of a deep market in high quality corporate bonds ("the Position Paper") for the purpose of determining, in accordance with IAS 19, the discount rate to be used for defined benefit obligations and other long-term benefits in the Israeli currency. According to the Position Paper, the transition from the use of yields based on Government bonds to market yields based on high quality corporate bonds linked to the Consumer Price Index should be accounted for prospectively as a change in accounting estimate. The effect of the change in the discount rate is immaterial.

NOTE 18: - CONTINGENT LIABILITIES AND COMMITMENTS

a. On August 23, 2010, the Company entered into a collaboration agreement with Baxter Healthcare Corporation ("Baxter"), an international biopharmaceutical company traded on the New York Stock Exchange, and specializing, among other things, in the development, manufacture, marketing and sale of pharmaceutical products. During 2015, Baxter has assigned all its rights under the collaboration agreement to Baxalta US Inc. ("Baxalta"). The collaboration agreement consists of three main agreements (1) the appointment of Baxalta as the sole distributer of the Company's AAT IV drug (" Glassia ") in the United States, Canada, Australia and New Zealand ("the Territory" and "the Distribution Agreement", respectively); (2) granting licenses to Baxalta for the use of the Company's knowhow and patents for the production, continued development and sale of Glassia and other IV products by Baxalta ("the License Agreement") in the Territory and (3) an agreement to provide raw materials, produced by Baxalta, and used for the production of Glassia ("the Raw Materials Supply Agreement"). Pursuant to the agreements, payments were set for the Company for meeting milestones at a total sum of $45 million, Glassia purchases at a minimum sum of $ 60 million over the first five years from the signing of the distribution agreement and royalties at a sum of no less than $5 million per year, starting from the beginning of the sale of Glassia produced by Baxalta in accordance with the License Agreement. Net sums received in advance were recorded as deferred revenues and are recognized as revenues according to the actual rate of sales, according to the sales forecast, in the Distribution Agreement period, which is currently expected to end by the end of 2018, with the start of production by Baxalta. Non-refundable revenues due to the achievement of milestones are recognized upon reaching the milestone.

In the case of clinical trials required in the Territory in connection with Glassia, the cost of these experiments apply to Baxalta and the Company will participate with such limited extent that may come, under certain conditions, up to $10 million over a period of several years.

According to the raw material supply agreement, which replaces a previous agreement between the parties, Baxalta undertook to provide the Company raw material used to produce the Glassia and other products of the Company. Baxalta will provide the Company, free of charge, all the quantities of raw materials required by the Company for manufacturing the Glassia sold to Baxalta for distribution by Baxalta accordance with the Distribution Agreement. In addition, Baxalta will provide raw material to the Company, for the development, production, sale and distribution of products by the Company.

The agreements expires in 2040, subject to the possibility of earlier termination due to events mentioned in the agreement.

Since 2013 and every year thereafter, the parties amended the license agreement and the distribution agreement by extending the period of minimum purchases of Glassia and the minimum purchase quantity.

NOTE 18: - CONTINGENT LIABILITIES AND COMMITMENTS (CONT.)

The latest amendment to the license agreement and the distribution agreement entered into on October 16, 2015.

The amendment extended the period of minimum purchases of Glassia to a total of eight years until 2018. The amendment increased the minimum revenue to $240 million compared with a minimum of $110 million in the original agreement executed in 2010.

In addition, the supply of Glassia to Baxalta has been extended through 2018 and the transition to royalty payments for Glassia produced by Baxalta is not expected to begin before 2019.

As of December 31, 2015, the Company received a total of $34.5 million for the achievement of part of the milestones and an advance in respect of the distribution agreement.

b. On August 2, 2012, the Company entered into a strategic agreement with CHIESI FARMACEUTICI S. P. A, a fully integrated European Pharmaceutical company focused on respiratory disease and special care products ("Chiesi "). According to the agreement, Chiesi will be an exclusive distributor of the AAT inhaled product of the Company for treatment of alpha-1 antitrypsin deficiency ("Product") in Europe. Chiesi will be responsible for, among other things, product marketing, patients screening and obtaining reimbursement approvals for the product ("distribution agreement"). As part of the distribution agreement, the Company shall be entitled to receive payments of up to $ 60 million, contingent of meeting regulatory and sales milestones. In addition, Chiesi has committed to purchase products in minimum quantities during a period of five years commencing after receiving reimbursement approvals required. The agreement is for a period of 12 years from signature.

In August, 2012, the Company received non-refundable upfront payment for the first milestone in the agreement. This amount was recorded under deferred revenue and revenue is recognized on a straight line basis over the expected period of achieving the milestone.

c. In accordance with the Law for the Encouragement of Industrial Research and Development, 1984, the Company received grants from the State of Israel for its research and development expenses, carried out pursuant to plans approved by the office of the Chief Scientist ("OCS"). In accordance with the letters of approval in question, the Company has undertaken to pay royalties to the OCS, calculated on the basis of the proceeds from the sale of products the Company took part in developing. The Company completed its obligation to pay royalties for active projects. The balance of the maximum sum of royalties for inactive projects, according to the Company's estimates, amounts to $ 469 thousands as of December 31, 2015. In April 2008, the Company filed a request to close inactive files, which was partially rejected by the OCS in September 2010, on grounds that the Company was making use of the knowhow accumulated in these files and it was required to pay royalties for certain products. During 2015 the Company paid a total amount of $ 92 thousands for OCS royalty payment. As of December 31, 2105 there is no provision for the OCS.

NOTE 18: - CONTINGENT LIABILITIES AND COMMITMENTS (CONT.)

d. The Company has engaged in operating lease agreements for office and storage spaces. These agreements will expire between 2016 and 2017.

Minimum future lease fees for the office and storage spaces as of December 31, 2015 are as follows:

	In thousands
2016	326
2017	82
	408

e. The Company has engaged in operating lease agreements for the vehicles in its possession. These agreements will expire between 2016 and 2018.

Minimum future lease fees for the existing vehicles as of December 31, 2015 are as follows:

	In thousands
2016	428
2017	180
2018	28
	636

f. In November 2006, an agreement was signed between the Company and a third party on the matter of research and development collaboration. As part of the agreement, the Company was licensed to use developments made by the third party. Furthermore, the third party will provide the Company with devices for carrying out the clinical trials, free of charge. In the event that the development is successful, the Company will pay the third party royalties based on sales of the devices. This obligation on behalf of the Company to pay royalties shall expire either when the patents expire or 15 years from the first commercial sale, whichever comes last. On the date of the expiry of the royalty period, the license will become non-exclusive and the Company shall be entitled to use the rights granted to it pursuant to the agreement without paying royalties or any other compensation. In addition, the third party would pay royalties of the total net sales exceeding a certain sum, according to a mechanism set in the agreement, until the patent expires or until 15 years pass from the first date of sale, whichever is earlier.

In February 2008, the parties signed an amendment to the agreement according to which the exclusive global license granted to the Company was expanded to two additional indications. It was also decided that sales to the additional indications would be added to the sales of the first two outlines covered by the original agreement. Royalties' payments will be according to the royalty model set in the original agreement.

NOTE 18: - CONTINGENT LIABILITIES AND COMMITMENTS (CONT.)

In addition, the parties signed a commercialization and supply agreement, which ensures long-term regular supply of the device at the basis of the collaboration and spare parts of this device.

g. In August 2007, the Company entered into a long-term agreement with a multinational European company for the purchase of a raw material used for the development and manufacture of medicines at graded amounts and prices. In addition to the price paid by the Company for the raw material, the Company will pay the supplier an additional sum upon the sale of the product manufactured from the raw material in the territories set in the agreement, after receiving regulatory approvals. As of December 31, 2015, the regulatory approval was not yet received.

h. On June 30, 2015 the Company's shareholders approved the employment terms of Mr. Amir London in his position as the Company's chief executive officer ("CEO"), effective as of July 1, 2015. Under the employment agreement, Mr. Amir London is entitled to a monthly gross salary of NIS 65,000 (or $16,658).

i. On July 1, 2015 Mr. David Tsur, who had served as the Company's CEO and as a Board member since the Company's inception in 1990, was replaced by Mr. Amir London as the Company's CEO and was appointed as the Active Deputy Chairman of the Board on a half-time basis, effective as of such date. Under the employment agreement, as amended, David Tsur is entitled to a monthly gross salary of NIS 45,000 (or $11,658) in addition to the cash consideration paid as a Board Member.

