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

FORM 20-F

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

OR

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

For the fiscal year ended December 31, 2019

OR

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

OR

☐ SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of event requiring this shell company report: Not applicable

For the transition period from ____ to _____

Commission file number 001-35948

Kamada Ltd.
(Exact name of registrant as specified in its charter)

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

State of Israel
(Jurisdiction of incorporation or organization)

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

Amir London, Chief Executive Officer
2 Holzman St., Science Park
Rehovot 7670402, Israel
+972 8 9406472
(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

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

Title of Each Class	Name of Each Exchange on which Registered
Ordinary Shares, par value NIS 1.00 each	The Nasdaq Stock Market LLC

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

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

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

As of December 31, 2019, the Registrant had 40,353,101 Ordinary Shares outstanding.

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

☐ Yes ☒ No

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.

☐ Yes ☒ No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

☒ Yes ☐ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or an emerging growth company. See definition of "large accelerated filer", "accelerated filer", and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☒ Non-accelerated filer ☐ Emerging growth company ☐

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards† provided pursuant to Section 13(a) of the Exchange Act. ☐

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

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

U.S. GAAP ☐	International Financial Reporting Standards as issued by the International Accounting Standards Board ☒	Other ☐

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

Item 17 ☐ Item 18 ☐

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

☐ Yes ☒ No

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

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

- *our expectation that our 2020 revenues will be in the range of $132 million to $137 million, with the year-over-year growth driven by increased sales of Proprietary IgG products portfolio and Alpha-1 Antitrypsin ("AAT") intravenous product, GLASSIA® ("GLASSIA"), in international markets, growth of the Distribution segment in Israel and increases sale of KEDRAB®, our anti-rabies immunoglobulin products ("KEDRAB"), in the U.S.;*

- *our expectation that we will continue to generate gross, operating and net profits as well as positive cash flows during 2020 and beyond;*

- *our expectation that the expected change in product sales mix, during 2020, as well as reduced plant utilization, is anticipated to result in an overall decrease in the Propriety Products segment's full-year gross margins of approximately three to five percentage points as compared to 2019;*

- *our expectation for an approximately 20% to 25% increase in research and development expenses during 2020, as compared to 2019, due to the planned acceleration of our pivotal Phase 3 InnovAATe clinical trial;*

- *our expectation that the minimum aggregate revenue from sales of GLASSIA to Takeda Pharmaceutical Company Limited ("Takeda"), for the year 2020 will be approximately $65 million, for the year 2021 to be in the range of $25 million to $50 million;*

- *our expectation that Takeda is planning to complete the technology transfer of GLASSIA, and pending FDA approval, will initiate its own production of GLASSIA for the U.S. market in 2021;*

- *our expectation that the planned transition of GLASSIA manufacturing to Takeda during 2021 will result in a significant reduction of our revenues and profitability during the years 2021 and 2022 as well as excess manufacturing plant capacity, which will reduce manufacturing efficiencies;*

- *our expectation that upon initiation of sales of GLASSIA manufactured by Takeda, Takeda will pay us royalties at a rate of 12% on net sales through August 2025, and at a rate of 6% thereafter until 2040, with a minimum of $5 million annually, for each of the years from 2022 to 2040, and our expectation that based on current GLASSIA sales in the United States and forecasted future growth, we will receive royalties from Takeda in the range of $10 million to $20 million per year for 2022 to 2040;*

- *our belief that our current cash and cash equivalents and short-term investments will be sufficient to satisfy our liquidity requirements for the next 12 months; and*

- *our belief that our relationships with our strategic partners, including with Takeda and Kedrion S.p.A ("Kedrion"), will continue without disruption;*

- *our expectation that continued business development efforts, focused on creating new growth opportunities through the identification of new product opportunities for our manufacturing plant and seeking complementary products via licensing and acquisition, are expected to result in resumed revenue and profitability growth beginning in 2023, which growth will be driven by an expected increase in Proprietary Products segment's sales in international markets, an anticipated continued increase in KEDRAB sales in the U.S., the commercial manufacturing of the new specialty hyper-immune globulin product at our facility beginning in 2023, expected growth in our Distribution segment, and the expected royalties to be paid by Takeda on GLASSIA sales;*

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

- *our belief that we will be able to continue to meet our customers demand for GLASSIA, KEDRAB, and other proprietary products;*

- *our expectation that sales of KamRAB through the Pan American Health Organization ("PAHO") will continue in 2020;*

- *our estimation that the total U.S. market for rabies treatment is approximately $150 million per year and our expectation that our market share for KEDRAB sales in the U.S. market will continue to grow in the coming years;*

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

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

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

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

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

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

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

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

- *our expectation that pursuant to our 12-year contract manufacturing agreement with an undisclosed partner, we will commercially manufacture the hyper-immune globulin product starting in early 2023, which we estimate will add $8 to $10 million to our annual revenues and have gross margin similar to average gross margin of products in our Proprietary Products segment;*

- *our expectation of launching PF 708 in Israel during 2022 upon receipt of regulatory approval from the Israeli Ministry of Health ("IMOH");*

- *our expectation of launching five other biosimilar products pursuant to an agreement with Alvotech during the years 2023-2025, subject to approval by the IMOH;*

- *our belief that the distribution of the six biosimilar products pursuant to an agreement with Alvotech will generate peak revenues in the range of $20 million to $30 million annually;*

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

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

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

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

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

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

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

- *our expectation that we will report final results from the Phase II clinical study of our intravenous AAT product to prevent lung transplantation rejection during 2020;*

- *our expectation that we will report interim results from the Phase II Investigator-Initiated clinical study of our intravenous AAT product for GvHD during 2020;*

- *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;*

- *our development plan of a recombinant AAT product and its future potential utilization;*

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

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

- *our expectations regarding taxation, including that we will not be classified as a passive foreign investment company for the taxable year ending December 31, 2020.*

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

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

The audited consolidated financial statements for the years ended December 31, 2019, 2018 and 2017 included in this Annual Report have been prepared in accordance with the international financial reporting standards ("IFRS") as issued by the international accounting standards board ("IASB"). None of the financial information in this Annual Report has been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP").

Unless otherwise noted, NIS amounts presented in this Annual Report are translated at the rate of $1.00 = NIS 3.456, the exchange rate published by the Bank of Israel as of December 31, 2019.

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, 2019, 2018 and 2017 and the consolidated balance sheets data as of December 31, 2019 and 2018 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, 2016 and 2015 and the summary consolidated balance sheet data as of December 31, 2017, 2016 and 2015 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,				
	2019	2018	2017	2016	2015
	(U.S. Dollars in thousands, except per share data)				
Consolidated Statements of Operations Data:					
Revenues from Proprietary Products	$ 97,696	$ 90,784	$ 79,559	$ 55,958	$ 42,952
Revenues from Distribution	29,491	23,685	23,266	21,536	26,954
Total revenues	127,187	114,469	102,825	77,494	69,906
Cost of revenues from Proprietary Products	52,425	52,796	51,335	37,723	30,901
Cost of revenues from Distribution	25,025	20,201	19,402	18,411	23,640
Total cost of revenues	77,450	72,997	70,737	56,134	54,541
Gross profit	49,737	41,472	32,088	21,360	15,365
Research and development expenses	13,059	9,747	11,973	16,245	16,530
Selling and marketing expenses	4,370	3,630	4,398	3,243	3,652
General and administrative expenses	9,194	8,525	8,273	7,353	6,607
Other expense	330	311	-	-	-
Operating income (loss)	22,784	19,259	7,444	(5,481)	(11,424)
Financial income	1,146	830	500	470	18
Income (expense) in respect of securities measured at fair value, net	(5)	(178)	(80)	(13)	68
Income (expense) in respect of currency exchange and translation differences and derivatives instruments, net	(651)	602	(612)	127	624
Financial expense	(293)	(172)	(82)	(114)	(556)
Income (loss) before taxes on income	22,981	20,341	7,170	(5,011)	(11,270)
Taxes on income	730	(1,955)	269	1,722	-
Net income (loss)	22,251	22,296	6,901	(6,733)	$ (11,270)
Income (loss) attributable to equity holders	22,251	22,296	6,901	(6,733)	$ (11,270)
Income (loss) per share attributable to equity holders:					
Basic	$ 0.55	$ 0.55	$ 0.18	$ (0.18)	$ (0.31)
Diluted	$ 0.55	$ 0.55	$ 0.18	$ (0.18)	$ (0.31)
Weighted-average number of ordinary shares used to compute income (loss) per share attributable to equity holders:					
Basic	40,320,888	40,275,374	37,970,697	36,418,833	36,245,813
Diluted	40,581,627	40,445,417	38,045,097	36,418,833	36,245,813
Consolidated Statements of Cash Flows:					
Cash flows from operating activities	$ 27,571	$ 10,546	$ 3,608	$ 1,897	$ (13,979)
Cash flows from investing activities	(564)	(5,176)	(15,608)	1,637	11,253
Cash flows from financing activities	(1,530)	(587)	15,320	1,490	(6,355)
Consolidated Balance Sheet Data:					
Cash, cash equivalents, restricted cash and short-term investments	$ 73,907	$ 50,592	$ 43,019	$ 28,632	$ 28,306
Trade receivables	23,210	27,674	30,662	19,788	23,071
Working capital [(1)]	110,823	87,321	67,486	49,871	57,655
Total assets	173,797	138,116	122,110	99,696	101,992
Total liabilities	38,478	25,740	32,618	32,953	29,485
Total shareholders' equity	135,319	112,376	89,492	66,743	72,507
Other Data:					
Adjusted net income (loss)[(2) (3)]	$ 23,414	$ 23,244	$ 7,384	$ (5,663)	$ (9,363)
Adjusted EBITDA[(2)]	$ 28,466	$ 23,910	$ 11,450	$ (909)	$ (6,290)

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

(2) We present adjusted net income (loss) and adjusted EBITDA because we use these non-IFRS financial measures to assess our operational performance, for financial and operational decision-making, and as a means to evaluate period-to-period comparisons on a consistent basis. Management believes these non-IFRS financial measures are useful to investors because: (1) they allow for greater transparency with respect to key metrics used by management in its financial and operational decision-making; and (2) they exclude the impact of non-cash items that are not directly attributable to our core operating performance and that may obscure trends in the core operating performance of the business.

Non-IFRS financial measures have limitations as an analytical tool and should not be considered in isolation from, or as a substitute for, our IFRS results. We expect to continue reporting non-IFRS financial measures, adjusting for the items described below, and we expect to continue to incur expenses similar to certain of the non-cash, non-IFRS adjustments described below. Accordingly, unless otherwise stated, the exclusion of these and other similar items in the presentation of non-IFRS financial measures should not be construed as an inference that these items are unusual, infrequent or non-recurring. Adjusted net income (loss) and adjusted EBITDA are not recognized terms under IFRS and do not purport to be an alternative to IFRS net income (loss) as an indicator of operating performance or any other IFRS measure. Moreover, because not all companies use identical measures and calculations, the presentation of adjusted net income (loss) or adjusted EBITDA may not be comparable to other similarly titled measures of other companies.

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

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

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

	Year Ended December 31,				
	2019	**2018**	**2017**	**2016**	**2015**
	(U.S. Dollars in thousands)				
Net income (loss)	$ 22,251	$ 22,296	$ 6,901	$ (6,733)	$ (11,270)
Non-cash share-based compensation expenses	1,163	948	483	1,071	1,907
Adjusted net income (loss)	$ 23,414	$ 23,244	$ 7,384	$ (5,663)	$ (9,363)

	Year Ended December 31,				
	2019	**2018**	**2017**	**2016**	**2015**
	(U.S. Dollars in thousands)				
Net income (loss)	$ 22,251	$ 22,296	$ 6,901	$ (6,733)	$ (11,270)
Income tax expense	730	(1,955)	269	1,722	-
Financial expense, net	(197)	(1,082)	274	(470)	(154)
Depreciation and amortization expense	4,519	3,703	3,523	3,501	3,227
Non-cash share-based compensation expenses	1,163	948	483	1,071	1,907
Adjusted EBITDA	$ 28,466	$ 23,910	$ 11,450	$ (909)	$ (6,290)

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

You should consider carefully the risks and uncertainties described below, together with all of the other information in this Annual Report, including the consolidated financial statements and the related notes included elsewhere in this Annual Report. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that adversely affect our business. If any of the following risks actually occurs, our business, financial condition, results of operations, and future prospects could be materially and adversely affected.

Risks Related to Our Proprietary Products Segment

Our business is currently highly concentrated on our flagship product, GLASSIA, and in 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 (see next risk factor for the effect of transition of GLASSIA manufacturing to Takeda in 2021).

We rely heavily upon the sales of our AAT intravenous product, GLASSIA. Revenue from our intravenous AAT products for the treatment of AATD comprised approximately 58%, 60% and 64% of our total revenues for the years ended December 31, 2019, 2018 and 2017, respectively. If GLASSIA were to lose significant sales, or were to be substantially or completely displaced in the market, we would lose a significant and material source of our total revenues. Similarly, if GLASSIA were to become the subject of litigation and/or an adverse governmental ruling requiring us to cease the manufacturing, export or sales of GLASSIA, our business would be adversely affected.

In addition, we have a partnership arrangement with Takeda, pursuant to which Takeda is the sole distributor of GLASSIA in the United States, Canada, Australia and New Zealand. The partnership agreement was originally executed in 2010 with Baxter International Inc. ("Baxter"). During 2015, Baxter assigned all its rights under the partnership agreement to Baxalta US Inc. ("Baxalta"), an independent public company which spun-off from Baxter. In 2016, Shire completed its acquisition of Baxalta, and as a result, all of Baxalta's rights under the partnership agreement were assigned to Shire. In January 2019, Takeda completed its acquisition of Shire. Revenue derived from our partnership with Takeda, which consists of sales of GLASSIA, milestone revenue and technology transfer services accounted for approximately 54%, 56% and 59% of our total revenues in the years ended December 31, 2019, 2018 and 2017, respectively. Additionally, we depend upon Takeda for the supply of fraction IV plasma for our production of GLASSIA to be sold in the United States. See also the following risks "— Based on current agreement with Takeda, we will cease to produce GLASSIA for Takeda after 2021 as Takeda begins its own production of GLASSIA, which will result in a significant reduction of our revenues and profitability, as well as excess manufacturing plant capacity, which will reduce manufacturing efficiencies." and "In our Proprietary Products segment, we currently rely on Takeda, which accounts for a significant portion of our total sales, and any disruption to our relationships with Takeda would have an adverse effect on our results of operations and profitability."

We also rely heavily on sales in the United States, which comprised approximately 66%, 66% and 59% of our total revenues for the years ended December 31, 2019, 2018 and 2017, respectively. If our U.S. sales were significantly impacted by material changes to government or private payor reimbursement, other regulatory developments, competition or other factors, then our business would be adversely affected.

Based on current agreement with Takeda, we will cease to produce GLASSIA for Takeda after 2021 as Takeda begins its own production of GLASSIA, which will result in a significant reduction of our revenues and profitability, as well as excess manufacturing plant capacity, which will reduce manufacturing efficiencies.

In September 2019, we announced the extension of our strategic supply agreement with Takeda for GLASSIA in the U.S., pursuant to which we will continue to produce GLASSIA for Takeda through 2021. Based on the licensing and technology transfer agreement signed in 2010, Takeda is planning to complete the technology transfer of GLASSIA, and pending FDA approval, will initiate its own production of GLASSIA for the U.S. market in 2021. Accordingly, following the transition of manufacturing to Takeda, we will terminate the manufacturing of GLASSIA for Takeda, and based on the agreement between the companies, upon initiation of sales of GLASSIA manufactured by Takeda, Takeda will pay royalties to us at a rate of 12% on net sales through August 2025, and at a rate of 6% thereafter until 2040, with a minimum of $5 million annually, for each of the years from 2022 to 2040. Based on current GLASSIA sales in the United States and forecasted future growth, we project receiving royalties from Takeda in the range of $10 million to $20 million per year for 2022 to 2040.

The transition of GLASSIA manufacturing to Takeda and the transition of the agreement to royalties phase, will result in a significant reduction of our revenue and profitability. As an illustration, in the event the transition of the agreement to its royalty phase would have taken place in 2019, our revenues would have been reduced by $68.1 million (which is the total revenues generated by GLASSIA sales to Takeda during the year ended December 31, 2019), our gross profit would have been reduced by a range of $27 million to $29 million. Such revenues and gross profitability reduction would have been offset by royalties that would have been paid by Takeda in the range of $10 million to $20 million. We also may suffer from reduced effectiveness in our manufacturing facility which may cause us to incur operating losses. See — "In our Proprietary Products segment, we currently rely on Takeda, which accounts for a significant portion of our total sales, and any disruption to our relationships with Takeda would have an adverse effect on our results of operations and profitability", and "We may have excess manufacturing plant capacity in our manufacturing facility, which may result in significant operating losses."

We may have excess manufacturing plant capacity in our manufacturing facility, which may result in significant operating losses.

After 2021, Takeda has no obligation to purchase a minimum amount of GLASSIA, and we estimate that Takeda will begin selling GLASSIA produced in its own manufacturing facility as early as 2022 and will only pay us royalties. As Takeda transitions to producing GLASSIA in its own facilities, we will incur a substantial reduction in revenues (as well as costs of goods sold) driven by the reduction in GLASSIA manufacturing. Our revenues will decrease and our operating results may be materially and adversely impacted if we are unable to continue operating our manufacturing facility at its current capacity and/or level of profitability, or otherwise to reduce direct and indirect costs relating to our manufacturing facility in line with any reduction in demand. In 2020, the reduced plant utilization (as well as the expected change in product sales mix) is anticipated to result in an overall decrease in the Propriety Products segment's full-year gross margins of approximately three to five percentage points as compared to 2019.

Following the transition of GLASSIA manufacturing to Takeda, we plan to utilize the excess manufacturing capacity in our manufacturing plant to support the growth of our other existing proprietary products, including KEDRAB. While we are capable of manufacturing more of these products, there is no assurance that there will be increased market demand for these products in the currently existing markets in which we distribute our products or other markets. The manufacturing of excess quantities of products which may not be sold due to lower demands may results in the need to write-down the value of inventories which may result in significant operating losses.

We believe the risk of not adequately adjusting to lower plant utilization could result in inefficiencies, reduced profitability or operating losses. In addition, these changes may require significant layoffs, which may be expensive and may lead to labor issues and strikes which could affect our ability to continue to manufacture products and may lead to increase costs, reduced profitability and operating losses.

Manufacturing of new plasma-derived products in our manufacturing facility requires a lengthy and challenging technology transfer project and obtaining necessary regulatory approvals, both of which may not materialize.

We are exploring opportunities to manufacture in our manufacturing plant other new plasma-derived products which we have not previously manufactured. The manufacturing of other plasma-derived products in our plant, including, a hyper-immune globulin product for which we executed a 12-year contract manufacturing agreement with an undisclosed partner, requires a lengthy and challenging technology transfer project through which we transfer the know-how and capabilities to manufacture the new product. Such projects are usually complex and involve investment of significant time (approximately two to four years) and resources. There is no assurance that such technology transfer projects will be successful and will allow us to manufacture the new product according to its required specifications.

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

In addition, there can be no assurance that we will be able to find and secure agreements for the manufacturing of other plasma-derived products to be manufactured in our manufacturing plant for various reasons, such as lack of relevant products, technological differences, capacity constraints, or inability to secure adequate commercial terms.

If we are unable to secure new agreements for manufacturing of new plasma-derived products or are unable to adequately complete the required technology transfer projects or subsequently obtain the required regulatory approvals, we will not be able to utilize the excess capacity of our manufacturing plant and may suffer reduced profitability or operating losses.

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

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

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

Pursuant to our partnership arrangement with Takeda, Takeda is the sole distributor of GLASSIA in the United States, Canada, Australia and New Zealand. Sales to Takeda accounted for approximately 54%, 56% and 59% of our total revenues in the years ended December 31, 2019, 2018 and 2017, respectively. We also depend upon Takeda for the supply of fraction IV plasma for our production of GLASSIA to be sold in the United States. See "—We would become supply-constrained and our financial performance would suffer if we were unable to obtain adequate quantities of source plasma or plasma derivatives or specialty ancillary products approved by the FDA, the EMA or the regulatory authorities in Israel, or if our suppliers were to fail to modify their operations to meet regulatory requirements or if prices of the source plasma or plasma derivatives were to raise significantly."

If we fail to maintain our relationship with Takeda, we could face significant costs in finding a replacement distributor for the markets Takeda serves for GLASSIA and a replacement supplier of fraction IV plasma for GLASSIA. Delays in establishing a relationship with a new distributor and supplier could lead to a decrease in our sales and a deterioration in our market share compared to one or more of our competitors. Any of the foregoing developments could have an adverse effect upon our sales, margins and profitability.

As Takeda transitions to producing GLASSIA in its own facilities, we will incur substantial reduction in revenues (as well as costs of goods sold), driven by the reduction in GLASSIA manufacturing. While we will receive royalty payments from Takeda based on its GLASSIA sales until 2040, and we may be able to partially offset the decrease in revenues by expanding sales of other products and in other territories, our revenues will decrease and our operating results may be materially and adversely impacted if we are unable to continue operating our manufacturing facility at its current capacity and/or level of profitability, or otherwise reduce fixed costs relating to our manufacturing facility in line with any reduction in demand.