During 2014 the Company recorded $27 thousands, for bonus to Mr. Tsur. There was no record for bonus to Mr. Tsur in 2015.

j. In October 2009, the Company entered into an agreement with a company specializing in administering clinical trials, Contract Research Organization ("CRO"), which will serve as CRO for the clinical trial (Phase II/III) in Europe for the inhaled AAT drug used for the treatment of AAT Deficiency. The study was extended in 2013 for an additional 12 months treatment for eligible patients. The total scope of payments to the CRO may reach $14.6 million, payable over the trial period, which was completed on December 14, 2014, and the additional results analysis over 2015. This amount was recorded in R&D expenses in accordance with its actual scope and progress rate. The payments include payments made through the CRO to the trial sites and to the various service providers regarding the trial at sums and payment conditions set following negotiations between the CRO and those sites and suppliers, and which were approved in advance by the Company. As of December 31, 2015, the Company accrued a provision of $0.4 million.

In October 2013, the Company entered into an agreement with another CRO for its phase II clinical trial for treatment of AAT for newly diagnosed type one diabetes patients. The total scope of payment to the CRO may reach $5.6 million, payable over the trial period which was initially designed to last over four years, including payments to trial sites and various service providers in the trial The completion of the trial was accelerated during 2015 and the parties are negotiating an amendment to reflect the change to the trial.

NOTE 18: - CONTINGENT LIABILITIES AND COMMITMENTS (CONT.)

In June 2013, the Company entered into an agreement with another CRO for its phase II clinical trial for the inhaled AAT drug used for the treatment of AAT deficiency. The total scope of payment to the CRO may reach $3.9 million, payable over the trial period which is expected to last over two years, including payments to trial sites and various service providers in the trial. In 2015, the parties agreed to increase the service fees for the CRO for additional services to be performed during the study, which is included in the scope mentioned above.

k. On July 19, 2011, the Company signed a strategic collaboration agreement with an international pharmaceutical company in the area of clinical development, marketing and sales in the United States of a post exposure profilacsys for the prevention of rabies in human beings, KamRAB, which was developed, manufactured and marketed by the Company. According to the agreement, the partner shall bear all of the costs required to carry out the third stage clinical trial. It was agreed that the costs involved in registering the drug at the U.S. Food and Drug Administration (FDA) will be divided equally between the parties. As of December 31, 2015 the study was completed and it had met the trial's primary endpoint. The Company expects to submit Biologics License Application (BLA) with the U.S. Food and Drug Administration (FDA) during 2016.

NOTE 19: - GUARANTEES AND CHARGES

1. In order to guarantee the rental payments for an office in Ness Ziona and other obligations, the Company provided bank guarantees as of December 31, 2015, in the amount of $ 174 thousands.

2. As collateral for the Company's loan in amount of NIS 770 thousands, the Company has pledged a specific asset which is the subject of this loan.

NOTE 20: - EQUITY

a. share capital

	December 31, 2015		December 31, 2014	
	Authorized	Outstanding	Authorized	Outstanding
ordinary shares of NIS 1 par value	60,000,000	36,418,741	60,000,000	35,988,563

b. Rights attached to Shares

Voting rights at the shareholders general meeting, rights to dividend, rights in case of liquidation of the Company and rights to nominate directors.

NOTE 20: - EQUITY (CONT.)

c. Convertible debentures and share options

During 2015, and 2014, 430,178 and 35,133 share options, respectively, were exercised into 430,178 and 27,837 ordinary shares of NIS 1 par value each for consideration of $1,253 thousands and $83 thousands, respectively.

On December 1, 2015 the Company paid all the remaining of outstanding convertible debenture (Series C) of NIS 1 par value. In 2015 there were no conversions to ordinary shares.

Regarding options granted to employees, see Note 21 below.

d. Capital management in the Company

The Company's goals in the management of its capital are to preserve capital ratios that will ensure stability and liquidity to support business activity and create maximum value for shareholders.

NOTE 21: - SHARE-BASED PAYMENT

a. Expense recognized in the financial statements

The share based payment expense that was recognized for services received from employees and directors is presented in the following table:

	For the Year Ended December 31		
	2015	2014	2013
	In thousands		
Cost of revenues	$ 564	$ 1,136	$ 406
Research and development	390	725	115
Selling and marketing	98	178	27
General and administrative	855	1,712	779
Total share-based payment	$ 1,907	$ 3,751	$ 1,327

On July 24, 2011, the Company's Board of Directors approved a new unlisted Options Plan ("2011 Option Plan "). Options are generally vesting 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% options vest at the end of each quarter thereafter.

On November 14, 2013 the Company Board of Directors approved an increase of the renewing pool of shares allocated for grant under the 2011 option plan to a total of 1,185,000 shares.

On April 27, 2015 the Company Board of Directors approved an increase to the renewing pool of shares allocated for grant under the 2011 option plan to a total of 645,000 shares.

NOTE 21: SHARE-BASED PAYMENT (CONT.)

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

On April 27, 2015, the Company's Board of Directors approved the grant, for no consideration, of 120,000 options to the CEO, exercisable into 120,000 ordinary shares at an exercise price of NIS 18.74. The fair value of the options was estimated at $176 thousands.

c. Option granted to the Company's Deputy Chairman of the Board of Directors (the former CEO)

1. On December 11, 2012, the Company's board of directors approved a grant of 120,000 options to the Company's former CEO to purchase 120,000 ordinary Company shares of NIS 1 par value each. The options were subject to the approval of the general shareholders meeting.

   On April 9, 2013, the Company's board of directors modified certain terms of the options granted to the Company's former CEO on December 11, 2012, by increasing the number of options granted from 120,000 to 150,000 and by changing the exercise price to NIS 41.47. The options are vested as follows: (1) 25% - at the end of the first year from the IPO; (2) 75% - over a period of three years, on a quarterly basis, after the vesting of the first 25% options. On May 26, 2013 ("the Grant Date"), the Company's general shareholders meeting approved the grant of the options to the Company's former CEO.

   The fair value of the options was estimated at $ 625 thousands according a calculation formula based on the Binominal Model.

2. On November 14, 2013 the Company's Board of Directors approved the grant, for no consideration, of 150,000 options to the former CEO, exercisable into 150,000 ordinary shares at an exercise price of NIS 56.94. On January 28, 2014, the Company's general shareholders meeting approved the grant of the options to the Company's former CEO. The fair value of the options was estimated at $896 thousands.

d. Employees options

1. During 2013, 2014 and 2015 the Company's Board of Directors approved the grant, for no consideration, of 732,850, 20,000 and 356,075 options, respectively to employees. The fair value of the options was estimated at $3,415 thousands, $140 thousands and $749 thousands, respectively.

NOTE 21: SHARE-BASED PAYMENT (CONT.)

2. On December 11, 2012, the board of directors approved a grant of 100,000 options to the Company Chief Financial Officer to purchase 100,000 ordinary Company shares of NIS 1 par value each. 20,000 options are exercisable in 13 installments, 25% of the options vest on the first anniversary of the grant date and 6.25% vest at the end of each quarter thereafter at an exercise price of NIS 31.90.

   The remaining 80,000 options have an exercise price of 90% of the Company initial public offering price in the NASDAQ - NIS 34.06 and vest as follows: (1) 25% - at the end of the first year from the IPO; (2) 75% - over a period of three years, on a quarterly basis, after the vesting of the first 25% options.

   According to a calculation formula based on the Binomial Model, the fair value of the options was estimated at $ 442 thousands.

e. Directors options

On April 27, 2015 the Company's Board of Directors approved the grant, for no consideration, of 25,000 options to the directors of the Company exercisable into 25,000 ordinary shares at an exercise price of NIS 18.74. On June 30, 2015, the Company's general shareholders meeting approved the grant of the options to the Company's directors. The fair value of the options was estimated at $37 thousands.

On November 14, 2013 the Company's Board of Directors approved the grant, for no consideration, of 180,000 options to the directors of the Company exercisable into 180,000 ordinary shares at an exercise price of NIS 56.94. On January 28, 2014, the Company's general shareholders meeting approved the grant of the options to the Company's directors. The fair value of the options was estimated at $1,075 thousands.

f. Consultants options

On April 27, 2015 the Company's Board of Directors approved the grant, for no consideration, of 3,000 options to two consultants of the Company exercisable into 3,000 ordinary shares at an exercise price of NIS 18.74. The fair value of the options was estimated at $4 thousands.

g. During 2015, 430,178 options were exercised by employees to 430,178 ordinary shares of NIS 1 par value, in consideration of $1,253 thousands.

NOTE 21: SHARE-BASED PAYMENT (CONT.)

Change during the Year

The following table lists the number of share options, the weighted average exercise prices of share options and modification in employee and service provider option plans during the year:

	2015		2014		2013	
	Number of Options	Weighted Average Exercise Price In NIS	Number of Options	Weighted Average Exercise Price In NIS	Number of Options	Weighted Average Exercise Price In NIS
Outstanding at beginning of year	2,396,891	37.98	2,471,507	37.53	1,674,781	20.55
Granted	504,075	18.28	20,000	54.68	1,102,850	56.00
Exercised	(430,178)	11.18	(35,133)	15.20	(262,773)	25.28
Forfeited	(189,295)	34.94	(59,483)	38.63	(43,351)	25.28
Outstanding at end of year	2,281,493	38.96	2,396,891	37.98	2,471,507	37.53
Exercisable at end of year	1,182,417	40.39	1,276,920	27.67	797,015	16.80
The weighted average remaining contractual life for the share options		4.15		3.84		4.88

The range of exercise prices for share options outstanding as of December 31, 2014 and 2015 were NIS 18- NIS 57.

Measurement of the fair value of equity-settled share options

The Company uses the binomial model when estimating the grant date fair value of equity-settled share options. The measurement was made at the grant date of equity-settled share options since the options were granted to employees.

The following table lists the inputs to the binomial model used for the fair value measurement of equity-settled share options for the above plan:

	2015	2014	2013
Dividend yield (%)	-	-	-
Expected volatility of the share prices (%)	42-64	30-50	29-53
Risk-free interest rate (%)	0.07 – 2.04	0.92 – 3.24	0.88 – 3.18
Contractual term of up to (years)	6.5	6.5	6.5
Exercise multiple	2	2	1.75-2
Weighted average share prices (NIS)	17.17	55.08	49.7
Expected average forfeiture rate (%)	0-5	0-5	0-5

NOTE 22: - TAXES ON INCOME

a. Tax laws applicable to the Company

Income tax (inflationary adjustments) law, 1985

According to the law, until 2007, the results for tax purposes were adjusted for the changes in the Israeli CPI.

In February 2008, the "Knesset" (Israeli parliament) passed an amendment to the Income Tax (Inflationary Adjustments) Law, 1985, which limits the scope of the law starting 2008 and thereafter. Since 2008, the results for tax purposes are measured in nominal values, excluding certain adjustments for changes in the Israeli CPI carried out in the period up to December 31, 2007.

Law for the Encouragement of Industry (Taxes), 1969

The Law for the Encouragement of Industry (Taxes), 1969 (the “Encouragement of Industry Law”), provides several tax benefits for “Industrial Companies.” Pursuant to the Encouragement of Industry Law, a company qualifies as an Industrial Company if it is a resident of Israel and at least 90% of its income in any tax year (exclusive of income from certain defense loans) is generated from an “Industrial Enterprise” that it owns. An Industrial Enterprise is defined as an enterprise whose principal activity, in a given tax year, is industrial activity.

An Industrial Company is entitled to certain tax benefits, including: (i) a deduction of the cost of purchases of patents, know-how and certain other intangible property rights (other than goodwill) used for the development or promotion of the Industrial Enterprise in equal amounts over a period of eight years, beginning from the year in which such rights were first used, (ii) the right to elect to file consolidated tax returns, under certain conditions, with additional Israeli Industrial Companies controlled by it, and (iii) the right to deduct expenses related to public offerings in equal amounts over a period of three years beginning from the year of the offering.

Eligibility for benefits under the Encouragement of Industry Law is not contingent upon the approval of any governmental authority The Company believes that it currently qualifies as an industrial company within the definition of the Industry Encouragement Law. The Company cannot assure that the Israeli tax authorities will agree that the Company qualifies, or, if qualified, that it will continue to qualify as an industrial company or that the benefits described above will be available to the Company in the future.

Law for the Encouragement of Capital Investments, 1959

Tax benefits prior to Amendment 60

The Company's facilities in Israel have been granted Approved Enterprise status under the Law for the Encouragement of Capital Investments, 1959, commonly referred to as the “Investment Law”. The Investment Law provides that capital investments in a production facility (or other eligible assets) may be designated as an Approved Enterprise. Until 2005, the designation required advance approval from the Investment Center of the Israel Ministry of Industry, Trade and Labor. Each certificate of approval for an Approved Enterprise ("certificate of approval") relates to a specific investment program, delineated both by the financial scope of the investment and by the physical characteristics of the facility or the asset.

NOTE 22: - TAXES ON INCOME (CONT.)

Under the Approved Enterprise programs, a company is eligible for governmental grants ("Grants Track"). Under the Grants Track the Company is eligible for investments grants awarded at various rates according to the development area in which the plant is located: in Development Zone A the rate is 24% and in Development Zone B the rate is 10%. In addition to the above grants, the Company is eligible to tax exemption at the first two years of the benefit period (as define below) and is subject to reduced corporate tax of 10% to 25% during the remaining five to eight years (depending on the extent of foreign investment in the Company) of the benefit period. The benefits period is limited to 12 years from completion of the investment or commencement of production ("Year of Operation"), or 14 years from the year in which the certificate of approval was obtained, whichever is earlier. The benefit period for part of the Company plants has ended, or up to 2017.

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

Tax benefits under Amendment 60

On April 1, 2005, an amendment to the Investment Law came into effect ("Amendment 60"). The amendment revised the criteria for investments qualified to receive tax benefits. An eligible investment program under the amendment will qualify for benefits as a Privileged Enterprise (rather than the previous terminology of Approved Enterprise). Among other things, the amendment simplifies the approval process.

In order to receive the tax benefits, the Amendment states that the company must make an investment in the Privileged Enterprise exceeding a certain percentage or a minimum amount specified in the Investments Law. Such investment may be made over a period of no more than three years ending at the end of the year in which the company requested to have the tax benefits apply to the Privileged Enterprise (the "Year of Election").

NOTE 22: - TAXES ON INCOME (CONT.)

The Company received a Tax Ruling from the Israeli Tax Authority that its activity is an industrial activity and the Company will be eligible for the status of a Privileged Enterprise, provided that it meets the requirements under the ruling. The year of Election is 2009.The Company also obtained 2012 as a Year of election.

The duration of tax benefits is subject to a limitation of the earlier of 7 to 10 years (depending on the extent of foreign investment in the company) from the first year in which the company generated taxable income (at, or after, the Year of Election) , or 12 years from the first day of the Year of Election. The amendment does not apply to investment programs approved prior to December 31, 2004. The new tax regime applies to new investment programs only.

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

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

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

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

NOTE 22: - TAXES ON INCOME (CONT.)

Preferred Enterprise

Tax Benefits under the 2011 Amendment

As of January 1, 2011 new legislation amending to the Investment Law came into effect (the “2011 Amendment”). The 2011 Amendment introduced a new status of “Preferred Company” and “Preferred Enterprise”, replacing the existed status of “Beneficiary Company” and “Beneficiary Enterprise”. Similarly to “Beneficiary Company”, a Preferred Company is an industrial company owning a Preferred Enterprise which meets certain conditions (including a minimum threshold of 25% export). However, under this new legislation the requirement for a minimum investment in productive assets was cancelled.

Under the 2011 Amendment, a uniform corporate tax rate will apply to all qualifying income of the Preferred Company, as opposed to the former law, which was limited to income from the Approved Enterprises and Beneficiary Enterprise during the benefits period. The uniform corporate tax rate will be 12.5% elsewhere in Israel (in development area A - 7%).

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

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

The Company has evaluated the effect of the adoption of the Amendment on its financial statements, and as of the date of the approval of the financial statements, the Company believes that it will not apply the Amendment. Accordingly, the Company has not adjusted its deferred tax balances as of December 31, 2015. The Company may change its position in the future.

b. Tax rates applicable to the Company

The Israeli corporate tax rate was 26.5% in 2015 and 2014 (25% in 2013). Commencing January 1, 2016 the Israeli corporate tax rate decreased to 25%.

On January 4, 2016, the Israeli Parliament's Plenum approved by a second and third reading the Bill for Amending the Income Tax Ordinance (No. 217) (Reduction of Corporate Tax Rate), 2015, which consists of the reduction of the corporate tax rate from 26.5% to 25%, effective of January 1, 2016.

NOTE 22: - TAXES ON INCOME(CONT.)

c. Tax assessments

1. Final tax assessments

The Company received final tax assessments through 2003.

2. Tax assessments in dispute

During 2010, the Company has received assessments made according to the best possible judgment for tax years 2004-2006 to the amount of approximately $ 5 million (including accumulated interest and linkage differentials), for which the Company has filed a reservation. In January 2012, the Company was issued a tax payment order for these years in accordance with section 152b of the Ordinance to the amount of approximately $ 4 million (including accumulated interest and linkage differentials). The Company has appealed the assessment in question in court. The Company estimates that the provision recognized in the financial statements covers its exposure with respect to the above disputed tax assessment.