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

Pursuant to the strategic distribution and supply agreement with Kedrion for the clinical development and marketing in the United States of KEDRAB, Kedrion is the sole distributor of KEDRAB in the United States. Sales to Kedrion accounted for approximately 13% and 10% of our total revenues in the years ended December 31, 2019 and 2018, respectively. We are dependent on Kedrion for its marketing and sales of KEDRAB in the United States.

We also depend upon a subsidiary of Kedrion for the supply of the hyper-immune plasma which is used for the production of KEDRAB to be sold in the United States. See "—We would become supply-constrained and our financial performance would suffer if we were unable to obtain adequate quantities of source plasma or plasma derivatives or specialty ancillary products approved by the FDA, the EMA or the regulatory authorities in Israel, or if our suppliers were to fail to modify their operations to meet regulatory requirements or if prices of the source plasma or plasma derivatives were to raise significantly."

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

In our Proprietary Products segment, we rely on third party distributers for the distribution and sales of our products in ex-U.S. markets (other than the Israeli market), and any disruption to our relationships with these third party distributers would have an adverse effect on our future results of operations and profitability.

We engage third party distributors in ex-U.S. markets to distribute and sell our Proprietary Products. Sales through distributors in ex-U.S. markets (other than the Israeli market) accounted for approximately 13%, 17% and 24% of our total revenues in the years ended December 31, 2019, 2018 and 2017, respectively. We are dependent of these third parties for marketing, distribution and sales of our products in these markets.

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

Our Proprietary Products segment operates in a highly competitive market.

We compete with well-established drug companies, including two to four large competitors for each of our products in the Proprietary Products segment. These large competitors include CSL Behring Ltd. ("CSL"), Takeda, and Grifols S.A. ("Grifols"), which acquired a competitor, Talecris Biotherapeutics, Inc. ("Talecris") in 2011, and Kedrion. We compete against these companies for, among other things, licenses, expertise, clinical trial patients and investigators, consultants and third-party strategic partners. We also compete with these companies for market share for certain products in the Proprietary Products segment. Our large competitors have advantages in the market because of their size, financial resources, markets and the duration of their activities and experience in the relevant market, especially in the United States and countries of the European Union. As a result, they may be able to devote more funds to research and development and new production technologies, as well as to the promotion of their products and business. These competitors may also be able to sustain for longer periods a deliberate substantial reduction in the price of their products or services. Some of them also have an additional advantage regarding the availability of raw materials, as they own companies that collect plasma and/or plants which fractionate plasma.

Our products generally do not benefit from patent protection and compete against similar products produced by other providers. Additionally, the development by a competitor of a similar or superior product or increased pricing competition may result in a reduction in our net sales or a decrease in our profit margins. For example, we believe that our two main competitors in the AAT market are Grifols and CSL. We estimate that Grifols' AAT by infusion product for the treatment of AATD, Prolastin A1PI, accounts for at least 50% market share in the United States and more than 70% of sales in the worldwide market for the treatment of AATD, which also includes sales of Prolastin in different European countries. Apart from its sales through Talecris' historical business, Grifols is also a local producer of the product in the Spanish market and operates in Brazil. CSL's intravenous AAT product is mainly sold in the United States. In 2015, CSL's intravenous AAT product was granted centralized marketing authorization in Europe and CSL launched the product in a few European countries during 2016. There is another, smaller local producer in the French market, LFB S.A. In addition, we estimate that each of Grifols and CSL owns approximately 200-250 operating plasma collection centers located across the United States.

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

In addition, our plasma-derived protein therapeutics face, or may face in the future, competition from existing or newly developed non-plasma products and other courses of treatments. New treatments, such as gene therapy, small molecules, correctors, monoclonal or recombinant products, may also be developed for indications for which our products are now used. Our competitors are attempting to develop similar products or products that could be a substitute for AAT product. For example, several of our competitors are conducting clinical trials for the development of gene therapy or correctors for AATD. While these products are in the early stages of development, they may eventually be successfully developed and launched, and could adversely impact our revenue and growth of sales of GLASSIA or GLASSIA -related royalties as well as affect our ability to launch our Inhaled AAT product, if approved.

We believe that there are two main competitors for KamRAB/KEDRAB, our anti-rabies products, worldwide: Grifols, whose product we estimate comprises approximately 75%-85% of the anti-rabies market in the United States, and CSL, which sells its anti-rabies product in Europe and elsewhere. In addition, 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 which are based on equine serum. Over the past several years, a number of companies have made attempts and some are still in the process of developing monoclonal antibodies for an anti-rabies treatment. These products, if approved, may be as effective as the currently available plasma derived anti-rabies vaccine and may potentially be significantly cheaper, and as such may result in loss of market share of KamRAB/KEDRAB.

While Kedrion is our strategic partner for KEDRAB, it is also one of our competitors for KamRho(D). In addition to its sales in the United States, Kedrion also markets a competing product in several EU countries as well as other countries world-wide. We believe there are three additional main suppliers of competitive products in this market: Grifols, CSL and Saol Therapeutics. There are also local producers in other countries that make similar products mostly intended for local markets.

We do not currently sell any propriety recombinant products. We have begun developing recombinant version of AAT, through external services of a Contract Development and Manufacturing Organization (“CDMO”), but we cannot be certain that such product will ever be approved or commercialized. See “Item 4. Information on the Company — Our Product Pipeline and Development Program — Recombinant AAT.” The main advantage of recombinant AAT is its potentially wider availability, and ease of large scale manufacturing. As a result, our product offerings may remain plasma-derived, even if our competitors offer competing recombinant or other non-plasma products or treatments.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Any new product must undergo lengthy and rigorous testing and other extensive, costly and time-consuming procedures mandated by the FDA and similar authorities in other jurisdictions, including the EMA and the regulatory authorities in Israel. Our facilities must be approved and licensed prior to production and remain subject to inspection from time to time thereafter. Failure to comply with the requirements of the FDA or similar authorities in other jurisdictions, including a failed inspection or a failure in our reporting system for adverse effects of our products experienced by the users of our products, or any other non-compliance, could result in warning letters, product recalls or seizures, monetary sanctions, injunctions to halt the manufacture and distribution of products, civil or criminal sanctions, import or export restrictions, refusal or delay of a regulatory authority to grant approvals or licenses, restrictions on operations or withdrawal of existing approvals and licenses. Furthermore, we may experience delays or additional costs in obtaining new approvals or licenses, or extensions of existing approvals and licenses, from a regulatory authority due to reasons that are beyond our control such as changes in regulations or a shutdown of the U.S. federal government, including the FDA, or similar governing bodies or authorities in other jurisdictions. In addition, we rely to a large extent on Takeda for purposes of most of our regulatory compliance for GLASSIA and product development and approvals in the United States relating to GLASSIA. Any failure by Takeda to properly advise us regarding, or properly perform tasks related to, regulatory compliance requirements, could adversely affect us. If our relationship with Takeda terminated for any reason, we may be unable to maintain regulatory compliance on a cost-effective basis, if at all. Any of these actions could cause direct liabilities, a loss in our ability to market GLASSIA, or a loss of customer confidence in us or GLASSIA, which could materially adversely affect our sales, future revenues, reputation, and results of operations. Similarly, we rely on other third-party vendors, for example, in the production, handling, and distributions of GLASSIA. If any of these companies incur enforcement action from regulatory authorities due to noncompliance, this could negatively affect product sales, our reputation and results of operations. In addition, we rely on other distributors of our products, such as Kedrion in the United States, for purposes of our regulatory compliance for the products they distribute in the territories in which they operate. Any failure by such distributors to properly advise us regarding, or properly perform tasks related to, regulatory compliance requirements, could adversely affect us.

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

In addition, changes in the regulation of our activities, such as increased regulation affecting safety requirements or new regulations such as limitations on the prices charged to customers in the United States, Israel or other jurisdictions in which we operate, could materially adversely affect our business. In addition, the requirements of different jurisdictions in which we operate may become less uniform, creating a greater administrative burden and generating additional compliance costs, which would have a material adverse effect on our profit margins.

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

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

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

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

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

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

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

Some of our required specialty ancillary products and other materials used in the manufacturing process are commonly used in the healthcare industry world-wide. If the global demand for these products increases due to healthcare issues and epidemics, such as the recent coronavirus (2019-nCoV) outbreak, our ability to secure adequate supply at reasonable cost of such products may be negatively affected, which would materially adversely affect our ability to manufacture and distribute our products, which would adversely affect our sales and results of operations.

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

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

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

When a new product is approved, the FDA or other regulatory authorities may require post-approval clinical trials, sometimes called Phase IV clinical trials. For example, the FDA has required that we conduct Phase IV clinical trials of GLASSIA, which began in 2015, and for KEDRAB, which began in 2017. Such Phase IV clinical trials are aimed at collecting additional safety data, such as the immune response in the body of a human or animal, commonly referred to as immunogenicity, viral transmission, levels of the protein in the lung, or epithelial lining fluid, and certain efficacy endpoints requested by the FDA. If the results of such trials are unfavorable and demonstrate a previously undetected risk or provide new information that puts patients at risk, or if we fail to complete such trials as instructed by the FDA, this could result in receiving a warning letter from the FDA and the loss of the approval to market the product in the United States and other countries, or the imposition of restrictions, such as additional labeling, with a resulting loss of sales. Other products we develop may face similar requirements, which would require additional resources and which may not be successful. We may also receive approval, which is conditional on successful additional data or clinical development, and failure in such further development may require similar changes to our product label or result in revocation of our marketing authorization.

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

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

Risks Related to Our Distribution Segment

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

Sales of products supplied by Bio Products Laboratories Ltd. ("BPL") and Biotest A.G., which are sold in our Distribution segment, together represented approximately 19%, 17% and 17% and of our total revenues for the years ended December 31, 2019, 2018 and 2017, respectively. While we have distribution agreements with each of our suppliers, these agreements do not obligate these suppliers to provide us with minimum amounts of our Distribution segment products. Purchases of our Distribution segment products from our suppliers are typically on a purchase order basis. We work closely with our suppliers to develop annual forecasts, but these forecasts are not obligations or commitments. However, if we fail to submit purchase orders that meet our annual forecasts or if we fail to meet our minimum purchase obligations, we could lose exclusivity or, in certain cases, the distribution agreement could be terminated.

These suppliers may experience capacity constraints that result in their being unable to supply us with products in a timely manner, in adequate quantities and/or at a reasonable cost. Contributing factors to supplier capacity constraints may include, among other things, industry or customer demands in excess of machine capacity, labor shortages, changes in raw material flows or shortages in raw materials which may result from different market conditions including, but not limited to, shortages resulting from increased global demand for these raw materials due to global healthcare issues and epidemics, such as the recent coronavirus (2019-nCoV) outbreak. These suppliers may also choose not to supply us with products at their discretion or raise prices to a level that would render our products noncompetitive. Any significant interruption in the supply of these products could result in us being unable to meet the demands of our customers, which would have a material adverse effect on our business, financial condition and results of operations as a result of being required to pay of fines or penalties, be subject to claims of reach of contract, loss of reputation or even termination of agreement.

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

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

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

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

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

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

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

The Israeli market for drug products includes a relatively small number of Health Maintenance Organizations ("HMOs") and several hospitals. Sales to Clalit Health Services, an Israeli HMO, accounted for approximately 46%, 43% and 34% of our Distribution Segment revenues in the years ended December 31, 2019, 2018 and 2017, respectively.

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

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

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

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

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

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

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

We may face competition in our Distribution segment.

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

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

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

We completed a Phase II clinical trial of our Inhaled AAT for AATD in the United States, which met its primary endpoint. However, when we presented the data from the European Phase II/III study to the FDA in April 2016, the FDA expressed concerns and questions about that data, primarily related to the safety and efficacy of Inhaled AAT for the treatment of AATD and the risk/benefit balance to patients based on that data. In order to address the FDA's concerns and questions, in April 2017, we submitted to the agency the results of the U.S. Phase II data together with a proposed Phase III synopsis. The FDA then provided us with guidance for further development of the synopsis and requested that we submit a complete proposed study protocol for the next phase prior to enabling us to continue clinical development and initiate the Phase III study in the United States. In July 2017, we submitted a full study protocol, and in August 2017, in response to the study protocol and previous submission, the FDA issued a letter stating that it continues to have concerns and questions about the safety and efficacy of the Inhaled AAT for AATD. We provided the FDA with data and information related to their concerns and in April 2018, the FDA issued a response letter providing further guidance regarding the proposed pivotal Phase III protocol, as well as additional questions focused on the Inhaled AAT product characteristics. This correspondence indicated that, while several issues had been addressed, the FDA had continued concerns and questions related to the safety profile of Inhaled AAT for AATD. Following a thorough assessment of the FDA response, we provided the requested information and data and implemented the proposed changes in the study protocol during the second half of 2018. In April 2019, the FDA stated that we satisfactorily addressed the concerns and questions regarding the Inhaled AAT for AATD, and based on the feedback received from the FDA regarding anti-drug antibodies (ADA) to the Inhaled AAT for AATD, we intend to concurrently conduct a sub-study in North America in which approximately 30 patients will be evaluated for the effect of ADA on AAT levels in plasma with Inhaled AAT for AATD and IV AAT treatments. We expect to receive further feedback from the FDA related to our Human Factor Study ("HFS"), which we completed in the third quarter of 2019, which was required to support the combination product, consisting of our Inhaled AAT and the investigational eFlow nebulizer system of PARI.

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

Clinical trials are expensive to conduct and may not result in receipt of regulatory approval.

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

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

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

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

- delays may occur in obtaining our clinical materials;
- our preclinical tests or clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical testing or clinical trials or to abandon strategic projects;
- the number of patients required for our clinical trials may be larger than we anticipate, enrollment in our clinical trials may be slower or more difficult than we anticipate, or participants may withdraw from our clinical trials at higher rates than we anticipate;
- delays may occur in reaching agreement on acceptable clinical trial agreement terms with prospective sites or obtaining institutional review board approval;
- our strategic partners may not achieve their clinical development goals and/or comply with their relevant regulatory requirements, which could affect our ability to conduct our clinical trials or obtain marketing authorization;
- we may be forced to suspend or terminate our clinical trials if the participants are being exposed to unacceptable health risks or if any participant experiences an unexpected serious adverse event;
- regulators or institutional review boards may require that we hold, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements;
- regulators may not authorize us to commence or conduct a clinical trial within a country or at a prospective trial site, or according to the clinical trial outline we propose;
- undetected or concealed fraudulent activity by a clinical researcher, if discovered, could preclude the submission of clinical data prepared by that researcher, lead to the suspension or substantive scientific review of one or more of our marketing applications by regulatory agencies, and result in the recall of any approved product distributed pursuant to data determined to be fraudulent;
- the cost of our clinical and preclinical trials may be greater than we anticipate;
- an audit of preclinical tests or clinical studies by the FDA, the EMA, the regulatory authorities in Israel or other regulatory authorities may reveal noncompliance with applicable regulations, which could lead to disqualification of the results of such studies and the need to perform additional tests and studies; and
- our product candidates may not achieve the desired clinical benefits, or may cause undesirable side effects, or the product candidates may have other unexpected characteristics.

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

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

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

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

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

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

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

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

We operate in highly innovative businesses. We currently rely on sales of GLASSIA for the treatment of AATD for a significant portion of our total revenues. However, our continued growth depends in large part on our ability to develop and obtain regulatory approvals of new products, new enhancements and/or new indications for our products and product candidates. Obtaining regulatory approval in any jurisdiction, including from the EMA or the FDA, involves significant uncertainty and may be time consuming and require significant expenditures. See "—Research and development efforts invested in our pipeline of specialty and other products may not achieve expected results." We have experienced delays at various stages of obtaining regulatory approval in the past, and failure to obtain regulatory approval of the Inhaled AAT for AATD product or of any of our other product candidates or additional indications in a timely manner or at all would materially adversely impact our business prospects. For example, the Phase II/III clinical trial in Europe for Inhaled AAT for AATD did not meet its primary or other pre-defined endpoints and, following our discussions with the EMA in regards to the study results, in June 2017, we withdrew the MAA in Europe for our Inhaled AAT for AATD. When we presented the data from the European Phase II/III study to the FDA, the agency expressed concerns and questions about that data, primarily related to the safety and efficacy of our Inhaled AAT for the treatment of AATD and the risk/benefit balance to patients based on that data. In April 2019, the FDA stated that we satisfactorily addressed the concerns and questions regarding the Inhaled AAT for AATD, and based on the feedback received from the FDA regarding anti-drug antibodies (ADA) to the Inhaled AAT for AATD, we intend to concurrently conduct a sub-study in North America in which approximately 30 patients will be evaluated for the effect of ADA on AAT levels in plasma with Inhaled AAT for AATD and IV AAT treatments. We expect to receive further feedback from the FDA related to our Human Factor Study ("HFS"), which we completed in the third quarter of 2019, which was required to support the combination product, consisting of our Inhaled AAT and the investigational eFlow nebulizer system of PARI. See also "—We may not be able to commercialize our product candidates in development for numerous reasons."

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

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

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

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

Accordingly, there can be no assurance that the continued development of our IV AAT (GLASSIA) for the treatment of GvHD, lung transplantation rejection, organ preservation and recombinant AAT will be successful and will result in an FDA and/or EMA approvable indication.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Financial Position and Capital Resources

We have incurred significant losses since our inception and while we were profitable in the year ended December 31, 2019, we may incur losses in the future and thus may never achieve sustained profitability.

As of December 31, 2019, our cash and cash equivalents and short-term investments were $73.9 million. Since inception, we have incurred significant operating losses. While our net profit was $22.2 million, $22.3 million and $6.9 million for the years ended December 31, 2019, 2018 and 2017, respectively, as of December 31, 2019, we had an accumulated deficit of $61.1 million. There can be no assurance that we could continue to generate profitability in future years.

Our business requires substantial capital, including potential investments in large capital projects, to operate and grow and to achieve our strategy of realizing increased operating leverage.

In order to obtain FDA, EMA and other regulatory approvals for product candidates and new indications for existing products, we may be required to enhance the facilities in which and processes by which we manufacture existing products, to develop new product delivery mechanisms for existing products, to develop innovative product additions and to conduct clinical trials. We face a number of obstacles that we will need to overcome in order to achieve our operating goals, including but not limited to the successful development of experimental products for use in clinical trials, the design of clinical study protocols acceptable to the FDA, the EMA and other regulatory authorities, the successful outcome of clinical trials, scaling our manufacturing processes to produce commercial quantities or successfully transition technology, obtaining FDA, EMA and other regulatory approvals of the resulting products or processes and successfully marketing an approved or new product with applicable new processes. To finance these various activities, we may need to incur future debt or issue additional equity. We may not be able to structure our debt obligations on favorable economic terms and any offering of additional equity would result in a dilution of the equity interests of our current shareholders. A failure to fund these activities may harm our growth strategy, competitive position, quality compliance and financial condition.

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

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

As of December 31, 2019, we had cash and short-term investments of $73.9 million, compared to cash and short-term investments of approximately $50.6 million as of December 31, 2018. We plan to fund our future operations through continued sale and distribution of our proprietary and distribution products, commercialization and or out-licensing of our pipeline product candidates, and raising additional capital through the sale of equity or debt. These amounts may not be sufficient to complete the research and development of all of our candidates, and there can be no assurances of the financial success of our commercialization activities or our ability to access the equity and debt capital markets on terms acceptable to us, if at all. To the extent we are unable to fund our research and development, our future product development activities could be materially adversely affected.

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

We have filed a registration statement on Form F-3 with the U.S. Securities and Exchange Commission (“SEC”) utilizing a “shelf” registration process, and such shelf registration statement was declared effective on July 13, 2017. Under this shelf registration process, we may offer from time to time up to an aggregate of $100,000,000 of our ordinary shares in one or more offerings. Pursuant to such shelf registration statement, in August 2017, we issued an aggregate of 3,833,334 ordinary shares in an underwritten public offering (including the exercise of the over-allotment option). To the extent that we raise additional funds through the sale of equity or securities that are convertible into or exchangeable for, or that represent the right to receive, ordinary shares or substantially similar securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a shareholder. Debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration, strategic alliance and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates, or grant licenses on terms that are not favorable to us. The shelf registration statement will remain effective until July 2020. If we do not file a new shelf registration statement prior to July 2020, the existing shelf registration statement will expire and we will not be able to publicly raise capital or issue debt until a new registration statement is filed and becomes effective. There can be no assurance that we will be eligible to file an automatically effective shelf registration statement at a future date when we may need to raise funds publicly.