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

As of December 31, 2015, the Company has carry forward losses and other temporary differences in the amount of $ 85.5 million.

e. Deferred taxes:

The Company did not recognize deferred tax assets for carry forward losses and other temporary differences, because their utilization in the foreseeable future is not probable.

f. Current taxes on income

There are no taxes on income in the profit or loss of 2015.

g. Theoretical tax:

The reconciliation between the tax expense, assuming that all the income and expenses, gains and losses in the statement of income were taxed at the statutory tax rate and the taxes on income recorded in profit or loss, does not provide significant information and therefore was not presented.

NOTE 23: - SUPPLEMENTARY INFORMATION TO THE STATEMENTS OF COMPREHENSIVE LOSS

	Year Ended December 31,		
	2015	2014	2013
	In thousands		
a. Additional information about revenues			
Revenues from major customers each of whom amount to 10% or more, of total revenues			
Customer A – Proprietary products	$ 26,032	$ 26,606	$ 28,376
Customer B – Proprietary products and Distribution Segment	10,306	12,352	8,747
	$ 36,338	$ 38,958	$ 37,123

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

	Year Ended December 31,		
	2015	2014	2013
	In thousands		
Israel	$ 30,624	$ 32,040	$ 26,280
U.S.A.	26,559	26,001	28,805
Europe	3,223	5,265	6,737
Latin America	6,036	5,121	5,943
Asia	2,900	2,120	2,856
Others	564	518	2
	$ 69,906	$ 71,065	$ 70,623

NOTE 23: - SUPPLEMENTARY INFORMATION TO THE STATEMENTS OF COMPREHENSIVE LOSS (CONT.)

		Year Ended December 31,		
		2015	2014	2013
		In thousands		
b.	Cost of goods sold			
	Cost of materials	$ 41,571	$ 42,265	$ 35,334
	Salary and related expenses	11,136	12,026	10,425
	Depreciation and amortization	2,383	2,019	2,245
	Other manufacturing expenses	(47)	(306)	588
		55,043	56,004	48,592
	Decrease (increase) in inventories	(935)	19	(4,376)
		$ 54,108	$ 56,023	$ 44,216
c.	Research and development			
	Salary and related expenses	$ 3,737	$ 3,852	$ 3,877
	Subcontractors	8,002	6,593	6,072
	Materials	117	185	94
	Allocation of facility cost	3,269	4,102	1,752
	Others	1,405	1,298	950
		$ 16,530	$ 16,030	$ 12,745
d.	Selling and marketing			
	Salary and related expenses	$ 1,166	$ 1,033	$ 546
	Marketing support	368	106	110
	Packing, shipping and delivery	454	403	355
	Marketing and advertising	560	352	243
	Registration and marketing fees	794	785	745
	Others	310	219	101
		$ 3,652	$ 2,898	$ 2,100

NOTE 23: - SUPPLEMENTARY INFORMATION TO THE STATEMENTS OF COMPREHENSIVE LOSS (CONT.)

		Year Ended December 31,		
		2015	2014	2013
		In thousands		
e.	General and administrative			
	Salary and related expenses (1)	$ 2,665	$ 3,244	$ 3,824
	Professional fees	1,482	1,796	992
	Depreciation and amortization	524	455	444
	Bad debt expenses, net	-	(53)	483
	Others	2,369	2,151	2,119
		$ 7,040	$ 7,593	$ 7,862
	(1) The Company incurred in 2013, $ 1,400 thousands of one-time management compensation expense related to the IPO.			
f.	Financial incomes and expenses			
	Financial incomes			
	Interest income and gains from marketable securities	$ 463	$ *404	$ *278
	Financial expenses			
	Interest and amortization from debentures	$ 731	$ 1,954	$ 3,089
	Fees paid to financial institutions	111	109	32
	Others	92	23	21
		$ 934	$ 2,086	$ 3,142

*Reclassified

NOTE 24: - INCOME (LOSS) PER SHARE

a. Details of the number of shares and income (loss) used in the computation of income (loss) per share

	Year Ended December 31,					
	2015		2014		2013	
	Weighted Number of Shares	Loss Attributed to equity holders of the Company	Weighted Number of Shares	Income Attributed to equity holders of the Company	Weighted Number of Shares	Income Attributed to equity holders of the Company
		In thousands		In thousands		In thousands
For the computation of basic income (loss)	36,245,813	$ (11,270)	35,971,335	$ (13,213)	32,714,631	$ 443
Effect of potential dilutive ordinary shares	-	-	-	-	671,020	-
For the computation of diluted income (loss)	36,245,813	$ (11,270)	35,971,335	$ (13,213)	33,385,651	$ 443

b. The computation of the diluted income per share in 2015, did not take into account the convertible debentures and the options due to their antidilutive effect.

NOTE 25: - OPERATING SEGMENTS

a. General

The operating segments are identified on the basis of information that is reviewed by the chief operating decision maker ("CODM") to make decisions about resources to be allocated and assess its performance. Accordingly, for management purposes, the Group is organized into operating segments based on the products and services of the business units and has two operating segments as follows:

Proprietary Products	Development, manufacture and sale of plasma-derived therapeutics products.
Distribution	Distribution of drugs in Israel manufacture by other companies, most of which are produced from plasma or its derivatives products.

Segment performance is evaluated based on revenues and gross profit in the financial statements.

The segment results reported to the CODM include items that are allocated directly to the segments and items that can be allocated on a reasonable basis. Items that were not allocated, mainly the Group's headquarter assets, general and administrative costs and financial costs (consisting of finance expenses and finance income and including fair value adjustments of financial instruments), are managed on a group basis.

NOTE 25: - OPERATING SEGMENTS (CONT.)

The segment liabilities do not include loans and financial liabilities as these liabilities are managed on a group basis.

Capital expenditures consist of additions to Property, plant and equipment and intangible assets.

d. Reporting on operating segments

	Proprietary Products	Distribution	Total
		In thousands	
Year Ended December 31, 2015			
Revenues	$ 42,952	$ 26,954	$ 69,906
Gross profit	$ 12,484	$ 3,314	$ 15,798
Unallocated corporate expenses			(27,222)
Finance income, net			154
Loss before taxes on income			$ (11,270)

	Proprietary Products	Distribution	Total
		In thousands	
Year Ended December 31, 2014			
Revenues	$ 44,389	$ 26,676	$ 71,065
Gross profit	$ 11,772	$ 3,270	$ 15,042
Unallocated corporate expenses			(26,521)
Finance expenses, net			(1,682)
Loss before taxes on income			$ (13,161)

NOTE 25: - OPERATING SEGMENTS (CONT.)

	Proprietary Products	Distribution	Total
		In thousands	
Year Ended December 31, 2013			
Revenues	$ 50,658	$ 19,965	$ 70,623
Gross profit	$ 23,554	$ 2,853	$ 26,407
Unallocated corporate expenses			(22,707)
Finance expenses, net			(3,233)
Income before taxes on income			$ 467

e. Revenues reported in the financial statements for a group of similar products in the Proprietary Product segment:

	Year ended December 31,		
	2015	2014	2013
		In thousands	
Plasma derived products	$ 41,739	$ 43,206	$ 48,484
Others	1,213	1,183	2,174
	$ 42,952	$ 44,389	$ 50,658

NOTE 26: - BALANCES AND TRANSACTIONS WITH RELATED PARTIES

a. Balances with related parties

	Related Parties
	In thousands
December 31, 2015	
Other accounts payables	$ 291
Employee benefit liabilities, net	$ 151
Trade receivable	$ 1,446
December 31, 2014	
Other accounts payables	$ 297
Employee benefit liabilities, net	$ 187
Trade receivable	$ 648

NOTE 26: - BALANCES AND TRANSACTIONS WITH RELATED PARTIES (CONT.)

b. Benefits to related parties

	Year Ended December 31,	
	2015	2014
	In thousands	
Salary and related expenses to those employed by the Company or on its behalf	$ 800	$ 1,316
Salary of directors not employed by the Company or on its behalf	$ 189	$ 269
Number of People to whom the Salary and Benefits Refer		
Related and related parties employed by the Company or on its behalf	2	2
Directors not employed by the Company	3	2
	5	4

c. Benefits to key executive personnel (including non-related parties)

	Year Ended December 31,		
	2015	2014	2013
	In thousands		
Short-term benefits	$ 2,144	$ 2,064	$ 2,884
Share-based payment	650	1,165	617
Other long-term benefits	61	(8)	5
	$ 2,855	$ 3,221	$ 3,506

d. Transactions with related parties

Year Ended December 31, 2015

	Controlling Shareholder	Related Parties
	In thousands	
Sales	$ -	$ 2,795
Selling and marketing expenses	$ -	$ 114
General and administrative expenses	$ -	$ 526

NOTE 26: - BALANCES AND TRANSACTIONS WITH RELATED PARTIES (CONT.)