Risks Related to Our Business and Industry

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

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

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

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

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

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

Any regulatory approval of our products is limited to those specific diseases and indications for which our products have been deemed safe and effective by the FDA or similar authorities in other jurisdictions. In addition to the regulatory approval required for new formulations, any new indication for an approved product also requires regulatory approval. Once we produce a plasma-derived protein therapeutic, we rely on physicians to prescribe and administer it as the product label directs and for the indications described on the labeling. To the extent any off-label (i.e., unapproved) uses and departures from the approved administration directions become pervasive and produce results such as reduced efficacy or other adverse effects, the reputation of our products in the marketplace may suffer. In addition, off-label uses may cause a decline in our revenues or potential revenues, to the extent that there is a difference between the prices of our product for different indications.

Furthermore, while physicians may choose to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those approved by regulatory authorities, our ability to promote the products is limited to those indications that are specifically approved by the FDA or other regulators. Although regulatory authorities generally do not regulate the behavior of physicians, they do restrict communications by companies on the subject of off-label use. If our promotional activities fail to comply with these regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, failure to follow FDA rules and guidelines relating to promotion and advertising can lead to other negative consequences that could hurt us, such as the suspension or withdrawal of an approved product from the market, enforcement letters, and corrective actions. Other regulatory authorities may impose separately penalties including, but not limited to, fines, disgorgement of money, operating restrictions, or criminal prosecution.

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

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

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

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

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

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

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

We are subject to risks associated with doing business globally.

Our operations are subject to risks inherent to conducting business globally and under the laws, regulations and customs of various jurisdictions and geographies. These risks include fluctuations in currency exchange rates, changes in exchange controls, loss of business in government and public tenders that are held annually in many cases, nationalization, expropriation and other governmental actions, availability of raw materials, changes in taxation, importation limitations, export control restrictions, changes in or violations of applicable laws, including the U.S. Foreign Corrupt Practices Act ("FCPA"), the U.K. Bribery Act of 2010, pricing restrictions, economic and political instability, disputes between countries, diminished or insufficient protection of intellectual property, and disruption or destruction of operations in a significant geographic region regardless of cause, including war, terrorism, riot, civil insurrection or social unrest. Failure to comply with, or material changes to, the laws and regulations that affect our global operations could have an adverse effect on our business, financial condition or results of operations.

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

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

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

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

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

We are subject to foreign currency exchange risk.

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

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

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

Developments in the economy may adversely impact our business.

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

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

The recent coronavirus (2019-nCoV) outbreak may adversely impact our business.

The recent coronavirus (2019-nCoV) outbreak and its continued progress may have an adverse impact on our business in many aspects, including, but not limited to the following:

- While we do not procure raw materials, products or services from China and we do not sell or distribute our products in the Chinese market, some of our raw materials, auxiliary materials and auxiliary products (the “Auxiliary Supplies”) required for the manufacturing of our products may be required by public and private health care service providers in order to treat or prevent 2019-cCoV. Increased demand for these Auxiliary Supplies may negatively affect our ability to secure adequate supply at reasonable cost of such Auxiliary Supplies, which would materially adversely affect our ability to manufacture and distribute our products, and would adversely affect our sales and results of operations.

- While we do not procure products or Auxiliary Supplies from the Chinese market, some of our suppliers in our Proprietary Products segment and the Distribution Products segment, may be procuring products or Auxiliary Supplies from the Chinese market. These suppliers’ inability to continue to secure supplies from the Chinese market may have an effect on their ability to supply us and our ability to continue manufacture and distribute products, which would adversely affect our sales and results of operations.

- While currently there has not been a significant 2019-nCoV outbreak in Israel, certain precautions are being taken by the IMOH, such as requiring individuals who returned from trips in certain countries, or who may have been exposed to the 2019-nCoV, or may have developed symptoms associated with being infected by the 2019-nCoV, to undergo a minimum of 14 days isolation period in order to minimize the spread of the epidemic. Such isolation period and potential infection of individuals in Israel may affect our employees and our ability to continuously and effectively operate. which would materially adversely affect our ability to manufacture and distribute our products, and would adversely affect our sales and results of operations.

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

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

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

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

Our product offerings in our Proprietary Products segment are predicted to increase. A failure to increase our manufacturing volume as needed or continued manufacturing at or close to our plant's maximum capacity levels may lead to an inability to supply products, may have an adverse effect on our business and could cause substantial harm to our business reputation and result in breach of our sales agreements and the loss of future customers and orders.

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

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

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

Our plasma raw materials must be transported at a temperature of -20 degrees Celsius (-4 degrees Fahrenheit) to ensure the preservation of their proteins. Not all shipping or distribution channels are equipped to transport plasma at these temperatures. If any of our shipping or distribution channels become inaccessible because of a serious accident, act of terrorism, strike or any other force majeure event, we may experience disruptions in our continued supply of plasma and other raw materials, delays in our production process or a reduction in our ability to distribute our plasma-derived protein therapeutics to our customers.

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

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

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

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

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

Pursuant to applicable privacy laws, we must comply with comprehensive privacy and security standards with respect to the use and disclosure of protected health information. If we do not comply with existing or new laws and regulations related to protecting privacy and security of personal or health information, we could be subject to monetary fines, civil penalties, or criminal sanctions. We may be required to comply with the data privacy and security laws of other countries in which we operate or from which we receive data transfers. For example, the General Data Protection Regulation (“GDPR”) which took effect May 25, 2018, has broad application and enhanced penalties for noncompliance. The GDPR, which is wide-ranging in scope, governs the collection and use of personal data in the European Union and imposes operational requirements for companies that receive or process personal data of residents of the European Union. The GDPR may apply to our clinical development operations. In addition, the Israeli Privacy Protection Regulations (Information Security), 2017, which apply to our operations in Israel, require us to take certain security measures to secure the processing of personal data. While we take reasonable and prudent steps to protect personal information and use such information in accordance with applicable privacy laws, a compromise in our security systems that results in patient personal information being obtained by unauthorized persons or our failure to comply with security requirements for financial transactions could adversely affect our reputation with our clients and result in litigation against us or the imposition of penalties, all of which may adversely impact our results of operations, financial condition and liquidity. In addition, given that the privacy laws and regulations in the jurisdictions in which we operate are new and subject to further judicial review and interpretation, it may be determined at a future time that although we take prudent measures to comply with such laws and regulations, such measures will not be sufficient to meet future elaborations or interpretations of such laws and regulations.

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

The healthcare regulatory environment in the U.S. is currently subject to significant uncertainty and the industry may in the future continue to experience fundamental change as a result of regulatory reform. In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "healthcare reform law"), a sweeping measure intended to expand healthcare coverage within the United States, primarily through the imposition of health insurance mandates on employers and individuals and expansion of the Medicaid program. The healthcare reform law, among other things: (i) addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; (ii) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations; (iii) established annual fees and taxes on manufacturers of certain branded prescription drugs; (iv) expanded the availability of lower pricing under the 340B drug pricing program by adding new entities to the program; and (v) established a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D. On April 1, 2016, final regulations issued by the Centers for Medicare and Medicaid Services to implement the changes to the Medicaid Drug Rebate Program under the healthcare reform law became effective. In addition, the new law established an abbreviated licensure pathway for products that are drugs made by a living organism or derived from a living organism, commonly referred to as biosimilars, to become FDA-approved biological products, with provisions covering exclusivity periods and a specific reimbursement methodology for biosimilars.

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

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

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

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

For example, under the Anti-Kickback Law, and similar state laws and regulations, even common business arrangements, such as discounted terms and volume incentives for customers in a position to recommend or choose drugs and devices for patients, such as physicians and hospitals, can result in substantial legal penalties, including, among others, exclusion from Medicare and Medicaid programs, if those business arrangements are not appropriately structured; therefore, our arrangements with referral sources must be structured with care to comply with applicable requirements. Also, certain business practices, such as payment of consulting fees to healthcare providers, sponsorship of educational or research grants, charitable donations, interactions with healthcare providers that prescribe products for uses not approved by the FDA and financial support for continuing medical education programs, must be conducted within narrowly prescribed and controlled limits and reported in accordance with the Physician Payments Sunshine Act to avoid any possibility of wrongfully influencing healthcare providers to prescribe or purchase particular products or as a reward for past prescribing. Significant enforcement activity has been the result of actions brought by relators, who file complaints in the name of the United States (and if applicable, particular states) under federal and state False Claims Act statutes and can be entitled to receive a significant portion (often as great as 30%) of total recoveries. Also, violations of the False Claims Act can result in treble damages, and each false claim submitted can be subject to a penalty of up to $22,927 per claim. Through the Physician Payments Sunshine Act, the healthcare reform law imposes reporting and disclosure requirements for pharmaceutical and medical device manufacturers with regard to a broad range of payments, ownership interests, and other transfers of value made to certain U.S. physicians and teaching hospitals. A number of states have similar laws in place and often require reporting for other categories of healthcare professionals, such as nurses. Additional and stricter prohibitions could be implemented by federal and state authorities. On the other hand, as President Trump has vowed to repeal the healthcare reform law, it is uncertain whether such data collection obligations would be repealed or replaced with new regulations. Where practices have been found to involve improper incentives to use products, government investigations and assessments of penalties against manufacturers have resulted in substantial damages and fines. Many manufacturers have been required to enter into consent decrees, corporate integrity agreements, or orders that prescribe allowable corporate conduct. Failure to satisfy requirements under the FDCA can also result in penalties, as well as requirements to enter into consent decrees or orders that prescribe allowable corporate conduct.

To market and sell our products outside the United States, we must obtain and maintain regulatory approvals and comply with regulatory requirements in such jurisdictions. The approval procedures vary among countries in complexity and timing. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all, and in such case, we would be precluded from commercializing products in those markets. In addition, some countries, particularly the countries of the European Union, regulate the pricing of prescription pharmaceuticals. In these countries, pricing discussions with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. Such trials may be time-consuming and expensive and may not show an advantage in cost-efficacy for our products. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, in either the United States or the European Union, we could be adversely affected. Also, under the FCPA, the United States has regulated conduct by U.S. businesses occurring outside of the United States, generally prohibiting remuneration to foreign officials for the purpose of obtaining or retaining business.

To enhance compliance with applicable health care laws, and mitigate potential liability in the event of noncompliance, regulatory authorities, such as the Department of Health and Human Services' Office of Inspector General ("OIG"), have recommended the adoption and implementation of a comprehensive health care compliance program that generally contains the elements of an effective compliance and ethics program described in Section 8B2.1 of the U.S. Sentencing Commission Guidelines Manual. Increasing numbers of U.S.-based pharmaceutical companies have such programs. We have not adopted U.S. healthcare compliance and ethics programs that generally incorporate the HHS OIG's recommendations. Even if we do, having such a program can be no assurance that we will avoid any compliance issues.

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

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

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

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

We regularly monitor our compliance with applicable financial reporting standards and review new pronouncements and drafts thereof that are relevant to us. As a result of new standards, changes to existing standards (including the new IFRS 15 on revenue from contracts with customers that we adopted in 2018 and IFRS 16 on leases that we adopted in 2019) and changes in their interpretation, we might be required to change our accounting policies, particularly concerning revenue recognition, to alter our operational policies so that they reflect new or amended financial reporting standards, or to restate our published financial statements. Such changes might have an adverse effect on our reputation, business, financial position, and profit, or cause an adverse deviation from our revenue and operating profit target.

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

Our business involves the controlled use of hazardous materials, various biological compounds and chemicals. The risk of accidental contamination or injury from these materials cannot be eliminated. If an accident, spill or release of any regulated chemicals or substances occurs, we could be held liable for resulting damages, including for investigation, remediation and monitoring of the contamination, including natural resource damages, the costs of which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of biohazardous materials and chemicals. Although we maintain workers' compensation insurance to cover the costs and expenses that may be incurred because of injuries to our employees resulting from the use of these materials, this insurance may not provide adequate coverage against potential liabilities. Additional or more stringent federal, state, local or foreign laws and regulations affecting our operations may be adopted in the future. We may incur substantial capital costs and operating expenses and may be required to obtain consents to comply with any of these or certain other laws or regulations and the terms and conditions of any permits required pursuant to such laws and regulations, including costs to install new or updated pollution control equipment, modify our operations or perform other corrective actions at our respective facilities. In addition, fines and penalties may be imposed for noncompliance with environmental, health and safety and other laws and regulations or for the failure to have, or comply with the terms and conditions of, required environmental or other permits or consents. We are subject to future audits by the Environmental Health Department of the Regional Health Bureau of the IMOH and the Ministry of Environmental Protection of Israel and may be required to perform certain actions from time to time in order to comply with these guidelines and their requirements. We do not expect the costs of complying with these guidelines to be material to our business. See "Item 4. Information on the Company — Environmental."

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

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

In December 2013, we signed a collective bargaining agreement with the employees' committee established by our employees at our Beit Kama production facility in Israel and the Histadrut (General Federation of Labor in Israel) ("Histadrut"), which expired in December 2017. In November 2018, we signed a new collective bargaining agreement with the employees' committee and the Histadrut, which will expire in December 2021. We have experienced labor disputes and work stoppages in the past and in July 2018, during the course of our negotiations with the Histadrut and the employees' committee on the extension of the initial collective bargaining agreement beyond the December 2017 expiration, the employee's committee commenced a labor strike, which continued for approximately one month. As a result of the labor strike, in the year ended December 31, 2018, we had a $1.8 million write-off of indirect manufacturing costs and $0.8 million of process materials scraps. Any future disputes with the committee and the Histadrut over the implementation or the interpretation or the renewal of the collective bargaining agreement may lead to additional labor costs and/or work stoppages, which could adversely affect our business operations, including through a loss of revenue and strained relationships with customers.

Tax legislation in the United States may impact our business.

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

Risks Related to Intellectual Property

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

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

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

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

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

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

Our patents also may not afford us protection against competitors or other third parties with similar technology. Because patent applications in the United States and many other jurisdictions are typically not published until 18 months after their filing, if at all, and because publications of discoveries in scientific literature often lag behind actual discoveries, neither we nor our licensors can be certain that we or they were the first to make the inventions claimed in our or their issued patents or pending patent applications, or that we or they were the first to file for protection of the inventions set forth in such patent applications. As a result, the patents we own and license may be invalidated in the future, and the patent applications we own and license may not be granted. For example, if a third party has also filed a patent application covering an invention similar to one covered in one of our patent applications, we may be required to participate in an adversarial proceeding, known as an “interference proceeding,” declared by the U.S. Patent and Trademark Office (“USPTO”) or its foreign counterparts to determine priority of invention. In 2012, the Leahy-Smith America Invents Act (“AIA”) created a new legal proceeding, the *inter partes review* petition, that allows third parties to challenge the validity of patents before the Patent Trials and Appeals Board.

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

Our patents expire at various dates between 2024 and 2029. However, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our products can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby limiting advantages of the patent. Our pending and future patent applications may not lead to the issuance of patents or, if issued, the patents may not be issued in a form that will provide us with any competitive advantage. We also cannot guarantee that: any of our present or future patents or patent claims or other intellectual property rights will not lapse or be invalidated, circumvented, challenged or abandoned; our intellectual property rights will provide competitive advantages or prevent competitors from making or selling competing products; our ability to assert our intellectual property rights against potential competitors or to settle current or future disputes will not be limited by our agreements with third parties; any of our pending or future patent applications will be issued or have the coverage originally sought; our intellectual property rights will be enforced in jurisdictions where competition may be intense or where legal protection may be weak; or we will not lose the ability to assert our intellectual property rights against, or to license our technology to, others and collect royalties or other payments. In addition, our competitors or others may design around our patents or protected technologies. Effective protection of our intellectual property rights may also be unavailable, limited or not applied in some countries, and even if available, we may fail to pursue or obtain necessary intellectual property protection in such countries. In addition, the legal systems of certain countries do not favor the aggressive enforcement of patents and other intellectual property rights, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. In order to preserve and enforce our patent and other intellectual property rights, we may need to make claims, apply certain patent or other regulatory procedures or file lawsuits against third parties. Such proceedings could entail significant costs to us and divert our management's attention from developing and commercializing our products. Lawsuits may ultimately be unsuccessful, and may also subject us to counterclaims and cause our intellectual property rights to be challenged, narrowed, invalidated or held to be unenforceable.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Ordinary Shares

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

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

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

Our share price may be volatile.

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

- actual or anticipated fluctuations in our financial condition and operating results;
- overall conditions in the specialty pharmaceuticals market;

- loss of significant customers or changes to agreements with our strategic partners;
- changes in laws or regulations applicable to our products;
- actual or anticipated changes in our growth rate relative to our competitors';
- announcements of clinical trial results, technological innovations, significant acquisitions, strategic alliances, joint ventures or capital commitments by us or our competitors;
- changes in key personnel;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- the issuance of new or updated research reports by securities analysts;
- disputes or other developments related to proprietary rights, including patents, litigation matters and our ability to obtain intellectual property protection for our technologies;
- announcement of, or expectation of, additional financing efforts;
- sales of our ordinary shares by us or our shareholders, including pursuant to the registration statement on Form F-3 that we filed in November 2016;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- recalls and/or adverse events associated with our products;
- the expiration of contractual lock-up agreements with our executive officers and directors; and
- general political, economic and market conditions.

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

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

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

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

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, 2019, we had 40,353,101 ordinary shares outstanding.

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

Furthermore, except for shares held by our affiliates as contemplated by Rule 144 under the U.S. Securities Act of 1933, as amended (the "Securities Act"), all of the ordinary shares that are outstanding as of December 31, 2019, as well as the 2,336,554 ordinary shares issuable upon exercise of outstanding options and the 145,896 restricted shares granted to certain officers and directors, are freely tradable in the United States without restrictions or further registration under the Securities Act. As of February 26, 2020, approximately 34% 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, pursuant to a registration rights agreement we entered into with FIMI Opportunity Funds on January 20, 2020, they have "demand" and "piggyback" registration rights covering the ordinary shares of our company held by them. All shares of FIMI Opportunity Funds sold pursuant to an offering covered by a registration statement would be freely transferable. Sales of a substantial number of shares of our ordinary shares, or the perception that the FIMI Opportunity Funds may exercise their registration rights, could put downward pressure on the market price of our ordinary shares and could impair our future ability to raise capital through an offering of our equity securities.

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

The FIMI Opportunity Funds (three of whose partners are members of our board of directors), Leon Recanati, the Chairman of our board of directors, and the Hahn family (including Jonathan Hahn, a member of our board of directors), beneficially owned, directly and indirectly, 21.13%, 8.15 % and 5.06% of our outstanding ordinary shares, respectively, as of February 26, 2020. For additional information, see "Item 7. Major Shareholders and Related Party Transactions — Major Shareholders." Accordingly, the FIMI Opportunity Funds, Leon Recanati, and the Hahn family through their equity ownership and board representation, individually and collectively, have significant influence over the outcome of matters required to be submitted to our shareholders for approval, including decisions relating to the election of our board of directors and the outcome of any proposed merger or consolidation of our company. Their interests may not be consistent with those of our other shareholders. In addition, these parties' significant interest in us may discourage third parties from seeking to acquire control of us, which may adversely affect the market price of our shares. On March 6, 2013, a shareholders agreement was entered into, effective March 4, 2013, pursuant to which Mr. Recanati and any company controlled by him (collectively, the "Recanati Group"), on the one hand, and Damar Chemicals Inc. ("Damar"), TUTEUR S.A.C.I.F.I.A ("Tuteur") (companies controlled by the Hahn family) and their affiliates (collectively, the "Damar Group"), on the other hand, have each agreed to vote the ordinary shares beneficially owned by them in favor of the election of director nominees designated by the other group as follows: (i) three director nominees, so long as the other group beneficially owns at least 7.5% of our outstanding share capital, (ii) two director nominees, so long as the other group beneficially owns at least 5.0% (but less than 7.5%) of our outstanding share capital, and (iii) one director nominee, so long as the other group beneficially owns at least 2.5% (but less than 5.0%) of our outstanding share capital. In addition, to the extent that after the designation of the foregoing director nominees there are additional director vacancies, each of the Recanati Group and Damar Group have agreed to vote the ordinary shares beneficially owned by them in favor of such additional director nominees designated by the party who beneficially owns the larger voting rights in our company. We are not party to such agreement or bound by its terms. As a result of such voting agreement, the Recanati Group and the Damar Group and their affiliates together have significant influence over the election of directors of the company.

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

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

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

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

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

We are a foreign private issuer and, as a result, are not subject to the same requirements as U.S. domestic issuers. Under the Exchange Act, we are subject to reporting obligations that, in certain respects, are less detailed and/or less frequent than those of U.S. domestic reporting companies. For example, we are not required to issue quarterly reports, proxy statements that comply with the requirements applicable to U.S. domestic reporting companies, or individual executive compensation information that is as detailed as that required of U.S. domestic reporting companies. We also have four months after the end of each fiscal year to file our annual reports with the SEC and are not required to file current reports as frequently or promptly as U.S. domestic reporting companies. Furthermore, our directors and executive officers will not be required to report equity holdings under Section 16 of the Exchange Act and will not be subject to the insider short-swing profit disclosure and recovery regime.

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

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

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

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

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

Risks Relating to Our Incorporation and Location in Israel

Conditions in Israel could adversely affect our business.

We are incorporated under Israeli law and our principal offices and manufacturing facilities are located in Israel. Accordingly, political, economic and military conditions in Israel directly affect our business. Since the State of Israel was established in 1948, a number of armed conflicts have occurred between Israel and its Arab neighbors. Although Israel has entered into various agreements with Egypt, Jordan and the Palestinian Authority, there has been terrorist activity with varying levels of severity over the years. During July and August 2014, Israel engaged in an armed conflict with Hamas in the Gaza Strip, resulting in thousands of rockets being fired from the Gaza Strip and missile strikes against civilian targets in various parts of Israel, which disrupted most day-to-day civilian activity, particularly in southern Israel, the location of our manufacturing facility. In the event that our facilities are damaged as a result of hostile action or hostilities otherwise disrupt the ongoing operation of our facilities or the airports and seaports on which we depend to import and export our supplies and products, our ability to manufacture and deliver products to customers could be materially adversely affected. Additionally, the operations of our Israeli suppliers and contractors may be disrupted as a result of hostile action or hostilities, in which event our ability to deliver products to customers may be materially adversely affected.

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

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

As of December 31, 2019, we had 429 employees, all of whom were based in Israel. Certain of our employees may be called upon to perform up to 36 days (and in some cases more) of annual military reserve duty until they reach the age of 40 (and in some cases, up to 45 or older) and, in emergency circumstances, could be called to active duty. In response to increased tension and hostilities, there have been occasional call-ups of military reservists, and it is possible that there will be additional call-ups in the future. Our operations could be disrupted by the absence of a significant number of our employees related to their, or their spouse's, military service or the absence for extended periods of one or more of our key employees for military service. Such disruption could materially adversely affect our business and results of operations. Additionally, the absence of a significant number of the employees of our Israeli suppliers and contractors related to military service or the absence for extended periods of one or more of their key employees for military service may disrupt their operations, in which event our ability to deliver products to customers may be materially adversely affected. The tax benefits that are available to us require us to continue to meet various conditions and may be terminated or reduced in the future, which could increase our costs and taxes.

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

One of our Israeli facilities was granted "Approved Enterprise" status by the Investment Center of the Ministry of Economy and Industry (formerly named the Ministry of Industry, Trade and Labor) of the State of Israel (the "Investment Center"), under the Israeli Law for the Encouragement of Capital Investments, 1959 (the "Investment Law"), which made us eligible for a grant and certain tax benefits under that law for a certain investment program. The investment program provided us with a grant in the amount of 24% of our approved investments, in addition to certain tax benefits, which applied to the turnover resulting from the operation of such investment program, for a period of up to ten consecutive years from the first year in which we generated taxable income. The tax benefits under the Approved Enterprise status expired at the end of 2017.

Additionally, we have obtained a tax ruling from the Israel Tax Authority according to which, among other things, our activity has been qualified as an "industrial activity," as defined in the Investment Law, and is also eligible for tax benefits as a "Privileged Enterprise," which apply to the turnover attributed to such enterprise, for a period of up to ten years from the first year in which we generated taxable income. The tax benefits under the Privileged Enterprise status are scheduled to expire at the end of 2020 and 2023.

In order to remain eligible for the tax benefits of a Privileged Enterprise, we must continue to meet certain conditions stipulated in the Investment Law and its regulations, as amended, and must also comply with the conditions set forth in the tax ruling. These conditions include, among other things, that the production, directly or through subcontractors, of all our products should be performed within certain regions of Israel. If we do not meet these requirements, the tax benefits would be reduced or canceled and we could be required to refund any tax benefits that we received in the past, in whole or in part, linked to the Israeli consumer price index, together with interest. Further, these tax benefits may be reduced or discontinued in the future. For example, while we do not expect that the transfer of manufacturing of GLASSIA to Takeda, or the grant to Takeda of the right to use our technology for such manufacturing, would result in the reduction or loss of these tax benefits, according to the tax ruling that we obtained, we may lose those benefits if it is determined that we do not comply with the conditions set forth in the tax ruling If these tax benefits are canceled, our Israeli taxable income would be subject to regular Israeli corporate tax rates. The standard corporate tax rate for Israeli companies was 26.5% for 2015, it decreased to 25% in 2016 and 24% in 2017, and further decreased to 23% in 2018 and thereafter. For more information about applicable Israeli tax regulations, see "Item 10. Additional Information — E. Taxation — Israeli Tax Considerations and Government Programs."

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

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

We are subject to the tax laws and regulations of the State of Israel and numerous other jurisdictions in which we do business. Many judgments are required in determining our provision for income taxes and other tax liabilities, and the applicable tax authorities may not agree with our tax positions. In addition, our tax liabilities are subject to other significant risks and uncertainties, including those arising from potential changes in laws and/or regulations in the State of Israel and the other countries in which we do business, the possibility of adverse determinations with respect to the application of existing laws, changes in our business or structure and changes in the valuation of our deferred tax assets and liabilities. As of December 31, 2019, we had net operating loss carryforwards ("NOLS") for tax purposes of approximately $47 million. If we are unable to fully utilize our NOLs to offset taxable income generated in the future, our future cash taxes could be materially and negatively impacted. For further detail regarding our NOLs, see Note 21 in our consolidated financial statements included in this Annual Report.

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

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

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

Since we are incorporated under Israeli law, the rights and responsibilities of our shareholders are governed by our articles of association and Israeli law. These rights and responsibilities differ in some respects from the rights and responsibilities of shareholders of U.S.-based corporations. In particular, a shareholder of an Israeli company has a duty to act in good faith and in a customary manner in exercising its rights and performing its obligations towards the company and other shareholders and to refrain from abusing its power in the company, including, among other things, in voting at the general meeting of shareholders on certain matters, such as an amendment to the company's articles of association, an increase of the company's authorized share capital, a merger of the company and approval of related party transactions that require shareholder approval. A shareholder also has a general duty to refrain from discriminating against other shareholders. In addition, a controlling shareholder or a shareholder who knows that it possesses the power to determine the outcome of a shareholders vote, or who has the power to appoint or prevent the appointment of an office holder in the company or has other powers towards the company, has a duty to act in fairness towards the company. However, Israeli law does not define the substance of this duty of fairness. See "Item 6. Directors, Senior Management and Employees — Fiduciary Duties and Approval of Specified Related Party Transactions under Israeli Law — Duties of Shareholders." There is limited case law available to assist us in understanding the nature of this duty or the implications of these provisions. These provisions may be interpreted to impose additional obligations and liabilities on our shareholders that are not typically imposed on shareholders of U.S. corporations.

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

Certain provisions of Israeli law and our articles of association could have the effect of delaying or preventing a change in control and may make it more difficult for a third party to acquire us or for our shareholders to elect different individuals to our board of directors, even if doing so would be beneficial to our shareholders, and may limit the price that investors may be willing to pay in the future for our ordinary shares. For example, Israeli corporate law regulates mergers and requires that a tender offer be effected when more than a specified percentage of shares in a public company are purchased. Under our articles of association, a merger shall require the approval of two-thirds of the voting rights represented at a meeting of our shareholders and voting on the matter, in person or by proxy, and any amendment to such provision shall require the approval of 60% of the voting rights represented at a meeting of our shareholders and voting on the matter, in person or by proxy. Further, Israeli tax considerations may make potential transactions undesirable to us or to some of our shareholders whose country of residence does not have a tax treaty with Israel granting tax relief to such shareholders from Israeli tax. With respect to certain mergers, while Israeli tax law permits tax deferral, the deferral is contingent on certain restrictions on future transactions, including with respect to dispositions of shares received as consideration, for a period of two years from the date of the merger. See "Item 10. Additional Information — B. Memorandum and Articles of Association — Acquisitions Under Israeli Law."

Item 4. Information on the Company

Corporate Information

We were incorporated under the laws of the State of Israel on December 13, 1990 under the name Kamada Ltd. In August 2005, we successfully completed an initial public offering on the TASE. In June 2013, we successfully completed an initial public offering in the United States on Nasdaq. The address of our principal executive office is 2 Holzman St., Science Park, P.O. Box 4081, Rehovot 7670402, Israel, and our telephone number is +972 8 9406472. Our website address is www.kamada.com. The reference to our website is intended to be an inactive textual reference and the information on, or accessible through, our website is not intended to be part of this Annual Report.

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

Capital Expenditures

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

Business Overview

We are a plasma-derived biopharmaceutical company focused on orphan indications, with an existing marketed product portfolio and a late-stage product pipeline. Our proprietary products are produced using our advanced proprietary technologies and know-how for the separation and purification of proteins derived from human plasma. We develop and produce our plasma-derived protein therapeutics in our advanced cGMP compliant, FDA-approved production facility located in Beit Kama, Israel. We use our proprietary platform technology and know-how for the extraction and purification of proteins from human plasma to produce AAT in a high purity liquid form which 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. In addition, using our technology, we extract and purify hyper immunoglobulin such as Anti-Rabies IgG, as well as other plasma-derived proteins.

Our business development strategy is focused on creating new growth opportunities through the identification of new product opportunities for our manufacturing plant and seeking complementary products via licensing and acquisition. We expect that our business growth, following the transition of GLASSIA manufacturing to Takeda during 2021, will also be driven by an expected increase in proprietary product sales in international markets, an anticipated continued increase in KEDRAB sales in the U.S., the commercial manufacturing of a new specialty hyper-immune globulin product at our facility beginning in 2023, expected growth in our Distribution segment, and the royalties to be paid to us by Takeda on GLASSIA sales. In addition, we remain focused on the AATD field, as we believe we have developed extensive commercial, scientific, manufacturing, clinical and regulatory experience (based on multiple clinical trials we performed in the United States and Europe*)* in that field. Accordingly, we aim to become the leading innovator in this field by developing different therapeutic approaches to AATD independently, or through collaborations with strategic partners. We are also continuing to explore the development of AAT for other indications, such as GvHD, lung transplantation rejection, organ preservation and/or the development of new immunoglobulins (IgG) through strategic collaborations. To that end, we are investing in additional indications/and products, primarily to the point of developing sufficient data, to enable us to attract such strategic partners.

We operate in two segments: the Proprietary Products segment, in which we develop and manufacture plasma-derived therapeutics and have a product line consisting of six plasma-derived biopharmaceutical products that we market in more than 20 countries; and the Distribution segment, in which we leverage our expertise and presence in the Israeli market by distributing drugs manufactured by third-parties for use in Israel.

We derived approximately 66%, 66% and 59% of our total revenues in the years ended December 31, 2019, 2018 and 2017, respectively, from sales in the United States, approximately 4%, 3% and 5% of our total revenues in the years ended December 31, 2019, 2018 and 2017, respectively, from sales in Europe, approximately 2%, 3% and 5% of our total revenues in the years ended December 31, 2019, 2018 and 2017, respectively, from sales in Asia (excluding Israel), approximately 3%, 3% and 5% of our total revenues in the years ended December 31, 2019, 2018 and 2017, respectively, from sales in Latin America and approximately 25%, 25% and 26% of our total revenues in the years ended December 31, 2019, 2018 and 2017, respectively, from sales in Israel.

Our flagship product, GLASSIA, was the first liquid, ready-to-use, intravenous plasma-derived AAT product approved by the FDA (GLASSIA is also approved for self-administration). GLASSIA is an intravenous AAT product that is indicated for chronic augmentation and maintenance therapy in adults with emphysema due to AATD. AAT is a naturally occurring protein found in a derivative of plasma known as fraction IV. AAT regulates the activity of certain white blood cells known as neutrophils and reduces cell inflammation. Patients with genetic AATD suffer from a chronic inflammatory state, lung tissue damage and a decrease in lung function. We market GLASSIA through a strategic partnership with Takeda in the United States. Our 2019 revenues from the sale of GLASSIA to Takeda totaled $68.1 million, as compared to $63.3 million during 2018. Based on our recently amended exclusive manufacturing, supply and distribution agreement with Takeda, we project that total revenues from sales of GLASSIA to Takeda for the years 2020 will be approximately $65 million and between $25 million to $50 million during 2021, based on Takeda's needs. Based on the licensing and technology transfer agreement between the parties, Takeda is planning to complete the technology transfer of GLASSIA, and pending FDA approval, will initiate its own production of GLASSIA for the U.S. market in 2021. Accordingly, based on the agreement between the companies, upon initiation of sales of GLASSIA manufactured by Takeda, it will pay royalties to Kamada at a rate of 12% on net sales through August 2025, and at a rate of 6% thereafter until 2040, with a minimum of $5 million annually for each of the years from 2022 to 2040.

The transition of the agreement to its royalties phase will result in a reduction of our revenue from Takeda and our operating results may be materially and adversely impacted if we are unable to reduce fixed costs relating to our manufacturing facility in line with any reduction in demand. While our topline revenues will be substantially reduced, we project that based on current GLASSIA sales in the U.S. and forecasted future growth, we will receive royalties from Takeda in the range of $10 million to $20 million per year for 2022 to 2040. As an illustration, in the event the transition of the agreement to its royalty phase would have taken place in 2019, our revenues would have been reduced by $68.1 million (which is the total revenues generated by GLASSIA sales to Takeda during the year ended December 31, 2019), our gross profit would have been reduced by a range of $27 million to $29 million. Such revenues and gross profitability reduction would have been offset by royalties that would have been paid by Takeda in the range of $10 million to $20 million.

We also market GLASSIA in other counties through local distributors. Total revenues derived from sales of GLASSIA in all other countries during 2019 was $5.5 million as compared to $5.0 million during 2018.

Our second leading product is KamRAB, a prophylactic treatment against rabies infection that is administered to patients after exposure to an animal suspected of being infected with rabies. KamRAB is a protein therapeutic derived from hyper-immune plasma, which is plasma that contains high levels of antibodies from donors that have been previously vaccinated by an active rabies vaccine. KamRAB is administered by a one-time injection. KamRAB has been sold by us in various markets outside the United States through local distributors since 2003. In July 2011, we signed a strategic distribution and supply agreement with Kedrion for the clinical development and marketing in the United States of KamRAB, and in August 2017 we received FDA approval for anti-rabies immunoglobulin as a post-exposure prophylaxis against rabies infection. In April 2018, we launched KamRAB in the United States, under the trademark "KEDRAB." Our overall revenues from sales of KEDRAB to Kedrion during 2019 and 2018 were $16.4 million and $11.8 million, respectively. Sales of KEDRAB by Kedrion in the United States during the year 2019 and 2018 totaled $31.4 million and $15.5 million, respectively. These sales represent approximately 20% and 10% market shares, respectively.

In December 2019, we entered into a binding term sheet for a 12-year contract manufacturing agreement with an undisclosed partner to manufacture a FDA-approved and commercialized specialty hyper-immune globulin product. Following the execution of the required technology transfer from the current manufacturer, and pending receipt of all required FDA approvals, we expect to commence commercial manufacturing of the product in early 2023. This binding term sheet supports our strategy to leverage our experience and available manufacturing capacity at our FDA-approved manufacturing facility to initiate the production of additional plasma-derived products following the transition of GLASSIA manufacturing to Takeda during 2021. Based on the current market sales volume of this specialty hyper-immune globulin product, we estimate that its manufacturing opportunity will add approximately $8 million to $10 million to our annual revenues, with estimated gross margin level similar to the average gross margins of our Proprietary Products segment.

In addition to our commercial operation, we invest in research and development of new product candidates and new indication for existing products activities. Our lead investigational product candidate is Inhaled AAT for AATD. We believe that this second generation AAT product is currently the only aerosolized AATD treatment in advanced stages of clinical development. We believe that Inhaled AAT for AATD, if approved, will increase patient convenience and reduce the need for patients to use intravenous infusions of AAT products, thereby decreasing the need for clinic visits or nurse home visits and reducing medical costs. In addition, because Inhaled AAT for AATD would be delivered directly to the affected tissue through a nebulizer using a lower AAT dosage, we believe that this product, if approved, will enable us to treat significantly more patients from the same amount of plasma and production capacity and therefore, may be more cost effective for patients and payors and may increase our profitability.

We completed a pivotal Phase II/III clinical trial for Inhaled AAT for AATD in Europe and filed the Marketing Authorization Application ("MAA") with the EMA in March 2016. The Phase II/III clinical trial in Europe, however, did not meet its primary or other pre-defined endpoints. Following our discussions with the EMA in regards to the study results, in July 2017, we withdrew the MMA in Europe for our Inhaled AAT for AATD, which relied on this single pivotal clinical trial. Following extensive discussions with the EMA, we concluded that the EMA did not view the data submitted as sufficient, in terms of safety and efficacy, for approval of the MAA, and that the supplementary data needed for approval required an additional clinical trial. Subsequently, and following several discussions with EMA, in July 2018, we received positive scientific advice from the Committee for Medicinal Products for Human Use ("CHMP") of the EMA related to the development plan for our proposed pivotal Phase III study for our Inhaled AAT for AATD. We requested scientific advice (protocol assistance) from the CHMP following the results of the previous Phase II/III (EU) and Phase II (US) (see below) studies conducted by us with respect to a proposed subsequent Phase III study design. The CHMP notified us that it concurred with the overall design of the proposed study, including its objectives, patient population, proposed endpoints and their clinical importance, and the safety monitoring plan. The CHMP had some minor comments, which we addressed in the final study protocol. See "—Our Product Pipeline and Development Program—Inhaled Formulations of AAT—AATD" and "Risk Factors— Risk Related to Development, Regulatory Approval and Commercialization of Product Candidates."

In the United States, we completed a Phase II clinical trial of our Inhaled AAT for AATD, which met its primary endpoint. However, when we presented the data from the European Phase II/III study to the FDA in April 2016, the FDA expressed concerns and questions about that data, primarily related to the safety and efficacy of Inhaled AAT for the treatment of AATD and the risk/benefit balance to patients based on that data. We understood that the FDA's questions and concerns need to be resolved before the agency would allow us to proceed with additional clinical development of Inhaled AAT in the United States. In order to address the FDA's concerns and questions, in April 2017, we submitted to the agency the results of the U.S. Phase II data, together with a proposed Phase III synopsis. The FDA then provided us in June 2017 with guidance for further development of the synopsis and requested that we submit a complete proposed study protocol for the next phase prior to enabling us to continue clinical development and initiate the Phase III study in the United States. In July 2017, we submitted a full study protocol, and in August 2017, in response to the study protocol and previous submission, the FDA issued a letter stating that it continues to have concerns and questions about the safety and efficacy of the Inhaled AAT. We have provided the FDA with data and information related to their concerns and in April 2018, the FDA issued a response letter providing further guidance regarding the proposed pivotal Phase III protocol, as well as additional questions focused on the Inhaled AAT product characteristics. This correspondence indicated that, while several issues had been addressed, the FDA had continued concerns and questions related to the safety profile of Inhaled AAT for AATD. Following a thorough assessment of the FDA response, we provided the requested information and data and implemented the proposed changes in the study protocol during the second half of 2018. In April 2019, we received a letter from the FDA stating that we had satisfactorily addressed the concerns and questions with respect to the proposed Phase III clinical trial. In addition, the FDA requested that prior to the initiation of the planned Phase III study, we complete a Human Factor Study (HFS) to support the combination product, consisting of our Inhaled AAT and the investigational eFlow nebulizer system of PARI Pharma GmbH. We expect to receive further feedback from the FDA related to our HFS, which we completed in the third quarter of 2019 and its results were submitted to the FDA at such time.

During December 2019, the first patient was randomized in Europe into our pivotal Phase 3 InnovAATe clinical trial evaluating the safety and efficacy of our proprietary inhaled Alpha-1 Antitrypsin (AAT) therapy for the treatment of Alpha-1 Antitrypsin Deficiency (AATD). The study is being led by Jan Stolk, M.D., Department of Pulmonology, Member of European Reference Network LUNG, Leiden University Medical Center, The Netherlands. InnovAATe is a randomized, double-blind, placebo-controlled, pivotal Phase 3 trial designed to assess the efficacy and safety of Inhaled AAT in patients with AATD and moderate lung disease. Up to 250 patients will be randomized 1:1 to receive either Inhaled AAT at a dose of 80mg once daily, or placebo, over two years of treatment. The primary endpoint of the InnovAATe trial is lung function measured by FEV1. Secondary endpoints include lung density changes as measured by CT densitometry, as well as other parameters of disease severity, such as additional pulmonary functions, exacerbation rate and six minute walk test. The safety profile will be monitored continuously by a Data Monitoring Committee with predefined rules to be applied after the first 60 subjects have completed six months of treatment. Based on recent feedback received from the FDA regarding anti-drug antibodies (ADA) to Inhaled AAT, we intend to concurrently conduct a sub-study in North America in which approximately 30 patients will be evaluated for the effect of ADA on AAT levels in plasma with Inhaled AAT and IV AAT treatments.

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

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

- Acute Graft versus Host Disease (aGvHD) - In November 2016, we initiated a Phase II/III clinical trial for the treatment of aGvHD in collaboration with Shire (now part of Takeda) in the United States. In June 2017, Shire informed us of its decision not to continue with the study. As the result of this decision, the study was halted. In January 2018, we announced a collaboration with a consortium of prominent hospitals led by Mount Sinai Hospital and initiated an investigator initiated Phase II clinical study to evaluate our AAT product for preemption of steroid refractory aGvHD (SR-aGvHD) utilizing a novel blood biomarker developed algorithm that may identify patients at high risk of developing SR-aGvHD and non-relapse mortality. During 2019, we concluded enrollment for this clinical trial and expect topline results to be available during 2020.