Year Ended December 31, 2014

	Controlling Shareholder	Related Parties
	In thousands	
Sales	$ -	$ 1,158
Selling and marketing expenses	$ -	$ 120
General and administrative expenses	$ -	$ 1,466

Year Ended December 31, 2013*

Sales	$ -	$ 453
Selling and marketing expenses	$ -	$ 110
General and administrative expenses	$ -	$ 2,037

* In addition, amount of $167 thousand was charged to equity as part of issuance expense.

e. Revenues and Expenses from Related and Interested Parties

Terms of Transactions with Related Parties

Sales to related parties are conducted at market prices. Balances that have yet to be repaid by the end of the year are not guaranteed, bear no interest and their settlement will be in cash. No guarantees were received or given for sums receivable or payable. For the years ended December 31, 2015, 2014 and 2013, the Company recorded no allowance for doubtful accounts for sums receivable from related parties.

1. On May 26, 2011, the Company announced its engagement in an amended agreement that revises and replaces the distribution agreement signed in 2001 between the Company and Tuteur SACIFIA, a company registered in Argentina, currently under the control of Hahn family. The amendment to the agreement was made as an arm's length transaction.

   Revision of the agreement is necessary in preparation for the expected completion of the product's registration in Argentina and the beginning of its marketing and constitutes an improvement to the terms of the 2001 agreement as far as the Company is concerned.

   On August 19, 2014 we amended the agreement in order to add KamRho(D) as an additional product to be distributed by Tuteur and expanded the territory to include Bolivia.

   Pursuant to the distribution agreement, Tuteur serves as the exclusive distributor of Glassia and KamRho(D), in Argentina, Paraguay, Uruguay and Bolivia.

NOTE 26: - BALANCES AND TRANSACTIONS WITH RELATED PARTIES (CONT.)

2. One of the Company's directors, Reuven Behar, is a partner of Fischer Behar Chen Well Orion Co., the Company's external legal counsel. Fees attributed to Fischer Behar Chen Well Orion Co. are included in the tables above.

3. On July 29, 2015 the Company's Board of Directors approved to engage Khairi S.A. ("Khairi"), a company that is held, inter alia, by Mr. Leon Recanati, the Chairman of our board of directors, Mr. Jonathan Hahn, a director in the company and his siblings and Mr. Reuven Behar, a director in the company, who serves as the chairman of the board of directors of Khairi, in a distribution agreement, for the distribution of Glassia and KamRho(D) in Uruguay. This distribution agreement with Khairi will be an arm's length transaction. This distribution agreement will be based on the terms of the distribution agreement signed with Tuteur and is currently under negotiation.

THIRD AMENDMENT TO THE
AMENDED AND RESTATED FRACTION IV-1 PASTE SUPPLY AGREEMENT

This Third Amendment to the Amended and Restated Fraction IV-1 Paste Supply Agreement ("**Third Amendment**") effective this 1st day of January, 2015 ("**Effective Date**"), by and between Baxter Healthcare Corporation having a place of business at One Baxter Way, Westlake Village, California 91361 (hereinafter "**BAXTER**"), and Kamada Ltd., having a place of business at Science Park, Kiryat Weizmann, 7 Sapir St., Ness-Ziona, 74036, Israel (hereinafter "**KAMADA**"). BAXTER and KAMADA shall collectively be referred to as the "Parties".

RECITALS

WHEREAS, the Parties entered into an Amended and Restated Fraction IV-1 Paste Supply Agreement ("**Agreement**") effective August 23, 2010; a First Amendment ("**First Amendment**") to the Amended and Restated Fraction IV-1 Paste Supply Agreement dated May 10, 2011; a Second Amendment ("**Second Amendment**") to the Amended and Restated Fraction IV-1 Paste Supply Agreement dated June 22, 2011; and

WHEREAS, the Parties desire to enter into a Third Amendment of the Agreement in order to replace the specifications referenced in Section 1 a. and Exhibit A of the Agreement; replace the contact notices in Section 11 of the Agreement; replace Exhibit B in its entirety; replace Exhibit C in its entirety; and, replace Exhibit D in its entirety from the Agreement.

NOW THEREFORE, it is hereby agreed as follows:

1. Section 1(a) of the Agreement and Exhibit A "Product Specifications" of the Agreement shall be deleted in its entirety and shall be replaced with the following paragraph and the attached Exhibit A and incorporated herein by reference to this Third Amendment.

   "Baxter shall supply to Kamada Paste that meets the specifications as set forth in Exhibit A which is attached to this Amendment and incorporated herein by reference in accordance with FDA regulations and guidelines (collectively, the "**Specifications**") for further processing by Kamada for use in humans."

2. Section 11 of the Agreement shall be deleted in its entirety and shall be replaced with the following paragraph and incorporated herein by reference to this Third Amendment.

   Notices. All notices given under this Agreement shall be in writing and shall be given as of the date it is in any one of the following methods: (1) hand delivered; (2) sent by facsimile or electronic transmission; (3) mailed (U.S. or international) to the parties at the addresses set forth below, or such other addresses as the parties may designate in writing.

[*****] Confidential portions of this document have been redacted and filed separately with the Securities and Exchange Commission.

Notice to:	Kamada Ltd. 7 Sapir St. Kiryat Weizmann Ness-Ziona 74036 Israel Attn: President/CEO
Notice to:	Baxalta US Inc. 4501 Colorado Boulevard Los Angeles, CA 90039 Attn: Plant Manager
Copy to:	Baxalta US Inc. – BioLife Plasma Services L.P. One Baxter Way Westlake Village, CA 91361 Attn: Logistics, Contract Manager

3. Per Section 12 "Assignment" Baxter Healthcare Corporation has assigned this Agreement to Baxalta US Inc. All references to Baxter in the Agreement shall now be read to refer to Baxalta.

4. Section 14 "Entire Agreement; Waiver" shall be deleted in its entirety and shall be replaced with the following paragraph and incorporated herein by reference to this Third Amendment.

"Entire Agreement; Waiver. This Agreement, including the Exhibits hereto, the TLA and the MSDA, constitute the entire agreement between the Parties relating to the subject matter thereof, and all prior proposals, discussions, letters and agreements by and between the Parties and relating to the subject matter herein are hereby suspended and rendered null and void, except for the Confidential Disclosure Agreement dated March 31, 2006. None of the terms of this Agreement shall be deemed to be waived by either Party or amended unless such waiver or amendment is written and signed by both Parties, and recites specifically that it is a waiver of, or amendments to, the terms of this Agreement. Unless the Parties agree in writing, including by mutual signature on Kamada's Purchase Orders, the terms of this Agreement shall take precedence over Purchase Orders, and any conflicting or inconsistent terms of Kamada's purchase Order shall be null and void".

5. Section 21 "Baxter Paste Record Inspection of Kamada" is added to this Agreement and reads asfollows:

"Baxter Paste Record Inspection. Baxter shall have the right to inspect Kamada's records for the purpose of verifying the traceability and reconciliation of the use of No Charge Paste (as defined in Exhibit C) from No Charge Paste receipt through manufacturing into finished Glassia product. Baxter shall have access to such documents provided for in this Agreement for the preceding [*****], at reasonable intervals (but no more frequently than once in any [*****] period) and upon not less than [*****] prior written notice. Upon receipt of written notice, Baxter and Kamada shall confer to agree upon an acceptable date for the inspection, taking into account normal activities of Kamada's manufacturing function. Baxter's access to Kamada's documents shall include No Charge Paste receipt reports, the Paste tractability information report from the No Charge Paste manufacturing batch records, No Charge Paste consumption reports and other available reports that link the traceability of No Charge Paste usage and manufacturing of paste lots into finished Glassia product. Preferably, such reports shall be provided from Kamada's validated ERP system(s) (or equivalent) if available. All expenses related to such inspection shall be borne by Baxter."

[*****] Confidential portions of this document have been redacted and filed separately with the Securities and Exchange Commission.

6. Exhibit A “Product Specifications” of the Agreement shall be deleted in its entirety and shall be replaced with a new Exhibit A “Product Specifications” as attached to this Third Amendment.