- Lung Transplantation Rejection - We have also initiated a Phase II clinical study with our intravenous AAT product to prevent lung transplantation rejection. In January 2018, we announced interim results from this study, which showed that our intravenous AAT demonstrated favorable safety and tolerability profile in 10 patients during first six months of treatment, consistent with previously observed results in other indications. In February 2019, we announced additional interim results from such study suggesting improvement in multiple key clinical outcomes. Final results are anticipated during 2020.

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

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

In prior years we tested our AAT product for the indication of newly diagnosed type-1 diabetes patients. We do not plan to further invest in this indication.

In preparation for future anticipated increased demand for AAT potentially resulting from greater awareness of AAT deficiency, as well as potential additional indications for Alpha 1 Antitrypsin, which are currently in clinical development, we have also initiated development of recombinant human Alpha 1 Antitrypsin (“rhAAT”). We engaged Cellca (CDMO located in Germany, part of Sartorius Stedim BioTech Group) to pursue the cell line development of rhAAT in Chinese Hamsters Ovaries (“CHO”) with high productivity and adequate product quality.

Our Product Portfolio

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

Proprietary Products Segment

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

We currently have products that target four product categories: respiratory, immunoglobulins, critical care and other. Our flagship product in the Proprietary Products segment is GLASSIA, sales of which, for the years ended December 31, 2019, 2018 and 2017, accounted for approximately 75%, 75% and 83% of our total revenues, in the Proprietary Products segment, respectively. Revenue from sales of GLASSIA (including sales to Takeda for further distribution in the U.S. market) comprised approximately 58%, 60% and 64% of our total revenues for the years ended December 31, 2019, 2018 and 2017, respectively. Revenues from sales of KEDRAB to Kedrion for further distribution in the U.S. market for the years ended December 31, 2019 and 2018, accounted for approximately 13% and 10% of our total revenues, respectively. Sales of KamRAB and KamRho (D) for the years ended December 31, 2019, 2018 and 2017 accounted for the substantial balance of total revenues in the Proprietary Products segment.

Product	Indication	Active Ingredient	Geography
Respiratory			
GLASSIA (or Ventia/Respikam in certain countries)	Intravenous AATD	Alpha-1 Antitrypsin (Human)	United States, Israel, Russia, Brazil, Argentina, Uruguay**, South Africa, Colombia**, Albania**, Kazakhstan**
Immunoglobulins			
KamRAB/KEDRAB	Prophylaxis of rabies disease	Anti-rabies immunoglobulin (Human)	United States, Israel, India, Thailand, El Salvador*, South Africa*, Bosnia, Russia, Mexico*, Georgia*, Sri Lanka*, Ukraine, Turkey, South Korea and Canada**, Argentina, Australia, Brazil, Chile, Nepal and Venezuela.
KamRho (D) IM	Prophylaxis of hemolytic disease of newborns	Rho(D) immunoglobulin (Human)	Israel, Brazil*, India, Argentina, Paraguay*, Chile*, Russia, Nigeria, Sri Lanka*, Thailand**, Costa Rica** and the Palestinian Authority
KamRho (D) IV	Treatment of immune thermobocytopunic purpura	Rho(D) immunoglobulin (Human)	Israel, India and Argentina*
Snake bite antiserum	Treatment of snake bites by the Vipera palaestinae and the Echis coloratus	Anti-snake venom	Israel
Other Products			
Human transferrin (diagnostical grade)	Not for human use	Transferrin	United States

* We have regulatory approval, but did not market the product in this country in 2019.

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

Respiratory — GLASSIA

GLASSIA is an intravenous AAT product produced from fraction IV plasma that is indicated by the FDA for chronic augmentation and maintenance therapy in adults with emphysema due to congenital AATD. While GLASSIA does not cure AATD, it supplements the patient's insufficient physiological levels of AAT and is administered as a chronic treatment. As such, the patient must take GLASSIA indefinitely over the course of his or her life in order to maintain the benefits provided by it.

In the United States and Europe, we believe that AATD is currently significantly under-diagnosed and under-treated, as we estimate that only approximately 8% and 2.5-3% of all potential cases of AATD are treated in the United States and Europe, respectively, with an aggregate of up to an estimated 180,000 to 190,000 patients suffering from AATD, of which less than 10% have been diagnosed. According to the Centers for Medicare and Medicaid Services published payment allowance limits for Medicare part B, the average sale price, as of January 2020, of 10 mg of GLASSIA is $4.855, resulting in an annual cost of between $80,000 and $100,000 per AATD patient. In the United States, in some of the European countries and in Israel, we believe that the majority of the cost of treatment is covered by medical insurance programs.

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

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

Currently, GLASSIA has been approved in nine countries. It is sold in five of those countries and also is sold in one additional country, where it has not been approved, on a non-registered named-patient basis. The majority of sales of GLASSIA are in the United States, where GLASSIA was approved by the FDA in July 2010 and sales began in September 2010. As part of the approval, the FDA requested that we conduct post-approval Phase IV clinical trials, as is common in the pharmaceutical industry, aimed at collecting additional safety and efficacy data for GLASSIA. In 2010, we submitted our proposed Phase IV clinical trials to the FDA. Such Phase IV clinical trials began in 2015. As a result of low patient recruitment for such study, in 2019 Takeda submitted a revised protocol to the FDA, which is currently under discussion between Takeda and the FDA. Pursuant to our agreement with Takeda, the Phase IV clinical trials are financed and managed by Takeda, provided that if the cost of such Phase IV clinical trials exceeds a pre-defined amount, we will participate in financing such trial up to a certain amount by offsetting such amounts from future milestones, sales of GLASSIA or royalties from Takeda.

We market GLASSIA in the United States through our partnership with Takeda. We market GLASSIA in Israel by ourselves and in other countries through local distributors. Sales to Takeda accounted for approximately 54%, 56% and 59% of our total revenues in the years ended December 31, 2019, 2018 and 2017, respectively. We plan to submit GLASSIA for marketing approval in additional countries. Revenues from sales of GLASSIA worldwide have grown from approximately $0.6 million in 2009 to $73.6 million in 2019, representing 55% compound annual growth rate.

Immunoglobulins

KamRAB

KamRAB is a prophylactic treatment against rabies infection that is administered to patients after exposure to an animal suspected of being infected with rabies. KamRAB is a protein therapeutic derived from hyper-immune plasma, which is plasma that contains high levels of antibodies from donors that have been previously vaccinated by an active rabies vaccine. KamRAB is administered by a one-time injection, and the precise dosage is a function of the patient's weight.

According to the World Health Organization, each year, more than 10 million people worldwide are exposed to potential rabies infection. We believe that there are market opportunities for KamRAB in developing countries, as well as in Canada and Australia. In many developing countries, patients do not receive treatment for suspected rabies due to the lack of availability of healthcare resources.

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

In July 2011, we signed a strategic distribution and supply agreement with Kedrion for the clinical development and marketing in the United States of KamRAB, pursuant to which Kedrion agreed to bear all the costs required for the Phase II/III clinical trials. See "— Strategic Partnerships — Kedrion.". In August 2017, we received marketing approval for KamRAB in the United States (under the trademark "KEDRAB") and in April 2018, KEDRAB was launched in the United States and initial shipments reached healthcare practitioners across the country. The FDA approval of KEDRAB for post-exposure prophylaxis (PEP) against rabies infection in 2017 was based on the results of a phase 2/3 study which demonstrated that KEDRAB was non-inferior to the comparator HRIG product in achieving Rabies Virus Neutralizing Antibody (RVNA) levels of ≥0.5 IU/mL on day 14, when each was co-administered with a rabies vaccine. KEDRAB was found to be well-tolerated with a safety profile similar to that of the comparator HRIG product. In addition, we recently completed the enrollment of 30 pediatric subjects in an FDA-required post-marketing trial in the U.S. with the primary objective of confirming the safety of KEDRAB in children aged 0 to 17 years. Results of this study are expected in the second half of 2020.

We believe that receiving FDA approval for marketing the product will assist us in our efforts to register KamRAB in additional countries where KamRAB is not currently registered, which we believe would lead to additional sales worldwide. In November 2017, we signed a supply agreement for sales of KamRAB outside of the United States with an undisclosed international organization. The agreement extends through 2020 and is expected to generate additional sales for KamRAB. In November 2018, we received marketing approval for KamRAB in Canada and following winning a recent supply tender we expect to start selling the product in Canada during 2020. We were also recently approved to supply KamRAB through the PAHO, the specialized international health agency for the Americas. We initiated sales of KamRAB through PAHO during 2019 and we expect sales to continue in 2020.

KamRho (D)

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

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

Snake Bite Antiserum

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

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

Other Products

In recent years, we sold small quantities of Human Transferrin, which is used as a cultural medium for diagnostic assays and cell cultures.

Distribution Segment

Our Distribution segment is comprised of sales in Israel of pharmaceutical products manufactured by third parties. We engage third party manufacturers, register their products with the IMOH, import the products to Israel and distribute them to local health care provider organizations, hospitals and pharmacists. Our primary products in the Distribution segment include pharmaceuticals for critical use delivered by injection, infusion or inhalation. Currently, most of the products in our Distribution segment are produced from plasma or plasma-derivatives, and are manufactured by European companies. IVIG is our primary product in the Distribution segment, comprising approximately 62%, 58% and 54% of total revenues in the Distribution segment for the years ended December 31, 2019, 2018 and 2017, respectively. Sales of IVIG accounted for approximately 14%, 12% and 12% of our total revenues for the years ended December 31, 2019, 2018 and 2017, respectively.

Over the past several years we continued to extend our Distribution segment products portfolio to non-plasma derived products as provided in the table below. In December 2019, we entered into an agreement with Alvotech, a global biopharmaceutical company, to commercialize Alvotech's portfolio of six biosimilar product candidates in Israel, upon receipt of regulatory approval from the IMOH. Alvotech's pipeline includes biosimilar product candidates aimed at treating autoimmunity, oncology and, inflammatory conditions. Subject to approval by the IMOH, we expect to launch the first of these products, PF708, in Israel during 2022. PF708 is a biosimilar candidate to teriparatide, an FDA approved product marketed by Eli Lilly and Company under the brand name Forteo®/Forsteo® for the treatment of osteoporosis in patients with a high risk of fracture. PF708 recently received an FDA approval and is known by the brand name, Bonsity™. Following receipt of FDA marketing approval by Alvotech, the remaining five products included in the agreement are, subject to approval by the IMOH, expected to be launched in Israel during the years 2023-2025.

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

Product	**Indication**	**Active Ingredient**
Respiratory		
Bramitob	Management of chronic pulmonary infection due to pseudomonas aeruginosa in patients six years and older with cystic fibrosis	Tobramycin
FOSTER	Regular treatment of asthma where use of a combination product (inhaled corticosteroid and long-acting beta2-agonist) is appropriate	Beclomethasone dipropionate, Formoterol fumarate
PROVOCHOLINE	Diagnosis of bronchial airway hyperactivity in subjects who do not have clinically apparent asthma	METHACHOLINE CHLORIDE
Immunoglobulins		
IVIG 5%	Treatment of various immunodeficiency-related conditions	Gamma globulins (IgG) (human)
Varitect	Preventive treatment after exposure to the virus that causes chicken pox and zoster herpes	Varicella zoster immunoglobulin (human)
Zutectra	Prevention of hepatitis B virus (HBV) re-infection in HBV-DNA negative patients 6 months after liver transplantation for hepatitis B induced liver failure	Human hepatitis B immunoglobulin
Hepatect CP	Prevent contraction of Hepatitis B by adults and children older than two years	Hepatitis B immunoglobulin (human)
Megalotect	Contains antibodies that neutralize cytomegalovirus viruses and prevent their spread in immunologically impaired patients	CMV immunoglobulin (human)
RUCONEST	Treatment of acute angioedema attacks in adults with hereditary angioedema (HAE) due to C1 esterase inhibitor deficiency	CONESTAT ALFA

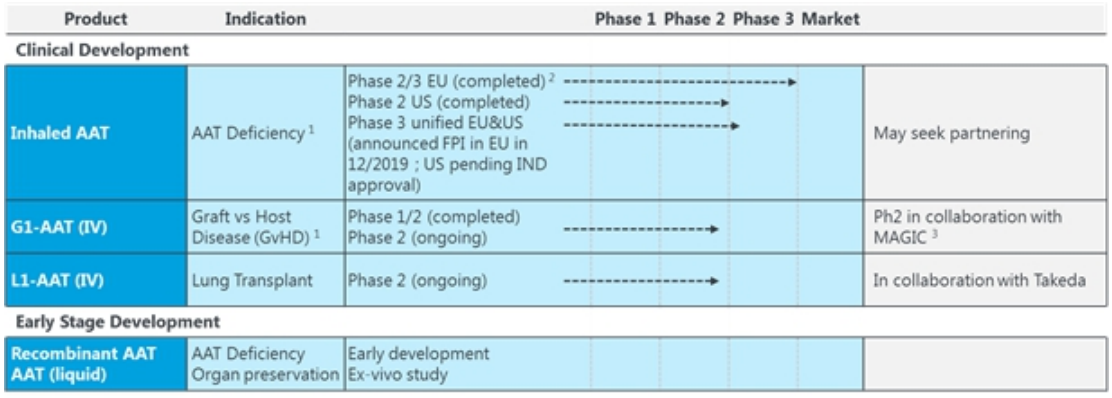
Critical Care		
Heparin sodium injection	Treatment of thrombo-embolic disorders such as deep vein thrombosis, acute arterial embolism or thrombosis, thrombophlebitis, pulmonary embolism, fat embolism. Prophylaxis of deep vein thrombosis and thromboembolic events	Heparin sodium
Albumin and Albumin 4%	Maintains a proper level in the patient's blood plasma	Human serum Albumin
Coagulation Factors		
Factor VIII	Treatment of Hemophilia Type A diseases	Coagulation Factor VIII (human)
Factor IX	Treatment of Hemophilia Type B disease	Coagulation Factor IX (human)
Vaccinations		
IXIARO	Active immunization against Japanese encephalitis in adults, adolescents, children and infants aged 2 months and older	Japanese encephalitis purified inactivated vaccine

Contract Manufacturing Services

In preparation for the transition of GLASSIA manufacturing to Takeda, expected by 2021, and in accordance with our business development strategy focused on creating new growth opportunities through identification of new product opportunities for our manufacturing plant, we are proactively exploring opportunities to leverage our experience and manufacturing capacity to initiate the production of new plasma-derived products. As such, in December 2019, we entered into a binding term sheet for a 12-year contract manufacturing agreement with an undisclosed partner to manufacture an FDA-approved and commercialized specialty hyper-immune globulin product. Following the execution of the required technology transfer from the current manufacturer, and pending receipt of all required FDA approvals, we expect to commence commercial manufacturing of the product in early 2023. Based on the current market sales volume of this specialty hyper-immune globulin product, we estimate that its manufacturing will add approximately $8 million to $10 million to our annual revenues, with estimated gross margin level similar to the average gross margins of our Proprietary Products segment.

Our Product Pipeline and Development Program

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



1. Orphan drug designation (US & EU); 2. Study failed to meet primary end-point &MAA withdrawn (6-2017);
3. Mount Sinai Acute GVHD International Consortium

Inhaled Formulations of AAT for AATD

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

We have been able to leverage our expertise gained from the production of GLASSIA to develop a stable, high purity Inhaled AAT for AATD, an inhaled AAT product candidate for the treatment of AATD. Existing treatment for AATD require weekly intravenous infusions of AAT therapeutics. We believe that Inhaled AAT for AATD, if approved, will significantly improve the patient's disease condition and the quality of life of the patients versus current invasive weekly treatment that requires uncomfortable infusion, consumption of time and administration by a medical professional. If approved, Inhaled AAT for AATD is estimated to be the first AAT product that is not required to be delivered intravenously but, instead is administered by a user-friendly, lightweight and silent nebulizer in up to two short daily sessions. We believe that Inhaled AAT for AATD, if approved, will increase patient convenience and reduce or replace the need for patients to use intravenous infusions of AAT products, decreasing the need for clinic visits or nurse home visits 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 may be more cost effective for patients and payors and may increase our profitability.

The current standard care for AATD in the United States and in certain European countries is intravenous infusion of an AAT therapeutic. We estimate that only 2% of the AAT dose reaches the lung when administered intravenously. We have conducted a U.S. phase II clinical study demonstrating that administration of inhaled formulations of AAT through inhalation results in greater dispersion of AAT to the target lung tissue including the lower lobes and lung periphery. Accordingly, we believe that an inhaled formulation of AAT would require a significantly lower therapeutic dose and would be more effective in reducing inflammation of the lung tissue and inhibiting the uncontrolled neutrophil elastase that causes the breakdown of the lung tissue and the emphysema. In addition, self-administration by inhalation is more convenient than intravenous infusion and would also reduce the burden on healthcare providers to administer treatments.

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

A double blind placebo controlled and randomized Phase II/III pivotal trial, under EMA guidance, started in January 2010 and was completed at the end of 2013. A total of 168 patients participated in the trial in seven countries in Europe and Canada. Subjects in this trial were administered with a daily dose of Inhaled AAT for AATD or equivalent dose of placebo for 50 consecutive weeks. The primary endpoint for the trial was the time from randomization to the first event-based exacerbation with a severity of moderate or severe. Other endpoints, which were secondary and tertiary, included other exacerbation measures, lung function, CT scan and quality of life. The trial was 80% powered based on the number of exacerbation events collected in the study, in order to detect a difference between the two groups one year later. A 20% difference between the two groups was required to prove efficacy and is considered to be clinically meaningful and would allow the decision to prescribe treatment. An open label extension of an additional 50 weeks on active drug was offered to study participants in most sites once they completed the initial 50 week period. Treatment in the open label extension of the trial was completed in November 2014.

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

Despite not meeting the primary or secondary endpoints for the ITT population, lung function parameters, including Forced Expiratory Volume in One Second ("FEV1") % of Slow Vital Capacity ("SVC"), FEV1 % predicted, FEV1 (liters) and Diffusing capacity ("DLCO"), which were collected to support safety endpoints, showed concordance of a potential treatment effect in the reduction of the inflammatory injury to the lung that is known to be associated with a reduced loss of respiratory function.

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

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

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

For lung function, overall one year effect:

- FEV1 (L) rose significantly in AAT treated patients and decreased in placebo treated patients (+15ml for AAT vs. -27ml for placebo, a 42 ml difference, p=0.0268)

- There was a trend towards better FEV1% predicted (0.54% for AAT vs. -0.62% for placebo, a 1.16% difference, p=0.065)

- FEV1/SVC% rose significantly in AAT treated patients and decreased in placebo treated patients (0.62% for AAT vs. -0.87% for placebo, a 1.49% difference, p=0.0074)

For lung function change at week 50 vs. baseline:

- There was a trend towards reduced FEV1 (L)decline (-12ml for AAT vs. -62ml for placebo, a 50 ml difference, p=0.0956)

- There was a trend towards a reduced decline in FEV1% predicted (-0.1323% for AAT vs. -1.6205% for placebo, a 1.4882% difference, p=0.1032)

- FEV1/SVC% rose significantly in AAT treated patients and decreased in placebo treated patients (0.61% for AAT vs. -1.07% for placebo, a 1.68% difference, p=0.013)

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

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

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

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

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

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

When we presented the data from the European Phase II/III study to the FDA, the agency expressed concerns and questions about that data, primarily related to the safety and efficacy of Inhaled AAT for the treatment of AATD and the risk/benefit balance to patients based on that data. In order to address the agency's concerns and questions, in April 2017, we submitted to the agency the results of the U.S. Phase II data together with a proposed Phase III synopsis. In July 2017, we submitted to the FDA for review a proposed pivotal Phase III protocol for our Inhaled AAT product. In August 2017, in response to the study protocol and previous submission, the FDA issued a letter to us stating that it continues to have concerns and questions about the safety and efficacy of the Inhaled AAT. We have provided the FDA with data and information related to their concerns and in April 2018, the FDA issued a response letter providing further guidance regarding the proposed pivotal Phase III protocol, as well as additional questions focused on the Inhaled AAT product characteristics. This correspondence indicated that, while several issues had been addressed, the FDA has continued concerns and questions related to the safety profile of Inhaled AAT for AATD. Following a thorough assessment of the FDA response, we provided the requested information and data and implemented the proposed changes in the study protocol during the second half of 2018. In April 2019, we received a letter from the FDA stating that we had satisfactorily addressed the concerns and questions with respect to the proposed Phase III clinical trial. In addition, the FDA requested that prior to the initiation of the planned Phase III study, we complete a Human Factor Study (HFS) to support the combination product, consisting of our Inhaled AAT and the investigational eFlow nebulizer system of PARI Pharma GmbH. We expect to receive further feedback from the FDA related to our HFS, which we completed in the third quarter of 2019 and its results were submitted to the FDA at such time.

During December 2019, the first patient was randomized in Europe into our pivotal Phase 3 InnovAATe clinical trial evaluating the safety and efficacy of our proprietary inhaled Alpha-1 Antitrypsin (AAT) therapy for the treatment of Alpha-1 Antitrypsin Deficiency (AATD). The study is being led by Jan Stolk, M.D., Department of Pulmonology, Member of European Reference Network LUNG, Leiden University Medical Center, The Netherlands. InnovAATe is a randomized, double-blind, placebo-controlled, pivotal Phase 3 trial designed to assess the efficacy and safety of Inhaled AAT in patients with AATD and moderate lung disease. Up to 250 patients will be randomized 1:1 to receive either Inhaled AAT at a dose of 80mg once daily, or placebo, over two years of treatment. The primary endpoint of the InnovAATe trial is lung function measured by FEV1. Secondary endpoints include lung density changes as measured by CT densitometry, as well as other parameters of disease severity, such as additional pulmonary functions, exacerbation rate and six minute walk test. The safety profile will be monitored continuously by a Data Monitoring Committee with predefined rules to be applied after the first 60 subjects have completed six months of treatment. Based on recent feedback received from the FDA regarding anti-drug antibodies (ADA) to Inhaled AAT, the Company intends to concurrently conduct a sub-study in North America in which approximately 30 patients will be evaluated for the effect of ADA on AAT levels in plasma with Inhaled AAT and IV AAT treatments.

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

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

GvHD occurs in 30-70% of patients who undergo a medical procedure of allogeneic hematopoietic stem cell transplantation (HSCT), usually as a treatment to hematologic disorders. 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. Acute 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 glucocorticoids is intended to suppress the T-cell-mediated immune attack on the host tissues; however, in high doses, this immune-suppression raises the risk of infections and cancer relapse. In addition, 40% - 60% of the patients do not respond to steroid treatment and consequently have very low survival rates.

Preliminary human and animal studies indicate that AAT may reduce the severity of acute GvHD. The immuno-modulatory effect of AAT may attenuate inflammation by lowering levels of pro-inflammatory mediators such as cytokines, chemokines and proteases associated with this severe complication. GvHD is a disease of unmet medical need and both the disease and current therapy options carry considerable side effects.

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

In January 2018, we announced a collaboration with the Mount Sinai Acute GvHD International Consortium ("MAGIC") for the conduct of a clinical trial assessing the safety and preliminary efficacy of our AAT product as preemptive therapy for patients at high-risk for the development of steroid-refractory acute GvHD ("SR-aGvHD"). The study is an open-label, single-arm study including 30 patients diagnosed to be at high-risk for SR-aGvHD according to biomarkers developed by Mount Sinai. The patients were treated with our IV AAT for 8 weeks with a follow-up period of one year after undergoing BMT. The primary endpoint measures the proportion of patients who developed SR-aGvHD by day 100 post-BMT. Other endpoints include safety, severity of GvHD and mortality. The study was conducted in five leading U.S. centers, all of which are members of MAGIC, which consists of 23 Bone Marrow Transplantation ("BMT") centers in the United States, Europe and Asia, and conducts clinical trials to prevent and treat GvHD following BMT. As an investigator-initiated study, such study was co-funded by Mount Sinai and our company, and sponsored by the Icahn School of Medicine at Mount Sinai (ISMMS). The study completed enrollment as planned, in the third quarter of 2019. Top line results are expected during 2020.

The Principal Investigator of the study is John Levine, M.D., M.S., Professor of Pediatrics and Medicine, Hematology and Medical Oncology at the Tisch Cancer Institute at ISMMS and Co-Director of MAGIC. The laboratory aspects of the study were led by James L.M. Ferrara, M.D., Professor of Pediatrics, Oncological Sciences and Medicine, Hematology and Medical Oncology at the Tisch Cancer Institute at ISMMS, and Co-Director of MAGIC. The study is based on an innovative approach of early intervention driven by biomarkers. Drs. Ferrara and Levine have developed an algorithm to diagnose patients at risk for non-relapse mortality on day seven following BMT. The MAGIC algorithm utilizes proprietary biomarkers for prediction of mortality risk. Non-relapse mortality is closely related to non-responsiveness to steroids, which are the current standard of care for aGvHD. Early intervention, based on risk prediction and prior to the development of the clinical symptoms of aGvHD, could prevent patients from further disease deterioration. To date, the MAGIC database includes data from over 2,500 BMT recipients. Pursuant to the agreement with ISMMS, we received the exclusive right to develop and commercialize AAT for GvHD using the MAGIC biomarkers.

AAT for Treatment of Lung Transplantation Rejection

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

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

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

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

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

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

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

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

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

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

Final results from this study are expected during 2020.

Liquid AAT for Organ Preservation Prior to Transplantation

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

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

Recombinant AAT

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

To ensure the success of this project, we have previously developed analytical tools (physicochemical, biochemical, in-vitro, and in-vivo) that will support the selection and characterization of functional rhAAT. In addition, we have established a significant understanding on several expression systems and finally selected Cellca (CDMO located in Germany, part of Sartorius Stedim BioTech Group) to pursue the cell line development of the rhAAT in Chinese Hamsters Ovaries (“CHO”) with high productivity and adequate product quality.

Strategic Partnerships

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

Takeda (GLASSIA)

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

The partnership arrangement with Takeda includes three main agreements: (1) an exclusive manufacturing, supply and distribution agreement, pursuant to which we will manufacture GLASSIA for sale to Takeda for further distribution in the United States, Canada, Australia and New Zealand; (2) a technology license agreement, which grants Takeda licenses to use our knowledge and patents to produce, develop and sell GLASSIA ; and (3) a fraction IV-I paste supply agreement, pursuant to which Takeda will supply us with fraction IV plasma, a plasma derivative, produced by Takeda, as discussed under "— Manufacturing and Supply — Raw Materials — Fraction IV plasma for GLASSIA.". As between us and Takeda, we retain all rights, including distribution rights, to any inhaled formulation of AAT in development, including Inhaled AAT for AATD. See — See "Item 3. Key Information — D. Risk Factors —We will cease to produce GLASSIA for Takeda through 2021 as Takeda begins its own production of GLASSIA in that period."

Sales to Takeda accounted for approximately 54%, 56% and 59% of our total revenues for the years ended December 31, 2019, 2018 and 2017, respectively.

Exclusive Manufacturing, Supply and Distribution Agreement

Pursuant to the exclusive manufacturing, supply and distribution agreement, we received an upfront and milestone payments of $25 million in total related to distribution rights. Additionally, Takeda is obligated to purchase a minimum amount of GLASSIA per year. Under the agreement, Takeda is also obligated to fund required Phase IV clinical trials related to GLASSIA up to a specified amount. If the costs of such clinical trials are in excess of this amount, we have agreed to fund a portion of the costs. Under the agreement, we have committed to reimburse Takeda for its GLASSIA marketing efforts up to a limited amount during the years 2017-2020. During the years since the initial execution of the agreement, the parties agreed to several amendments to the agreement, mainly related to supply quantities of GLASSIA by us to Takeda and transfer pricing. On August 30, 2019, we signed the sixth amendment to the exclusive manufacturing, supply and distribution agreement with Takeda to extend the period of minimum purchases by Takeda of GLASSIA until the end of 2021 and increase the minimum purchases under the distribution agreement. Pursuant to the amendment, our 2019 revenues from the sale of GLASSIA to Takeda totaled $68.1 million and we project that total revenues from sales of GLASSIA to Takeda for 2020 will be approximately $65 million and between $25 million to $50 million for 2021, based on Takeda's needs. According to the terms of the agreement, following its compliance with its purchasing obligations until the end of 2021, Takeda will have no further obligation to purchase a minimum amount of GLASSIA ; however, Takeda's failure to purchase a specified minimum amount of GLASSIA over a period of 24 consecutive months until the expiration of the agreement provides us with the right to terminate the agreement.

Pursuant to the technology license agreement described below, Takeda is planning to complete the technology transfer of GLASSIA manufacturing, and pending FDA approval, will initiate its own production of GLASSIA for the U.S. market in 2021, following which we do not anticipate to continue to manufacture and supply GLASSIA to Takeda under the exclusive manufacturing, supply and distribution agreement.

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

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

Technology License Agreement

The technology license agreement provides an exclusive license to Takeda, with the right to sub-license to certain manufacturing parties, of our intellectual property and know-how regarding the manufacture and additional development of GLASSIA for use in Takeda's production and sale of GLASSIA in the United States, Canada, Australia and New Zealand. Pursuant to the technology license agreement, we are entitled to receive payments for the achievement of certain milestones for an aggregate of up to $20.0 million, of which $15.0 million are development-based milestones related to the transfer of technology to Takeda and $5.0 million are sales-based milestones. To date, we have received $14.5 million of the total aggregate milestone payments under the agreement.

Takeda is planning to complete the technology transfer of GLASSIA manufacturing, and pending FDA approval, will initiate its own production of GLASSIA for the U.S. market in 2021. Accordingly, based on the technology license agreement between the companies, and in addition to the above mentioned milestone payments, upon initiation of commercial sales of GLASSIA manufactured by Takeda, Takeda will pay royalties to us at a rate of 12% on net sales through August 2025, and at a rate of 6% thereafter until 2040, with a minimum of $5 million annually, for each of the years from 2022 to 2040.

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

The technology license agreement expires in 2040. Either party may terminate the agreement, in whole or solely with respect to one or more countries covered by the distribution agreement, pursuant to customary termination provisions. Takeda also has the right to terminate the agreement, upon prior written notice, in the event that: (i) our manufacturing process technology for GLASSIA is determined to materially infringe upon a third party's intellectual property rights, and we have not obtained a license to such third party's intellectual property or provided an alternative non-infringing manufacturing process; (ii) there are certain decreases in GLASSIA sales in the United States unless such decreases are due to transfers to Inhaled AAT for AATD; or (iii) the regulatory approval process in the United States has been withdrawn or rejected as a result of our inaction or lack of diligent effort, provided such withdrawal or rejection was not primarily caused by the breach by Takeda of its obligations. We have the right to terminate the agreement, upon prior written notice: (i) if Takeda contests or infringes upon our intellectual property; (ii) if regulatory approval in one or more countries covered by the technology license agreement is withdrawn or rejected and not reversed, provided it was not primarily caused by the breach by us of our obligations; (iii) in the event that GLASSIA produced by Takeda, other than as a result of our manufacturing process technology, is determined to materially infringe upon a third party's intellectual property rights, provided that the termination right is limited only to the country in which such judgment is binding; or (iv) if the first sale of GLASSIA produced by Takeda did not occur by June 15, 2017 and Takeda has not used commercially reasonable efforts to sell by that date. Following any termination, other than expiration of the agreement, all licensed rights will revert to us. Upon expiration of the agreement, we are obligated to grant to Takeda a non-exclusive, perpetual, royalty free license.

Kedrion (KEDRAB)

On July 18, 2011, we signed an agreement with Kedrion, an international pharmaceutical company engaged in the manufacture of life saving drugs based on human plasma which complement our products, and which are marketed in Europe, the United States and approximately 40 other countries worldwide. The agreement provides for exclusive cooperation on completing the clinical development, and marketing and distribution of our anti-rabies pharmaceutical, KamRAB, in the United States under the name KEDRAB, if the product is approved. Pursuant to the agreement, Kedrion will bear all the costs of the Phase 2/3 clinical trials in the United States of our product for rabies. Costs related to any Phase IV clinical trials, if required, and the FDA Prescription Drug User fee that is required for all FDA new drug approvals, will be divided equally between us and Kedrion. An addendum to the agreement was executed dated as of October 15, 2016, with respect to the performance of a safety clinical trial for the treatment of pediatric patients in the United States. According to such addendum, Kedrion and us agreed to equally share the cost of such trial. A second addendum to the agreement was executed dated as of October 11, 2018, with respect to the purchases prices of KEDRAB under the agreement.

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

In 2014, the Phase 2/3 study was completed and successfully met the trial's primary endpoint of non-inferiority when measured against an IgG reference product, and in September 2016, the BLA was submitted to the FDA. In August 2017, we received FDA approval of anti-rabies immunoglobulin as a post-exposure prophylaxis against rabies infection. In April 2018, we launched KEDRAB in the United States. See "Item 4. Information on the Company — *immunoglobulins* — KEDRAB". Our overall revenues from the sales of KEDRAB to Kedrion during 2019 and 2018 were $16.4 million and $11.8 million, respectively. Sales of KEDRAB by Kedrion in the United States during the years 2019 and 2018 totaled $31.4 million and $15.5 million, respectively. These sales represent approximately 20% and 10% market share, respectively.

The term of the agreement is for six years following the receipt of FDA approval, subject to Kedrion's option to extend the agreement by two years. In addition to customary termination provisions, either party can terminate the agreement for any reason prior to the commencement of clinical trials for FDA approval. Kedrion also has the right to terminate the agreement, upon prior written notice, (i) for any reason after receipt of FDA approval, (ii) in the event that the FDA Biologics License Application is suspended or revoked and cannot be reinstated within a certain period of time, or (iii) a major regulatory change occurs that materially and adversely increases the clinical trial costs. We have the right to terminate the agreement in the event that (i) a major regulatory change occurs that materially and adversely increases the manufacturing costs of KEDRAB, (ii) a major regulatory change occurs that poses considerable difficulties on submission of an application for FDA approval or (iii) clinical trials are not initiated within a certain time after either receipt by Kedrion of enough product or FDA approval to begin clinical trials.

PARI

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

Pursuant to the Original PARI Agreement, we agreed to pay PARI royalties from sales of inhaled formulations of AAT, after certain deductions, at the rates specified in the agreement. We have agreed to pay PARI tiered royalties ranging from the low single digits up to the high single digits based on the annual net sales of inhaled formulations of AAT for the applicable indications. The royalties will be paid for each country separately, until the later of (1) the expiration of the last of certain specified patents covering the "eFlow" nebulizer, or (2) 15 years following the first commercial sale of an inhaled formulation of AAT in that country (the "PARI royalties period"). During the PARI royalties period, PARI is obligated to pay us specified percentages of its annual sales of the "eFlow" nebulizer for use with inhaled formulations of AAT above a certain threshold defined in the agreement and after certain deductions. On February 21, 2008, we entered into an addendum to the Original PARI Agreement (together with the Original PARI Agreement, the "PARI Agreement"), which extended the exclusive global license granted to us to use the "eFlow" nebulizer, including the associated technology and intellectual property, for the clinical development, registration and commercialization of inhaled formulations of AAT for two additional indications of lung disease, namely cystic fibrosis and bronchiectasis. At present, the development of cystic fibrosis and bronchiectasis products is suspended as we prioritize other products. Pursuant to the addendum, each party will be responsible for developing and adapting its own product for the additional indications and will bear the costs involved. Additionally, we and PARI will supply, each at its own expense, inhaled formulations of AAT and the "eFlow" nebulizers, respectively, and in the quantities required for all phases of clinical studies worldwide. In addition, PARI will provide to us, at its expense, technical and regulatory support regarding the "eFlow" nebulizer. Sales of the inhaled formulation of AAT for the additional indications will be added to sales of the first two indications covered by the original agreement as the basis for calculating the royalties to be paid by us to PARI.

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

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

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

Manufacturing and Supply

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

Our production plant passed various Health Authorities inspections. The plant was initially inspected by the US FDA during 2010, and in March 2017 the FDA completed an inspection of our facility in connection with our GLASSIA and KEDRAB products with no critical observations. The Israeli MOH conducted a GMP inspections in each of 2011, July 2013, February 2016 and November 2018, with no critical observations. In July 2018, Health Canada (the department of the government of Canada with responsibility for national public health) completed an audit in connection with the KamRAB product, with no critical observations. In February 2019, the Croatian health agency completed a GMP inspection of our facility in connection with GLASSIA and our Inhaled AAT for AATD product, with no critical observations. In March 2019, the Mexican heath agency completed a GMP inspection of our facility in connection with the KamRAB product, with no critical observations. The Kazakhstan health agency has also completed a GMP inspection in April 2019, with no critical observations.

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

Raw Materials

The main raw materials in our Proprietary Products segment are hyper-immune 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.

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

In the years ended December 31, 2019, 2018 and 2017, we incurred $31.5 million, $25.5 million and $19.9 million of expenses for the purchase of raw materials, respectively.

Plasma derived Fraction IV paste for GLASSIA manufacturing

On August 23, 2010, in conjunction with the partnership arrangement with Takeda, we signed a fraction IV paste supply agreement with Takeda for the supply of fraction IV for use in the production of GLASSIA to be sold in the United States. Under this agreement, Takeda also supplies us with fraction IV to continue the development, pre-clinical and clinical studies of GLASSIA and other AAT derived products and for the production, sale and distribution of GLASSIA in jurisdictions other than those which are covered under the exclusive manufacturing, supply and distribution agreement with Takeda as well as for and other AAT derived products (e.g., Inhaled AAT). Takeda receives no payment for the supply of fraction IV plasma to be used by us for the manufacture of GLASSIA to be sold to Takeda. If we require fraction IV for other purposes, we are entitled to purchase it from Takeda at a predetermined price. While we are dependent on Takeda for the supply of fraction IV plasma, Takeda is currently dependent on us to produce GLASSIA for sale in the United States, as it does not yet have its own FDA approved production capabilities of GLASSIA. Takeda is planning to complete the technology transfer of GLASSIA manufacturing, and pending FDA approval, will initiate its own production of GLASSIA for the U.S. market in 2021.

The supply agreement terminates on August 23, 2040, subject to an option for earlier termination in the event of a material breach.

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

Hyper-immune Plasma

We have a number of suppliers in the United States for hyper-immune plasma with which we have long-term supply agreements. Hyper-immune plasma is used for the production of KamRAB and KamRho(D). In addition to long-term supply agreements, we work to secure availability of hyper-immune plasma on an annual basis by providing forecasts to our suppliers based on our customers' actual and forecasted orders. We continue to seek to enter into long-term supply agreements for hyper-immune plasma with additional plasma-collection companies.

In January 2012, we entered into a plasma purchase agreement with KedPlasma, a subsidiary of Kedrion, for the supply of anti-rabies hyper-immune plasma required for the manufacturing of KamRAB (including for manufacturing of KEDRAB for sale to Kedrion for further distribution in the U.S. market). The agreement provides for a commitment to supply certain minimum annual quantities at predetermined prices, and was extended multiple times and is currently in effect through the end of 2020.

Research and Development

Our research and development activity includes conducting pre-clinical and clinical trials and other development activities for our pipeline products, including Inhaled AAT for AATD, intravenous plasma-derived AAT for various indications, and rhAAT, advanced understanding of the mechanism of action of AAT, improving existing products and processes, development work at the request of regulatory authorities and strategic partners, as well as communication with regulatory authorities related to our commercial products as well as clinical programs. We incurred approximately $13.1 million, $9.7 million and $12 million research and development expenses in the years ended December 31, 2019, 2018 and 2017, respectively.

Marketing and Distribution

In the Proprietary Products segment, we receive orders for our products and, other than for GLASSIA and KEDRAB sales in the U.S. market, we received requests for participation in tenders for the supply of plasma-derived protein therapeutics from potential distributors and from existing distributors. We sell GLASSIA to Takeda and to other distributors in additional non-U.S. countries. We sell KEDRAB to Kedrion and sell KamRAB and KamRho to other distributers in additional non-U.S. countries.

For our products, we market, in most cases, by means of agreements with local distributors in each country through a tender process and the private market. The tender process is conducted on a regular basis by the distributors, sometimes on an annual basis. For existing customers, our existing relationship does not guarantee additional orders from the same customers in these tenders. The decisive parameter is generally the price proposed in the tender. The distributor purchases plasma-derived protein therapeutics from us and sells them to its customers (either directly or by means of sub-distributors). In most cases, we do not sign agreements with the end users, and as such, we do not fix the price to the end user or its terms of payment and are not exposed to credit risks of the end users. In the vast majority of cases, our agreements with the local distributors award the various distributors exclusivity in the distribution of our plasma-derived protein therapeutics in the relevant country. The distribution agreements are, usually made for a specific initial period and are subsequently renewed for certain agreed periods, where the parties have the right to cancel or renew the agreements with prior notice of 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 in some cases, reimburse the local distributor for an agreed amount of its actual marketing expenses. In Israel, we market our plasma-derived protein therapeutics independently to the healthcare providers and medical centers, or through a logistic partner company that specializes in the supply of equipment and pharmaceuticals to healthcare providers.

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

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

We have supply and distribution agreements with our suppliers in our Distribution segment, including with each of our two largest suppliers to be their exclusive distributor in Israel for a number of their manufactured products; however, we purchase our Distribution segment products from those suppliers on a purchase order basis. We work closely with those suppliers to develop annual forecasts, but these forecasts do not obligate our suppliers to provide us with their products.

Customers

For the year ended December 31, 2019, sales to Takeda, Kedrion and Clalit Health Services, an Israeli HMO, accounted for 54%, 13% and 11%, respectively, of our total revenues. For the year ended December 31, 2018, sales to Takeda and Kedrion accounted for 56% and 10%, respectively, of our total revenues. For the year ended December 31, 2017, sales to Takeda and Clalit Health Services accounted for 59% and 9%, respectively, of our total revenues.