7. Exhibit B “Quality Agreement” of the Agreement shall be deleted in its entirety and shall be replaced with a new Exhibit B “Quality Agreement” as attached to this Third Amendment. The Parties acknowledge and agree that the Quality Agreement in Exhibit B of the Agreement may be modified and replaced from time to time as mutually agreed to by the Parties and that any future modified version of the Quality Agreement will not require an amendment to the Agreement with the sole exception of any change made to the Product Specification Fr. IV-1 Paste, Los Angeles which will require an amendment.

8. Exhibit C “Prices and Payment Terms” shall be deleted in its entirety and shall be replaced with a new Exhibit C “Prices and Payment Terms” as attached to this Third Amendment.

9. Exhibit D “Forecasting” shall be deleted in its entirety and shall be replaced with a new Exhibit D “Forecasting” as attached to this Third Amendment.

Except as specifically modified herein, all other terms and conditions of the Agreement and Exhibits shall remain in full force and effect and are hereby affirmed, confirmed and ratified.

IN WITNESS WHEREOF, the Parties have caused this Third Amendment to be executed by their duly authorized representatives.

BAXALTA US INC.

By:/s/ Ludwig Hantson
Name: Ludwig Hantson
Title: CVP, President – Bioscience

Date: July 19, 2015

KAMADA LTD.

By: /s/ David Tsur
Name: David Tsur
Title: Chief Executive Officer

Date: 5/28/15

By: /s/ Gil Efron
Name: Gil Efron
Title: Chief Financial Officer

Date: 5/28/15

[*****] Confidential portions of this document have been redacted and filed separately with the Securities and Exchange Commission.

Exhibit A to the Third Amendment
of the Amended and Restated Fr. IV-1 Paste Supply Agreement

Product Specifications

1. **Product Specifications** - Paste is manufactured according to the specifications attached as Attachment 1, "Product Specification Fr. IV-1 Paste, Los Angeles" attached hereto.

2. **Paste Dating** - At time of delivery, all batches of the Paste supplied to Kamada hereunder shall be no older than [*****] from the date of separation; provided a batch of Paste may be up to [*****] from the date of separation with the prior written approval of Kamada.

3. **Paste Flavor** - Each manufacturing pool consists exclusively of either recovered plasma or source plasma. Beginning [*****], the paste supply to Kamada shall solely consist of paste that is manufactured by filter press from source or recovered plasma.

4. **Paste Samples** - Each shipment of Paste shall include representative Fr. IV-1 Paste samples for each manufactured lot shipped therein. [*****] aliquots of not less than [*****] each of Fr. IV-1 Paste from each lot are to be collected and transferred to [*****] individual [*****] polypropylene test tubes. The sample test tubes shall be marked with the lot number and shall be placed in Can A of each lot for each shipment. Such samples shall be frozen at a temperature no warmer than -20° Celsius until shipment.

5. **Required Documentation** - Original or scanned and e-mailed shipment documents are to be presented to Kamada at the time of shipment and are to include:

- Commercial Invoice
- Packing List
- Shipper's Letter of Instructions
- Certificate of Analysis (template attached to this Exhibit A as Attachment 2)
- Packing List stating lot number and kilogram weights for each lot; can weight per lot will be included on a separate document
- Certificate of Origin
- Airway bill of Bill of Lading (issued by Kamada's freight forwarder)

A preliminary invoice should be sent to Kamada via e-mail approximately [*****] before a shipment and is to include the Fr. IV-1 paste lots numbers and weights that will be shipped under the final Commercial Invoice, as known at the time of issuance of the preliminary invoice. In case of changes with lots numbers or/and weights, a revised preliminary invoice should be sent to Kamada once the information is available.

In case there are any differences between the preliminary invoice and the commercial invoice, then such differences must be communicated by Baxter no later than the time of shipment.

Attachment 1	"Product Specification for Fr. IV-1 Paste, Los Angeles"
Attachment 2	Certificate of Analysis (template)
Attachment 3	Labeling Guidelines

[*****] Confidential portions of this document have been redacted and filed separately with the Securities and Exchange Commission.

Exhibit C to the Third Amendment
of Amended and Restated Fr. IV-1 Paste Supply Agreement

Prices and Payment Terms

1. **No Charge Paste.** Baxter shall provide to Kamada at no charge (other than shipping costs and applicable tax or other related charges) all quantities of Paste required in order to support Kamada's obligations under the TLA and the MSDA (taking into account also reasonable quantity of rejected in-process Paste and rejected Products) ("No Charge Paste"). The No Charge Paste supports Kamada's obligations to further manufacture and supply the A1PI finished product to Baxter for Baxter's distribution to its geographies. All purchase orders of No Charge Paste submitted by Kamada to Baxter shall reference the appropriate product code number [*****].

   [*****].

2. **Supplementary Paste**. In addition to the provision of the No Charge Paste described under Section 1 above, Baxter shall provide to Kamada Paste that will be used by Kamada for its own needs, not to be sold or transferred to re-sellers or brokers ("Supplementary Paste"), at the price stated in Section 2(b) below. The Supplementary Paste supply shall be in accordance to the "Supplementary Forecast" as described in Section 2 of Exhibit D and shall be in accordance to the following terms:

   (a) Order of Supplementary Paste by Kamada shall be made in accordance to Section 3 of Exhibit D. All purchase orders of Supplementary Paste submitted by Kamada to Baxter shall reference the amount of Paste lots (purchase orders shall consist of multiples of [*****] kilograms) and shall reference the appropriate Baxter product code number [*****]. Baxter shall supply to Kamada up to a maximum quantity of [*****] kilograms of Supplementary Paste manufactured by the filter press process per each [*****] month calendar period. Long range supply meetings will be held on an annual basis and either Party shall contact the other Party at least [*****] days prior to the end of each calendar year to discuss the Supplementary Paste supply for the following calendar year(s). To the extent Kamada wishes to order, during any calendar year, Supplementary Paste at a quantity which exceeds [*****] kilograms of Supplementary Paste, it will provide Baxter a prior written notice in this respect in the annual long range supply meeting, in accordance with following table:

Paste Quantity (aggregate amount on an annual basis)	Forecast Notice
[*****]	[*****]*
[*****]	[*****]*

* Breakdown to be provided in the rolling forecast

[*****] Confidential portions of this document have been redacted and filed separately with the Securities and Exchange Commission.

(b) The price is to be determined by Baxter in its sole discretion (the "Supplementary Paste Price"); provided, however, that the price shall not exceed [*****] per kilogram for the Supplementary Paste processed by filter press [*****]. Kamada shall send purchase orders ninety days (90) days in advance for the Supplementary Paste in accordance to the instructions listed in Exhibit D supply via email to:

[*****]; and to,
[*****].

(c) Beginning [*****]. Both Parties agree that the commodity “Biological products for human use” under commodity code [*****] shall be used as the designated item for the percentage change as listed in the Producer Price Index.

3. **Purchase of Re-designated Paste Equivalent (to A1PI Finished Product).** Beginning [*****], Kamada shall have the option to purchase from Baxter re-designated paste equivalent (to A1PI finished product), which was originally received as No Charge Paste ("Re-designated Paste Equivalent") for its own needs, under the following conditions:

(a) Kamada shall provide a written request to Baxter of Kamada’s desire to purchase Re-designated Paste Equivalent from Baxter for its own needs. Such written request shall be provided prior to Kamada’s labelling of the AIPI finished product, and the request shall include the corresponding Fr. IV-1 Paste lot #(s); the amount of requested Re-designated Paste Equivalent and the desired date of purchase. Within [*****] calendar days of Baxter’s receipt of such request, Baxter shall notify Kamada of Baxter’s approval or non-approval of Kamada’s order request. Such order request shall not be unreasonably withheld by Baxter. In the event that Baxter accepts Kamada’s purchase request, Kamada shall issue Baxter a purchase order including the aforementioned details of the Re-designated Paste Equivalent and the appropriate Baxter Product Code [*****]. Kamada shall issue the purchase order via email for the purchase of the Re-designated Paste Equivalent to:

[*****]; and
[*****].

(b) Kamada agrees to pay Baxter [*****] for such Re-designated Paste Equivalent [*****]. The [*****] price will be adhered to in accordance with Section 2(b). [*****].

(c) [*****]. Kamada will report the corresponding Fr. IV-1 Paste lot #(s) and the amount of Re-designated Paste on a quarterly basis. For such Re-designated Paste Equivalents, the purchase price designated in Section 3(b) above shall not apply, however, the purchase price shall be the Supplementary Paste price designated in Section 2(b) above.