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

Our primary customers in the Distribution segment are health maintenance organizations and hospitals in Israel, including Clalit Health Services and Maccabi Healthcare Services.

Competition

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

Proprietary Products Segment

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

Our large competitors have advantages in the market because of their size, financial resources, markets and the duration of their activities and experience in the relevant market, especially in the United States and countries of the European Union. Most of them have an additional advantage regarding the availability of raw materials, as they fractionate plasma internally and own plasma collection centers and/or companies that collect or produce raw materials such as plasma.

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

GLASSIA. GLASSIA has several competitors, including plasma derived companies such as Grifols, CSL and Takeda, all of which have competing plasma derived AAT products approved for AATD and are marketed in the U.S. as well in some countries in the EU. We estimate that: Grifols' AAT by infusion product for the treatment of AATD, Prolastin, accounts for at least 50% market share in the United States and more than 70% of sales worldwide, and until 2015 it was the only AAT product that was approved for sale in both – key European countries and the United States. In September 2017 Grifols announced that the FDA approved a liquid formulation of its AAT product. Apart from its sales of the past Talecris product, Grifols is also a local producer of an additional AAT product, Trypsone, which is marketed in Spain and in some Latin American countries, including Brazil. CSL's AAT by IV product, Zemaira, is mainly sold in the United States, and during 2015 received centralized marketing authorization approval in the European Union. CSL launched the product in few selected EU markets during 2016 under the brand name Respreeza. Takeda is our strategic partner for sales of GLASSIA and it also serves existing patients in the United States with its own proprietary product, Aralast. As far as we know Takeda is proactively marketing GLASSIA in the United States, while maintaining existing patients on Aralast. In addition, we are aware of a smaller local producer of AAT in the French market, Laboratoire Français du Fractionnement et des Biotechnologies, S.A ("LFB"). We do not believe any new suppliers are expected to enter the United States market for plasma derived 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 Phase IV study results were not accepted by the FDA as proof of required efficacy while Grifols SPARTA phase IV study is ongoing. In summary, to the best of our knowledge, to date, our other competitors did not yet initiate or have not yet completed their trials or their results have not yet been published.

In addition, we have several other competitors such as Vertex Pharmaceuticals, Inhibrx, ApicBio and Mereo, all of which have development stage programs for new medications for treatment of AATD. Based on available public information, Vertex, a Boston, MA headquartered company, is in early stage clinical development of VX-814 and VX-864, two AATD small molecules utilizing a correction approach to prevent protein misfolding in the liver of AATD patients, which can otherwise aggregate and ultimately be pro-inflammatory in the lung. Vertex believes small molecule correctors for protein misfolding could address both liver and lung disease manifestations, possibly avoiding the need for conventional augmentation therapy, further differentiating its product candidates as a novel therapeutic approach. Inhibrx, a California based company, is in early clinical development of INBRX-101 a recombinantly produced AAT replacement protein specifically designed to address the limitations of plasma derived AAT replacement therapy. The modifications introduced into INBRX-101 aim to improve the pharmacokinetic profile (PK) and neutrophil elastase inhibitory function. This could offer superior clinical activity to the current commercial plasma derived AAT by providing sustained enhanced serum concentration with a less frequent, monthly dosing regimen. Apic Bio, a Boston, MA based company is in early stage development of APB-101 a "liver-sparing" gene therapy designed as a one-time treatment for Alpha-1 patients. In pre-clinical studies, APB-101 demonstrated the ability to reduce levels of the mutant Alpha-1 protein (Z-AAT) and at the same time program liver cells to produce the correct Alpha-1 protein (M-AAT). Mereo, a UK based company, is in clinical stage of development of MPH-966 as an oral neutrophil elastase inhibitor being explored for the potential treatment of AATD. These product candidates, if approved, may have an adverse effect on the AATD market and reduce or eliminate the need for the currently approved plasma derived AAT augmentation therapy, and thus may affect our ability to continue and generate revenues and earnings from our GLASSIA. In addition, these product candidates, if approved, may have a negative effect on our ability to continue the development of our Inhaled AAT, and if approved, to market Inhaled AAT and obtain a meaningful market share.

KamRAB/KEDRAB. We believe that there are two main competitors for this anti-rabies product worldwide: Grifols, whose product we estimate comprises of approximately 75%-85% of the anti-rabies market in the United States, and CSL, which sells its anti-rabies product in Europe and elsewhere. Sanofi Pasteur, the vaccines division of Sanofi S.A., has a product registered for the United States market, but the product is primarily sold in Europe and not currently sold in significant quantities in the United States. There are a number of local producers in other countries that make similar anti-rabies products. Most of these products are based on equine serum, which we believe results in inferior products, as compared to products made from human plasma. Over the past several years, a number of companies have made attempts and some are still in the process of developing monoclonal antibodies for an anti-rabies treatment. These products, if approved, may be as effective as the currently available plasma derived anti-rabies vaccine and may potentially be significantly cheaper, and as such may result in loss of market share of KamRAB/KEDRAB.

KamRho(D). While Kedrion is our strategic partners for KEDRAB, it is also one of our competitors for KamRho(D). In addition to its sales in the United States, Kedrion also markets a competing product in several EU countries as well as other countries world-wide. We believe there are three additional main suppliers of competitive products in this market: Grifols, CSL and Saol Therapeutics. There are also local producers in other countries that make similar products mostly intended for local markets.

Distribution Segment

We believe that there are a number of companies active in the Israeli market distributing the products of several manufacturers whose comparable products compete with our products in the Distribution segment. In the plasma area, these manufacturers include Grifols, Takeda, CSL, Omrix Biopharmaceuticals Ltd. (a Johnson & Johnson company), while in other specialties we may be competing against products produced by some of largest pharmaceutical manufacturers in the world, such as, Novartis AG, AstraZeneca AB, Sanofi UK and GlaxoSmithKline. These competing manufacturers have advantages of size, financial resources, market share, broad product selection and extensive experience in the market, although we believe that we have established expertise in the Israeli market. Each of these competitors sells its products through a local subsidiary or a local representative in Israel.

Government Regulation

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

U.S. Drug Development Process

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

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

1. preclinical laboratory tests and animal tests;

2. submission to the FDA of an IND application for human clinical testing, which must become effective before human clinical trials may commence;

3. adequate and well-controlled human clinical trials to establish the safety and efficacy of the product;

4. submission to the FDA of a BLA or supplemental BLA;

5. FDA pre-approval inspection of product manufacturers; and

6. FDA review and approval of the BLA or supplemental BLA.

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

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

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

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

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

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

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

The results of the preclinical studies and clinical trials, together with other detailed information, including information on the manufacture and composition of the product, are submitted to the FDA as part of a BLA requesting approval to market the product candidate for a proposed indication. Under the Prescription Drug User Fee Act, as amended, the fees payable to the FDA for reviewing a BLA, as well as annual fees for commercial manufacturing establishments and for approved products, can be substantial. The BLA review fee alone can exceed $2,400,000, subject to certain limited deferrals, waivers and reductions that may be available. Each BLA submitted to the FDA for approval is typically reviewed for administrative completeness and reviewability within 45 to 60 days following submission of the application. If found complete, the FDA will "file" the BLA, thus triggering a full review of the application. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission. The FDA's established goals are to review and act on 90% of priority BLA applications and priority original efficacy supplements within six months of the 60-day filing date and receipt date, respectively. The FDA's goals are to review and act on 90% of standard BLA applications and standard original efficacy supplements within 10 months of the 60-day filing date and receipt date, respectively. The FDA, however, may not be able to approve a drug within these established goals, and its review goals are subject to change from time to time. Further, the outcome of the review, even if generally favorable, may not be an actual approval but an "action letter" that describes additional work that must be done before the application can be approved. Before approving a BLA, the FDA may inspect the facilities at which the product is manufactured or facilities that are significantly involved in the product development and distribution process, and will not approve the product unless cGMP compliance is satisfactory. The FDA may deny approval of a BLA if applicable statutory or regulatory criteria are not satisfied, or may require additional testing or information, which can delay the approval process. FDA approval of any application may include many delays or never be granted. If a product is approved, the approval will impose limitations on the indicated uses for which the product may be marketed, will require that warning statements be included in the product labeling, may impose additional warnings to be specifically highlighted in the labeling (e.g., a Black Box Warning), which can significantly affect promotion and sales of the product, may require that additional studies be conducted following approval as a condition of the approval, may impose restrictions and conditions on product distribution, prescribing or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval. To market a product for other uses, or to make certain manufacturing or other changes requires prior FDA review and approval of a BLA Supplement or new BLA. Further post-marketing testing and surveillance to monitor the safety or efficacy of a product is required. Also, product approvals may be withdrawn if compliance with regulatory standards is not maintained or if safety or manufacturing problems occur following initial marketing. In addition, new government requirements may be established that could delay or prevent regulatory approval of our product candidates under development.

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

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

Special Development and Review Programs

Orphan Drug Designation

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

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

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

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

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

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

Post-Approval Requirements

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

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

The FDA also may require a Boxed Warning (e.g., a specific warning in the label to address a specific risk, sometimes referred to as a "Black Box Warning"), which has marketing restrictions, and post-marketing testing, or Phase IV testing, as well as a Risk Evaluation and Minimization Strategy (REMS) plans and surveillance to monitor the effects of an approved product or place conditions on an approval that could otherwise restrict the distribution or use of the product.

Other U.S. Healthcare Laws and Compliance Requirements

In the United States, our activities are potentially subject to regulation and enforcement by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services other divisions of the United States Department of Health and Human Services (e.g., the Office of Inspector General), the U.S. Federal Trade Commission, the U.S. Department of Justice and individual United States Attorney's offices within the Department of Justice, state attorneys general and state and local governments. To the extent applicable, we must comply with the fraud and abuse provisions of the Social Security Act, the federal False Claims Act, the privacy and security provisions of the Health Insurance Portability and Accountability Act, and similar state laws, each as amended. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veterans Health Care Act of 1992, each as amended, as well as the "Anti-Kickback Law" provisions of the Social Security Act. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Under the Veterans Health Care Act ("VHCA"), drug companies are required to offer certain pharmaceutical products at a reduced price to a number of federal agencies, including the United States Department of Veterans Affairs and United States Department of Defense, the Public Health Service and certain private Public Health Service-designated entities in order to participate in other federal funding programs including Medicare and Medicaid. Legislative changes have purported to require that discounted prices be offered for certain United States Department of Defense purchases for its TRICARE program via a rebate system. Participation under the VHCA requires submission of pricing data and calculation of discounts and rebates pursuant to complex statutory formulas, as well as the entry into government procurement contracts governed by the Federal Acquisition Regulations. Furthermore, the FCPA prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions. The failure to comply with laws governing international business practices may result in substantial penalties, including civil and criminal penalties.

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

Europe/Rest of World Government Regulation

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

Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. For example, in the European Union, a clinical trial application ("CTA") must be submitted to each member state's national health authority and an independent ethics committee. The CTA must be approved by both the national health authority and the independent ethics committee prior to the commencement of a clinical trial in the member state. The approval process varies from country to country and the time may be longer or shorter than that required for FDA approval. In addition, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country. In all cases, clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

To obtain marketing approval of a drug under European Union regulatory systems, we may submit marketing authorization applications either under a centralized, decentralized or national procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states. The centralized procedure is compulsory for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, and products with a new active substance indicated for the treatment of certain diseases, and optional for those products that are highly innovative or for which a centralized process is in the interest of patients. For our products and product candidates that have received or will receive orphan designation in the European Union, they will qualify for this centralized procedure, under which each product's marketing authorization application will be submitted to the EMA. Under the centralized procedure in the European Union, the maximum time frame for the evaluation of a marketing authorization application is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the Scientific Advice Working Party of the Committee of Medicinal Products for Human Use ("CHMP")). Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, defined by three cumulative criteria: the seriousness of the disease, such as heavy disabling or life-threatening diseases, to be treated; the absence or insufficiency of an appropriate alternative therapeutic approach; and anticipation of high therapeutic benefit. In this circumstance, the EMA ensures that the opinion of the CHMP is given within 150 days.

The decentralized procedure provides possibility for approval by one or more other, or concerned, member states of an assessment of an application performed by one member state, known as the reference member state. Under this procedure, an applicant submits an application, or dossier, and related materials, including a draft summary of product characteristics, and draft labeling and package leaflet, to the reference member state and concerned member states. The reference member state prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. Within 90 days of receiving the reference member state's assessment report, each concerned member state must decide whether to approve the assessment report and related materials. If a member state cannot approve the assessment report and related materials on the grounds of potential serious risk to public health, the disputed points may eventually be referred to the European Commission, whose decision is binding on all member states.

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

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

Pharmaceutical Coverage, Pricing and Reimbursement

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

Several significant laws have been enacted in the United States which affect the pharmaceutical industry and additional federal and state laws have been proposed in recent years. For example, as a result of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), a Medicare prescription drug benefit (Medicare Part D) became effective at the beginning of 2006. Medicare is the federal health insurance program for people who are 65 or older, certain younger people with disabilities, and people with End-Stage Renal Disease. Medicare coverage and reimbursement for some of the costs of prescription drugs may increase demand for any products for which we receive FDA approval. However, we would be required to sell products to Medicare beneficiaries through entities called "prescription drug plans," which will likely seek to negotiate discounted prices for our products.

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

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

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

- increases the minimum level of Medicaid rebates payable by manufacturers of brand-name drugs from 15.1% to 23.1%;
- requires Medicaid rebates for covered outpatient drugs to be extended to Medicaid managed care organizations;
- requires manufacturers of drugs covered under Medicare Part D to participate in a coverage gap discount program, under which they must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible Medicare beneficiaries during their coverage gap period; and
- imposes a non-deductible annual fee on pharmaceutical manufacturers or importers who sell "branded prescription drugs" to specified federal government programs.

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

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

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

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

Intellectual Property

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

Patents

As of December 31, 2019, we owned for use within our field of business nine families of patents or patent applications, which are registered or applied for in the United States and also in the European Union, Russia, Turkey, Israel, certain Latin American countries, Canada, Australia and other countries, six PCT patent applications and two US provisional applications. At present, one patent protecting our manufacturing process is considered to be material to the operation of our business as a whole. Such patent has been issued in a variety of jurisdictions, including Australia, Austria, Belgium, Canada, Denmark, Estonia, Israel, Finland, France, Germany, Greece, Ireland, Italy, Netherlands, Slovenia, Poland, Spain, Portugal, Sweden, Switzerland, Turkey, the United Kingdom and the United States, and expires in 2024.

Our patents generally relate to the separation and purification of proteins and their respective pharmaceutical compositions. Our patents and patent applications further relate to the use of our products and their delivery methods. Our patents and patent applications are expected to expire at various dates between 2024 and 2029. We also rely on trade secrets to protect certain aspects of our separation and purification technology.

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

Trademarks

We rely on trade names, trademarks and service marks to protect our name brands. Our registered trademarks in several countries, such as United States and the European Union, Israel, and certain Latin American countries, include the trademarks GLASSIA, RESPIKAM, KAMRAB, KEDRAB, RESPIRA, KamRHO VENTIA, KAMADA and Rebinolin.

Trade Secrets and Confidential Information

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

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

Property

Our production plant was built on land that Kamada Assets (2001) Ltd. ("Kamada Assets"), our 74%-owned subsidiary, leases from the Israel Land Administration pursuant to a capitalized long-term lease. Kamada Assets subleases the property to us. The property covers an area of approximately 16,880 square meters. The initial sublease expires in 2058 and we have an option to extend the sublease for an additional term of 49 years. The production plant includes our manufacturing facility, manufacturing support systems, packaging, warehousing and logistics areas, laboratory facilities and an area for the manufacture of snake bite anti-serum, as well as office buildings.

Since January 2017, we have leased approximately 2,200 square meters of a building located in the Kiryat Weizmann Science Park in Rehovot, Israel, which replaced our former Ness Ziona premises. This property houses our head office, our research and development laboratory and additional departments such as our research and development, clinical, medical, regulatory and business development departments. We sublease approximately 500 square meters of such premises to a third party renter.

Environmental

We believe that our operations comply in material respects with applicable laws and regulations concerning the environment. While it is impossible to predict accurately the future costs associated with environmental compliance and potential remediation activities, compliance with environmental laws is not expected to require significant capital expenditures and has not had, and is not expected to have, a material adverse effect on our earnings or competitive position.

Organizational Structure

Our significant subsidiaries are set forth below. All subsidiaries are either 100 percent owned by us or controlled by us. All companies are incorporated and registered in the country in which they operate as listed below:

Legal Name	Jurisdiction
Kamada Biopharma Limited	England and Wales
Kamada Inc.	Delaware
Kamada Ireland Limited	Ireland
Kamada Assets (2001) Ltd.	Israel

Legal Proceedings

We are subject to various claims and legal actions during the ordinary course of our business. We believe that there are currently no claims or legal actions that would have a material adverse effect on our financial position, operations or potential performance.

Item 4A. Unresolved Staff Comments

Not applicable.

Item 5. Operating and Financial Review and Prospects

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

The audited consolidated financial statements for the years ended December 31, 2019, 2018 and 2017 in this Annual Report have been prepared in accordance with IFRS as issued by the IASB. None of the financial information in this Annual Report has been prepared in accordance with U.S. GAAP.

Overview

We are a plasma-derived biopharmaceutical company focused on orphan indications, with an existing marketed product portfolio and a late-stage product pipeline. We use our proprietary platform technology and know-how for the extraction and purification of proteins from human plasma to produce Alpha-1 Antitrypsin (AAT) in a highly-purified, liquid form, as well as other plasma-derived immune globulins. Our flagship product is GLASSIA, the first liquid, ready-to-use, intravenous plasma-derived AAT product approved by the FDA. We market GLASSIA in the U.S. through a strategic partnership with Takeda and in other counties through local distributors. our second leading product is KamRab, a rabies immune globulin (Human) for post-exposure prophylaxis against rabies infection. KAMRAB is FDA approved and is being marketed in the U.S. under the brand name KEDRAB through a strategic partnership with Kedrion. In addition to GLASSIA and KEDRAB, we have a product line of four other plasma-derived pharmaceutical products administered by injection or infusion that are marketed through distributors in more than 15 countries, including Israel, Russia, Brazil, India and other countries in Latin America and Asia. We have late-stage products in development, including an inhaled formulation of AAT for the treatment of AAT deficiency. In addition, our intravenous AAT is in development for other indications, such as GvHD, prevention of lung transplant rejection and type-1 diabetes. We also leverage our expertise and presence in the plasma-derived protein therapeutics market by distributing more than 20 complementary products in Israel that are manufactured by third parties. For further details on our business, products and product candidates, see "Item 4 – Information on the Company."

Our Segments

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

Segment performance is evaluated based on revenues and gross profit (loss). Items that are not allocated to our segments consist mainly of research and development costs, sales and marketing expenses, general and administrative costs, financial expenses, net and tax on income, each of which are managed on a group basis. For the year ended December 31, 2019, we derived $97.7 million of revenues from our Proprietary Products segment, or 77% of total revenues, and $29.5 million of revenues from our Distribution segment, or 23% of total revenues. For the year ended December 31, 2018, we derived $90.8 million of revenues from our Proprietary Products segment, or 79% of total revenues, and $23.7 million of revenues from our Distribution segment, or 21% of total revenues. For the year ended December 31, 2017, we derived $79.5 million of revenues from our Proprietary Products segment, or 77% of total revenues, and $ 23.3 million of revenues from our Distribution segment, or 23% of total revenues.

Factors Affecting Our Results of Operations

Demand for our Products

Over the past few years, we have seen an increase in demand for products in our Proprietary Products segment. For full-year 2020, we expect total revenue to be in the range of $132 million and $137 million. The year-over-year revenue growth in 2020 as compared to 2019 is expected to be driven by increased sales of our Proprietary IgG products portfolio and GLASSIA in international markets, expected growth of the Distribution segment in Israel, and increased sales in the U.S. of KEDRAB. We project that total revenues from sales of GLASSIA to Takeda during 2020 will be approximately $65 million, and between $25 million to $50 million during 2021, based on Takeda's needs. Takeda is planning to complete the technology transfer of GLASSIA, and pending FDA approval, will initiate its own production of GLASSIA for the U.S. market in 2021. Accordingly, following the transition of manufacturing to Takeda, we will terminate the manufacturing and sale of GLASSIA to Takeda resulting in a significant reduction in revenues. Pursuant to the agreement, upon initiation of sales of GLASSIA manufactured by Takeda, Takeda will pay us royalties at a rate of 12% on net sales through August 2025, and at a rate of 6% thereafter until 2040, with a minimum of $5 million annually, for each of the years from 2022 to 2040. Although the transition of the agreement to its royalties phase will result in a reduction of our revenue from Takeda, based on current GLASSIA sales in the U.S. and forecasted future growth, we project receiving royalties from Takeda in the range of $10 million to $20 million per year for 2022 to 2040.