4. **Supply Shortage**. In the event Baxter materially fails to supply the No Charge Paste to Kamada as contemplated in this Agreement, Kamada reserves the right to:

manufacture the A1PI finished product for distribution in the Baxter Territory using alternative paste from an alternative raw material supplier or suppliers; provided that all regulatory requirements and Specifications for the A1PI finished product are met. In such event, the transfer price charged to Baxter shall be adjusted to reflect the actual incremental costs (if any) incurred by Kamada for such alternative paste; provided, however, that in no event shall the transfer price exceed [*****] of the then prevailing Market Price for A1PI finished product.

5. **Delivery Terms.** Delivery of Paste - [*****] (INCOTERMS 2000). Delivery charges are the responsibility of Kamada from [*****]. Loading and shipping of the Fraction IV-1 Paste shall be according to the previously validated procedure "Validation of Shipment of Paste Intermediates via Envirotainer [*****] container", Final Report [*****], or as otherwise agreed by the Parties in writing. Paste shall be shipped to the address provided by Kamada as follows:

Inventory Planner
Karnada Ltd.
Kibutz Beit Kama
M.P. Negev 85325
Israel
Tel Direct: 972-8-9913103
Tel General: 972-8-9913111

Baxter shall label Paste per Attachment 3 of Exhibit A.

[*****] Confidential portions of this document have been redacted and filed separately with the Securities and Exchange Commission.
Exhibit C to the Third Amendment of Amended and Restated Fr. IV-1 Paste Supply Agreement

6. PAYMENT TERMS:

(a) **Supplementary Paste purchases**: Baxter shall invoice Kamada for each shipment of Supplementary Paste upon pickup of such Supplementary Paste shipment from Baxter's facility in Van Nuys. Payment shall be due at Net [*****] days of the date of Baxter's invoice, subject to Section 2 of this Agreement and provided that upon rejection/supply shortage, as described in Section 4 hereof, such invoice shall be due Net [*****] days following receipt of the replacement Supplementary Paste.

All payments shall be made in US Dollars by way of wire transfer to such bank account that shall be designated from time to time by Baxter. It is agreed that any delay in transfer of any payment hereunder because of telecommunication and other inter-banks issues shall not be considered default by Kamada.

Kamada to remit payment by wire transfer through the following instructions:

Bank:	[*****]
City, State:	[*****]
Country:	[*****]
Account No.:	[*****]
Tax ID No:	[*****]
ABA No.:	[*****]
Account Name:	[*****]

Kamada to reference the document #s when remitting payment to Baxter. Kamada to provide remittance advice to: [*****]

[*****] Confidential portions of this document have been redacted and filed separately with the Securities and Exchange Commission.

Baxter to bill to:	Kamada Ltd. Science Park P.O. Box 4081 Kiryat Weizmann Ness-Ziona 74140, Israel Attn: Mr. David Tsur	cc. Kamada Ltd. Kibutz Beit Kama M.P. Negev 85325 Israel Attn: Planning

(b) **Re-designated Paste Equivalent Purchases**: Baxter shall invoice Kamada upon Baxter's receipt of Kamada's purchase order providing details of the Re-designated Paste Equivalent per Section 3(a), and the invoice shall reflect the price in accordance to Section 3(b) or 3(c) (if applicable) of this Exhibit. The payment terms shall be immediately due and payable upon Kamada's receipt of Baxter's invoice and remittance shall be made as indicated on the invoice. If payment is not received within [*****] calendar days of receipt of invoice, a late fee of [*****] shall be applied for every [*****] day delay at full payment of invoice.

[*****] Confidential portions of this document have been redacted and filed separately with the Securities and Exchange Commission.

Exhibit D to the Third Amendment of the
Amended and Restated Fr. IV-1 Paste Supply Agreement

Forecasting

1. Paste Forecasting. On a monthly basis, between the [*****] and the [*****] days of each calendar month, the Parties will hold a monthly conference call or meeting (the "**Monthly Operations Meeting**") during which Baxter and Kamada will discuss, based on an agreed upon format, the status of the Paste supply plan and Products production plan and, reconcile any changes between this planning cycle and the previous one. Where mutual consent cannot reconcile any changes over the previous plan, the terms of the Exclusive Manufacturing, Supply and Distribution Agreement effective August 23, 2010 ("Distribution Agreement") shall prevail.

   During the Monthly Operations Meeting:

   a. Baxter will provide Kamada an updated plan containing:

      1. A1PI Finished Products requirements plan for the next rolling [*****] months;

      2. No Charge Paste delivery schedule (paste processed by Filter Press will not be older than [*****] months from teardown to delivery date) for the next rolling [*****] months, specifying the teardown date and source (Source/Recovered) as planning allows;

      3. Actual performance of the Paste supply plan and any deviations from the plan during the previous [*****] months.

   b. Kamada will provide Baxter the following data based on historical performance or good faith non-binding estimate consistent with the data provided in Section a. above, as the case may be:

      1. Monthly yields per kg of input Paste for finished Products (with a one month time lag);

      2. Planned lead time from suspension of Paste until release of finished Products for each available pathway;

      3. Number of manufacturing batches planned for Products to be supplied to Baxter per month for the next rolling [*****] months and actual performance compared to planned for the previous month;

      4. Manufacturing plan for the consumption of Paste to be used for the production of Products to be supplied to Baxter for the next rolling [*****] months and actual consumption of Paste compared to planned consumption for the previous month;

      5. Products release planned schedule for all current Paste to be used for the manufacturing of Products to be delivered to Baxter, based on the terms of Section 4.2(b) of the Distribution Agreement and actual release of Products compared to planned release for the previous month (release planned schedule to cross-match Paste Lot to finished Products);

      6. Supplementary Paste requirements for Kamada territories including required source (Source/Recovered) for the next rolling [*****] months.

[*****] Confidential portions of this document have been redacted and filed separately with the Securities and Exchange Commission.

Exhibit D to the Third Amendment of the
Amended and Restated Fr. IV-1 Paste Supply Agreement

Forecasting

2. Paste Forecasting under Section 2 of Exhibit C (Supplementary Paste). Concurrently with the Forecast, as specified in Section 1 above, Kamada shall provide Baxter in writing a good faith monthly forecast of Kamada's expected requirements for delivery of Paste under Section 2 of Exhibit C (consistent with the Specifications (including then current packaging requirements)), for each month in the following [*****] month period ("Supplementary Forecast"). The first [*****] months included in each such Supplementary Forecast shall constitute a binding commitment on Kamada's behalf to purchase the quantities of Paste set forth in such Supplementary Forecast. Kamada shall not be obligated to purchase nor shall it have any liability in respect of the remaining [*****] months of any Supplementary Forecast.

3. No Charge Paste and Supplementary Paste – Purchase Orders. Without derogating from Kamada's obligations to purchase the quantities of Pastes set forth in the binding portion of the No Charge Forecastand the Supplementary Forecast, from time to time, Kamada shall deliver binding purchase orders in accordance with the Forecast or the Supplementary Forecast, as the case may be, for Paste by written or electronic purchase order (or by any other means agreed to by the Parties) to Baxter. Baxter shall either: (i) acknowledge and accept or (ii) reject any Kamada purchase order in writing within [*****] days of receipt. All such purchase orders shall be irrevocable. Purchase orders shall set forth the desired date of delivery with respect to the Paste ordered and shall be placed at least [*****] days prior to such desired date of delivery, unless otherwise agreed to by the Parties in writing. All Paste ordered by Kamada under this Agreement shall be delivered on or before the delivery date set forth in the applicable purchase order, unless otherwise agreed to by the Parties in writing, provided that each shipment shall be pre-coordinated with the logistics and planning department of Kamada.

4. Deemed Acceptance. If (i) Baxter does not provide an acknowledgement to Kamada within [*****] days of its receipt of a purchase order and (ii) the aggregate quantities set forth in the purchase orders for delivery in the applicable month do not exceed the quantity set forth in the Supplementary Forecast (unless Baxter has otherwise affirmatively agreed in writing to meet the excess quantities ordered), Baxter shall be deemed to have accepted each purchase order from Kamada.

[*****] Confidential portions of this document have been redacted and filed separately with the Securities and Exchange Commission.

Exhibit 4.30

FOURTH AMENDMENT
TO THE
EXCLUSIVE MANUFACTURING, SUPPLY AND DISTRIBUTION AGREEMENT

This FOURTH Amendment to the Exclusive Manufacturing, Supply and Distribution Agreement dated August 23rd, 2010 as amended on September 6th, 2012, May 14th, 2013, and February 15, 2014 by and between Baxalta US Inc., having a place of business at One Baxter Way, Westlake Village, California 91361 (hereinafter "Baxalta") and Kamada Ltd., having a place of business at Science Park, Kiryat Weizmann, 7 Sapir St., Ness-Ziona, 74036, Israel (hereinafter "Kamada") (the "Agreement") is entered into as of this 10th day of August, 2015 (the "Effective Date"). Baxalta and Kamada shall collectively be referred to as the "Parties".

RECITALS

WHEREAS, the Parties desire to enter into a fourth amendment to the Agreement in order to amend the Minimum Purchase Levels and the Production Capacity as set under the Agreement, as elaborated hereunder (hereinafter the "Fourth Amendment").

NOW THEREFORE, it is hereby agreed as follows:

1. Section 4.5 of the Agreement shall be replaced with the following paragraph:

   4.5 Post-2018 Forecasting. Baxalta shall notify Kamada in writing, no later than [*****] with respect to its expectations for the continued supply of Product by Kamada, for calendar years 2019 and beyond.

2. Section 6.4(a) of the Agreement shall be replaced with the following paragraph:

   6.4 Minimum Purchase Levels.

   (a) During each calendar year following the Effective Date (each a "***Minimum Period***"), for a period terminating on December 31, 2018 (the "***Minimums Term***"), Baxalta shall be obligated to purchase minimum volumes (the "***Minimum Purchase Levels***") of the Product as follows:

<<Table on Following Page>>

Minimum Period (Calendar Year)	**Minimum Purchase Levels** (50 mL vials)
2010	[*****]
2011	[*****]
2012	[*****]
2013	[*****]
2014	[*****]
2015	[*****]
2016	[*****]
2017	[*****]
2018	[*****]

3. Section 1.77 of the Agreement is hereby amended to read as follows:

1.77 "*Production Capacity*" of 50 mL vials of Product for delivery to Baxalta shall mean:

Calendar Year	50 mL vials/month
2010	[*****]
2011	[*****]
2012	[*****]
2013	[*****]
2014	[*****]
2015	[*****]
2016	[*****]
2017	[*****]
2018	[*****]

4. A new section 5.4 (c) shall be added to the Agreement, as follows:

In consideration of the undertakings by Kamada for the years [*****], Baxalta agrees to pay Kamada such amounts at such dates as specified in the table below, representing prepayment of a portion of the Transfer Price, until [*****].

Amount	Payment Date
[*****]	Thirty (30) days after reaching Net Sales for the Product and Baxalta's Product of [*****] during the period of [*****] through [*****].
[*****]	Thirty (30) days after reaching Net Sales for the Product and Baxalta's Product of [*****] during the period of [*****] through [*****].

5. As Baxter Healthcare Corporation has assigned the Agreement to Baxalta, all references to Baxter in the Agreement shall now be read to refer to Baxalta.

6. All provisions of the Agreement which are not expressly amended by the terms of this Third Amendment shall remain in effect and without change.

IN WITNESS WHEREOF, the Parties have caused this Fourth Amendment to be executed by their duly authorized representatives.

BAXALTA US INC.

By: /s/ Ludwig Hantson
Name: Ludwig Hantson
Title: CEO & President
Date: 10/15/15

KAMADA LTD.

By: /s/ Amir London
Name: Amir London
Title: Chief Executive Officer
Date: August 25, 2015

By: /s/ Gil Efron
Name: Gil Efron
Title: Deputy CEO and Chief Financial Officer
Date: August 25, 2015

SECOND AMENDMENT
TO THE
TECHNOLOGY LICENSE AGREEMENT

This Second Amendment to the Technology License Agreement dated August 23rd, 2010, and amended 14th of May, 2013, by and between Baxter Healthcare SA, a Swiss corporation organized under the laws of Switzerland, which was succeeded by Baxalta GmbH, a corporation organized under the laws of Switzerland (hereinafter "Baxalta") and Kamada Ltd., a corporation organized under the laws of Israel (hereinafter "Kamada") (the "Agreement") is entered into as of this 25th day of August, 2015 (the "Effective Date"). Baxalta and Kamada shall collectively be referred to as the "Parties".

RECITALS

WHEREAS, the Parties desire to enter into a second amendment to the Agreement in order to amend the sales milestones and processes for utilization of Kamada personnel by Baxalta pursuant to the Technology Sharing activities, as described hereunder and set applicable payment schedule in connection thereto (hereinafter the "Second Amendment").

NOW THEREFORE, it is hereby agreed as follows:

1. Acknowledgement of Assignment of Agreement. Kamada hereby acknowledges and consents to the assignment of the Agreement by Baxter Healthcare SA to Baxalta. Baxalta hereby accepts all of the terms and conditions of the Agreement. All mentions of "Baxter" in the Agreement are amended to read "Baxalta".

2. Section 1.68 of the Agreement is amended to read as follows:

"1.68" Technology Sharing Term" shall mean, subject to earlier termination pursuant to this Agreement, the earlier of: (i) the end of the Minimums Term (as such term is defined in the MSDA); or (ii) the date that lots are produced under FDA approval of the manufacturing of a Baxalta Product."

3. Section 5.3 of the Agreement is amended to read as follows:

"5.3 Milestones. In consideration of the undertakings by Kamada pursuant to this Agreement, and the grant of the License by Kamada to Baxalta hereunder, Baxalta agrees that it shall, within thirty (30) calendar days after Kamada's written notice of the achievement of the applicable milestone set forth below (each a "Milestone"), pay to Kamada the applicable non-refundable, non-creditable milestone amount (each, a "Milestone Payment") set forth below adjacent to such activity. Milestone Payments are not guaranteed payments, and Baxalta shall not be obligated to make a Milestone Payment unless all conditions precedent to such Milestone Payment have been fully satisfied, unless otherwise stated below.

Milestone	Milestone Payment (USD)
[*****]	[*****] [PAID]
[*****]	[*****] [PAID]
[*****]	[*****] [PAID]
[*****]	[*****]
[*****]	[*****]

4. All provisions of the Agreement which are not expressly amended by the terms of this Second Amendment shall remain in effect and without change.

IN WITNESS WHEREOF, the Parties have caused this Second Amendment to be executed by their duly authorized representatives.

BAXALTA GMBH

By: /s/ Stasia L. Ogden

Name: Stasia L. Ogden
Title: Associate General Counsel
Date: Aug 25, 2015

By: /s/ Michael K. Kirschner

Name: Michael K. Kirschner
Title: Assistant General Counsel
Date: August 25, 2015

KAMADA LTD.

By: /s/ Amir London

Name: Amir London
Title: Chief Executive Officer
Date: August 25, 2015

By: /s/ Gil Efron

Name: Gil Efron
Title: Deputy CEO and Chief Financial Officer
Date: August 25, 2015

Exhibit 8.1

SIGNIFICANT SUBSIDIARIES

Our significant subsidiaries are set forth below, all of which are 100% owned or controlled by us.

Legal Name	Jurisdiction
Kamada Biopharma Limited	England and Wales
Kamada Inc.	Delaware
Bio-Kam Ltd.	Israel
Kamada Assets Ltd.	Israel

Exhibit 12.1

I, Amir London, certify that:

1. I have reviewed this annual report on Form 20-F of Kamada Ltd.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: February 25, 2016

/s/ Amir London
Amir London
Chief Executive Officer

Exhibit 12.2

I, Gil Efron, certify that:

1. I have reviewed this annual report on Form 20-F of Kamada Ltd.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: February 25, 2016

/s/ Gil Efron
Gil Efron
Deputy Chief Executive Officer and Chief Financial Officer

Exhibit 13.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Kamada Ltd. (the "Company") on Form 20-F for the period ended December 31, 2015 as filed with the Securities and Exchange Commission (the "Report"), I, Amir London, Chief Executive Officer of the Company, hereby certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) the Report fully complies with the requirements of section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 25, 2016

/s/ Amir London
Amir London
Chief Executive Officer

In connection with the Annual Report of Kamada Ltd. (the "Company") on Form 20-F for the period ended December 31, 2015 as filed with the Securities and Exchange Commission (the "Report"), I, Gil Efron, Chief Financial Officer of the Company, hereby certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) the Report fully complies with the requirements of section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 25, 2016

/s/ Gil Efron
Gil Efron
Deputy Chief Executive Officer and Chief Financial Officer

Exhibit 15.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (File Nos 333-192720 and 333-207933) of Kamada Ltd. (the "Company") of our report dated November 10, 2015 with respect to the financial statements of the Company and its subsidiaries included in this Annual Report on Form 20-F for the year ended December 31, 2015.

Tel Aviv, Israel

February 25, 2016

/S/ KOST, FORER, GABBAY & KASIERER

A member of Ernst & Young Global