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

It is estimated that there are approximately 40,000 rabies post-exposure prophylaxis treatments administered in the U.S. each year, representing a total market of approximately $150 million per year. Sales of KEDRAB, by Kedrion in the U.S. during the year 2019 and 2018 totaled $31.4 million and $15.5 million, respectively. These sales represents approximately 20% and 10% market share, respectively. We expect that our market share for KEDRAB will continue to grow in the coming years.

Sales of our Distribution segment products are made through public tenders of Israeli hospitals and HMOs on an annual basis. The prices we can offer, as well as the availability of products, are key factors in meeting the local demand of the Israeli market. Our Distribution segment experienced a 25% growth in sales during 2019, despite the growing competition. The Distribution segment may continue to grow if we will be able to increase our product portfolio or win more tenders.

Strategic Partnerships

In July 2010, we received FDA approval for the marketing of GLASSIA in the United States. Following this approval, we entered into a 30 year strategic arrangement with Takeda (originally executed with Baxter, which subsequently assigned the agreement to Baxalta, which was subsequently acquired by Shire, which was acquired by Takeda), for the marketing and distribution of GLASSIA in the United States, Canada, Australia and New Zealand and for the licensing of our technology, granting Takeda rights to manufacture GLASSIA for sales in these territories. We began recognizing revenues from sales of GLASSIA in the United States under this strategic arrangement with Takeda in September 2010. From the inception of the strategic arrangement through December 31, 2019, we have received $39.5 million from Takeda for distribution rights, a portion of which has been accrued as deferred revenue, and for achieving milestones set forth in the distribution and licensing agreements. We have recognized cumulative revenues until December 31, 2019 from Takeda in the amount of $380.1 million. We currently generate revenues from sales of GLASSIA to Takeda, and incur cost of revenues to produce it. We project that total revenues from sales of GLASSIA to Takeda during 2020 will be approximately $65 million, and between $25 million to $50 million during 2021, based on Takeda's needs. Based on the licensing and technology transfer agreement signed by us and Takeda in 2010, Takeda is planning to complete the technology transfer of GLASSIA, and pending FDA approval, will initiate its own production of GLASSIA for the U.S. market in 2021. Accordingly, based on the agreement between the companies, upon initiation of sales of GLASSIA manufactured by Takeda, it will pay royalties to us at a rate of 12% on net sales through August 2025, and at a rate of 6% thereafter until 2040, with a minimum of $5 million annually, for each of the years from 2022 to 2040. Although the transition of the agreement to its royalties phase will result in a reduction of our revenue from Takeda, based on current GLASSIA sales in the U.S. and forecasted future growth, we project that we will receive royalties from Takeda in the range of $10 million to $20 million per year for 2022 to 2040. See "Item 3. Key Information — D. Risk Factors — In our Proprietary Products segment, we currently rely on one of our strategic partners that accounts for a significant portion of our total sales and our distribution plan for our principal product candidate relies on another strategic partner, and any disruption to our relationships with these distributors would have an adverse effect on our results of operations and profitability."

In addition, in July 2011, we signed a strategic agreement with Kedrion to cooperate in the clinical development and exclusive marketing and sales in the United States of KEDRAB, our hyper-immune anti-rabies prophlaxis treatment, which was launched in the United States in April 2018. We have recognized cumulative revenues until December 31, 2019 from sales of KEDRAB to Kedrion in the amount of approximately $28 million.

Product Development Costs

Since our company was founded, we have focused on developing a broad portfolio of plasma-derived protein therapeutics for a variety of indications. The development of plasma-derived protein therapeutics is characterized by significant up-front product development costs, including, for example, costs for conducting pre-clinical and clinical trials to obtain regulatory approvals, regulatory expenses, costs for materials for development, external consulting and services fees and opportunity costs for reallocating our production facility to produce clinical trial materials and conforming our production processes for regulatory purposes. In order to reduce costs related to the development and regulatory approval of new protein therapeutics, in some cases we seek to share development costs with strategic partners, such as Takeda for post marketing required clinical trials for GLASSIA in the United States and Kedrion for the clinical trials for KEDRAB in the United States required for product approval and post marketing commitments. See "Item 4. Information on the Company — Strategic Partnerships — Takeda (GLASSIA)" and "Business — Strategic Partnerships — Kedrion (KEDRAB)."

Product development costs may fluctuate from period to period, as our product candidates pass through various stages of development. For example, for the years ended December 31, 2019, 2018 and 2017, we incurred research and development expenses related to clinical trials related to Inhaled AAT for AATD in Europe and the United States, AAT for the treatment of newly diagnosed Type-1 diabetes and lung transplantation rejection and GvHD. We expect to continue to incur research and development expenses related to clinical trials, as well as other ongoing, planned or future clinical trials with regards to our product pipeline. See "Item 4. Information on the Company — Our Product Pipeline and Development Program."

Product Competition

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

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

Costs of Raw Materials

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

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

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

Key Components of Our Results of Operations

Revenues

In our Proprietary Products segment, we generate revenues from the sale of products to strategic partners and distributors, as well as from the licensing of our technology. We derived a significant portion of our total revenues from sales of GLASSIA to Takeda. Sales to Takeda accounted for approximately 54%, 56% and 59% of our total revenues in the years ended December 31, 2019, 2018 and 2017, respectively. Revenue from all sales of GLASSIA comprised approximately 58%, 60% and 64% of our total revenues for the years ended December 31, 2019, 2018 and 2017, respectively. Sales of KEDRAB to Kedrion during the years ended December 31, 2019 and 2018 accounted for approximately 13% and 10% of our total revenues, respectively.

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

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

In our Distribution segment, we generate revenues from the sale in Israel of imported products produced by third parties. During the three year period ended December 31, 2019, sales of IVIG accounted for approximately 14%, 12% and 12% of our total revenues for the years ended December 31, 2019, 2018 and 2017, respectively.

For full-year 2020, we expect total revenue to be in the range of $132 million and $137 million. The year-over-year revenue growth in 2020 as compared to 2019 is expected to be driven by increased sales of our Proprietary IgG products portfolio and GLASSIA in international markets, expected growth of the Distribution segment in Israel, and increased sales in the U.S. of KEDRAB. We project that total revenues from sales of GLASSIA to Takeda during 2020 will be approximately $65 million, and between $25 million to $50 million during 2021, based on Takeda's needs. Based on the licensing and technology transfer agreement signed by us and Takeda in 2010, Takeda is planning to complete the technology transfer of GLASSIA, and pending FDA approval, will initiate its own production of GLASSIA for the U.S. market in 2021. Accordingly, based on the agreement between the companies, upon initiation of sales of GLASSIA manufactured by Takeda, it will pay royalties to us at a rate of 12% on net sales through August 2025, and at a rate of 6% thereafter until 2040, with a minimum of $5 million annually, for each of the years from 2022 to 2040. Although the transition of the agreement to its royalties phase will result in a reduction of our revenue from Takeda, based on current GLASSIA sales in the U.S. and forecasted future growth, we project that we will receive royalties from Takeda in the range of $10 million to $20 million per year for 2022 to 2040. In the future, while the planned transition of GLASSIA manufacturing to Takeda is expected to decrease our revenue and profitability during the years 2021 and 2022, our continued business development efforts are expected to result in resumed revenue and profitability growth beginning in 2023. This growth will be driven by an expected increase in Proprietary Product sales in international markets, an anticipated continued increase in KEDRAB sales in the U.S., the commercial manufacturing of the new specialty hyper-immune globulin product at our facility beginning in 2023, expected growth in our Distribution segment, and the royalties to be paid to us by Takeda on GLASSIA sales.

Cost of Revenues

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

In addition to the successful strategic partnerships with Takeda and Kedrion and successful penetration to the U.S. market, we have focused during the years ended December 31, 2019, 2018 and 2017 on increasing our production outputs and improving efficiencies.

Gross Profit

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

Our gross margins are generally higher in our Proprietary Products segment (46%, 42% and 35% for the years ended December 31, 2019, 2018 and 2017, respectively) than in our Distribution segment (15%, 15%, 17% for the years ended December 31, 2019, 2018, and 2017, respectively).

In 2020, the expected change in product sales mix, as well as reduced plant utilization, is anticipated to result in an overall decrease in the Propriety Products segment's full-year gross margins of approximately three to five percentage points as compared to 2019.

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

Research and Development Expenses

Research and development expenses are incurred for the development of new products and newly revised processes for existing products and includes expenses for pre-clinical and clinical trials, development activities in the different fields, the advanced understanding of the mechanism of action of our products, improving existing products and processes, development work at the request of regulatory authorities and strategic partners, as well as communication with regulatory authorities related to our commercial products and clinical programs. In addition, such expenses include development materials, payroll for research and development personnel, including scientists and professionals for product registration and approval, external advisors and the allotted cost of our manufacturing facility for research and development purposes. While research and development expenses are unallocated on a segment basis, the activities generally relate to our existing or in development proprietary products.

Research and development expenses increased in 2019 specifically due to the initiation of our pivotal Phase 3 InnovAATe clinical trial. In 2020, due to the planned acceleration of this clinical study, we expect an approximately 20% to 25% increase in research and development expenses, as compared to 2019. Actual spending could differ if our plans change or if we potentially reduce our anticipated funding on research for existing products or partner with other parties to fund development of current product candidates.

Selling and Marketing Expenses

Selling and marketing expenses principally consist of expenditures incurred for sales incentive, advertising, marketing or promotional activities, shipping and handling costs, product liability insurance and business development activities, as well as marketing authorization fees to regulatory agencies. Due to our strategic partnerships in our Proprietary Products segment, we expect these costs to remain at a similar level other than ongoing effort to increase sales of existing products. However, we may incur higher expenses in the future, mainly due to the distribution of our products outside the U.S. market which is done through local distributers. We market our products in our Distribution segment to HMOs and hospitals in Israel.

General and Administrative Expenses

General and administrative expenses consist of compensation for employees in executive and administrative functions (including payroll, bonus, equity compensation and other benefits), office expenses, professional consulting services, public company costs, legal and audit fees as well as employee welfare costs. We expect general and administrative expenses to remain stable.

Financial Income

Financial income is comprised of interest income on amounts invested in bank deposits and short-term investments.

Income (expense) in respect of securities measured at fair value, net

Income (expense) in respect of securities measured at fair value, net comprised the changes in the fair value of financial assets measured at fair value through other comprehensive income.

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

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

Financial Expenses

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

Taxes on Income

We have not been required to pay income taxes since 1997 other than tax withheld in a foreign jurisdiction in 2012 and 2016 and a $1.3 million payment to the Israel Tax Authority in 2016 as a settlement agreement for the tax years 2004-2006. In 2018, we initially recognized a deferred tax asset for a portion of our carryforward losses and in 2019, we recognized a tax expense as a portion of the deferred tax asset on account of earnings that were offset against the carryforward losses.

One of our Israeli facilities has Approved Enterprise status granted by the Israel Investment Center under the Investment Law, which made us eligible for a grant and certain tax benefits under that law for a certain investment program. The investment program provided us with a grant in the amount of 24% of our approved investments, in addition to certain tax benefits, which applied to the turnover resulting from the operation of such investment program, for a period of up to ten consecutive years from the first year in which we generated taxable income. The tax benefits under the Approved Enterprise status expired at the end of 2017. Additionally, we have obtained a tax ruling from the Israel Tax Authority according to which, among other things, our activity has been qualified as an “industrial activity,” as defined in the Investment Law, and is also eligible for tax benefits as a Privileged Enterprise, which apply to the turnover attributed to such enterprise, for a period of up to ten years from the first year in which we generated taxable income. The tax benefits under the Privileged Enterprise status are scheduled to expire at the end of 2020 and 2023. As of the date of this Annual Report, we have not utilized any tax benefits under the Investment Law, other than the receipt of grants attributable to our Approved Enterprise status.

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

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

As of December 31, 2019, we have net operating loss carryforwards for tax purposes of approximately $47.4 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,		
	2019	**2018**	**2017**
	(U.S. Dollars in thousands)		
Revenues from Proprietary Products segment	$ 97,696	$ 90,784	$ 79,559
Revenues from Distribution segment	29,491	23,685	23,266
Total revenues	127,187	114,469	102,825
Cost of revenues from Proprietary Products segment	52,425	52,796	51,335
Cost of revenues from Distribution segment	25,025	20,201	19,402
Total cost of revenues	77,450	72,997	70,737
Gross profit	49,737	41,472	32,088
Research and development expenses	13,059	9,747	11,973
Selling and marketing expenses	4,370	3,630	4,398
General and administrative expenses	9,194	8,525	8,273
Other expense	330	311	-
Operating income (loss)	22,784	19,259	7,444
Financial income	1,146	830	500
Income (expense) in respect of securities measured at fair value, net	(5)	(172)	(82)
Income (expense) in respect of currency exchange differences and derivatives instruments, net	(651)	602	(612)
Financial expense	(293)	(178)	(80)
Income (loss) before taxes on income	22,981	20,341	7,170
Taxes on income	730	(1,955)	269
Net income (loss)	$ 22,251	$ 22,296	$ 6,901

Year Ended December 31, 2019 Compared to Year Ended December 31, 2018

Segment Results

			Change 2019 vs. 2018	
	2019	**2018**	**Amount**	**Percent**
	(U.S. Dollars in thousands)			
Revenues:				
Proprietary Products	$ 97,696	$ 90,784	$ 6,912	8%
Distribution	29,491	23,685	5,806	25%
Total	127,187	114,469	12,718	11%
Cost of Revenues:				
Proprietary Products	52,425	52,796	(371)	-1%
Distribution	25,025	20,201	4,824	24%
Total	77,450	72,997	4,453	6%
Gross Profit:				
Proprietary Products	$ 45,271	$ 37,988	$ 7,283	19%
Distribution	4,466	3,484	982	28%
Total	$ 49,737	$ 41,472	$ 8,265	20%

Revenues

In the year ended December 31, 2019, we generated $127.2 million of total revenues, compared to $114.5 million in the year ended December 31, 2018, an increase of $12.7 million, or approximately 11%. This increase was primarily due to a $6.9 million increase in our Proprietary Products segment revenues, mainly due increase of sales of KEDRAB and GLASSIA in United States during 2019, and a $5.8 million increase in our Distribution segment, mainly attributable to increased sales of IVIG product.

Cost of Revenues

In the year ended December 31, 2019, we incurred $77.5 million of cost of revenues, compared to $73.0 million in the year ended December 31, 2018, an increase of $4.4 million, or approximately 6%. The increase is mainly attributable to a $4.8 million in increase in cost of revenues in our Distribution segment, primarily due to an increase in volume of sales, offset in part by a decrease of $0.4 million in the Proprietary segment, mainly attributed to improved manufacturing efficiencies.

Gross profit

Gross profit in our Proprietary Products segment increased by $7.3 million in 2019, primarily due to the sales of GLASSIA and KEDRAB in the United States and resulting in improved products sales mix and improved manufacturing efficiencies. Gross profit in our Distribution segment increased by $1.0 million in 2019, primarily due to increased sales volume. As a percentage of total revenues, gross margin increased to 39.1 % for the year ended December 31, 2019 from 36.2% for the year ended December 31, 2018. Gross margin for the Proprietary Products segment, as a percentage of revenues from that segment, was 46.3% and 41.8% for the years ended December 31, 2019 and 2018, respectively. Gross margin for the Distribution segment, as a percentage of revenues from that segment, was 15.1% and 14.7% for the years ended December 31, 2019 and 2018, respectively. The increase in gross profit margin was primarily driven by an increase in the Proprietary Products segment revenues and high profitability of KEDRAB.

Research and Development Expenses

In the year ended December 31, 2019, we incurred $13.1 million of research and development expenses, compared to $9.7 million in the year ended December 31, 2018, an increase of $3.4 million, or approximately 34%. This increase was primarily due to a $3.2 million increase in clinical trial expenses, mainly attributed to an increase in expenses in connection with the initiation of our pivotal Phase 3 InnovAATe clinical trial of approximately $2.8 million and costs associated with a proof-of-concept clinical trial of our IV-AAT as preemptive therapy for patients at high-risk for the development of steroid-refractory acute GvHD of approximately $0.3 million. Research and development expenses accounted for approximately 10.2% and 8.5% of total revenues for the years ended December 31, 2019 and 2018, respectively.

Set forth below are the research and development expenses associated with our major development programs in the years ended December 31, 2019 and 2018:

	Year ended December 31,	
	2019	**2018**
	(U.S. Dollars in thousands)	
Inhaled AAT	$ 3,192	$ 356
AAT IV for treatment of GvHD	666	356
Anti-Rabies	272	208
Recombinant AAT	352	223
AAT IV for lung transplantation rejection	34	194
Unallocated salary	5,816	5,823
Unallocated facility cost allocated to research and development	2,146	1,990
Unallocated other expenses	581	597
Total research and development expenses	$ 13,059	$ 9,747

Unallocated expenses are expenses that are not managed by project and are allocated between various tasks that are not always related to a major project. In the years ended December 31, 2019 and 2018, we incurred $5.8 million and $5.8 million, respectively, of unallocated salary expenses which represent all research and development salary expenses, $2.1 million and $2.0 million, respectively, of facility costs allocated to research and development and $0.6 million and $0.6 million, respectively, of unallocated other expenses.

Our current intentions with respect to our major development programs are described in "Business — Our Product Pipeline and Development Program". In 2020, due to the planned acceleration of this clinical study, we expect an approximately 20% to 25% increase in research and development expenses, as compared to 2019. However, we cannot determine with full certainty the duration and completion costs of the current or future clinical trials of our major development programs or if, when, or to what extent we will generate revenues from the commercialization and sale of any product candidates. We or our strategic partners may never succeed in achieving marketing approval for any product candidates. The duration, costs and timing of clinical trials and our major development programs will depend on a variety of factors, including the uncertainties of future clinical and preclinical studies, uncertainties in clinical trial enrollment rates and significant and changing government regulation and whether our current or future strategic partners are committed to and make progress in programs licensed to them, if any. In addition, the probability of success for each product candidate will depend on numerous factors, including competition, manufacturing capability and commercial viability. See "Item 3. Key Information — D. Risk Factors — Risk Related to Development, Regulatory Approval and Commercialization of Product Candidates."

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

Selling and Marketing Expenses

In the year ended December 31, 2019, we incurred $4.4 million of selling and marketing expenses, compared to $3.6 million in the year ended December 31, 2018, an increase of $0.8 million, or approximately 20%. This increase was primarily due to a $0.4 million increase in registration and marketing fees and a $0.4 million increase in marketing and advertising expenses. Selling and marketing expenses accounted for approximately 3.43% and 3.2% of total revenues for the years ended December 31, 2019 and 2018, respectively

General and Administrative Expenses

In the year ended December 31, 2019, we incurred $9.2 million of general and administrative expenses, compared to $8.5 million in the year ended December 31, 2018, an increase of $0.7 million, or approximately 8%. This increase was primarily due to an increase of $0.4 million in salary and related expenses and $0.3 million in professional fees and employees welfare. General and administrative expenses accounted for approximately 7.2% and 7.4% of total revenues for the years ended December 31, 2019 and 2018, respectively.

Other expenses

In each of the years ended December 31, 2019, and 2018 we incurred $0.3 million of other expenses related to an ongoing technology transfer project preformed with an external service provider that is planned to be completed during 2020.

Financial Income

In the years ended December 31, 2019 and December 31, 2018, we generated $1.1 million and $0.8 million of financial income, respectively, from our short term investment portfolio and bank deposits.

Income (expense) in respect of securities measured at fair value, net

In the year ended December 31, 2019, we incurred $5 thousand of expenses in respect of securities measured at fair value, net, compared to $0.2 million in the year ended December 31, 2018.

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

In the year ended December 31, 2019, we incurred $0.6 million of expenses in respect of currency exchange differences on balances in other currencies versus the U.S. dollar and derivatives impact compared to income of $0.6 million in the year ended December 31, 2018.

Financial Expenses

In the year ended December 31, 2019, we incurred $0.3 million of financial expenses, compared to $0.2 million in the year ended December 31, 2018.

Taxes on Income

In the year ended December 31, 2019, we recognized $0.7 million tax expenses. In the year ended December 31, 2018, we recognized a deferred tax asset representing a portion of carryforward losses that we estimate that we will realize in the coming years, resulting in tax income of $2.0 million for such period.

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

Segment Results

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

Revenues

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

Cost of Revenues

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

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

Gross profit

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

Research and Development Expenses

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

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

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

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

Selling and Marketing Expenses

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

General and Administrative Expenses

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

Other expenses

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

Financial Income

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

Income (expense) in respect of securities measured at fair value, net

In the year ended December 31, 2018, we incurred $0.2 million of expenses in respect of securities measured at fair value, net, compared to $0.1 million in the year ended December 31, 2017.

Expense in respect of currency exchange differences and derivatives instruments, net

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

Financial Expenses

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

Taxes on Income

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

Quarterly Results of Operations

The following tables set forth unaudited quarterly consolidated statements of operations data for the four quarters of fiscal years 2019 and 2018. 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, 2019	September 30, 2019	June 30, 2019	March 31, 2019	December 31, 2018	September 30, 2018	June 30, 2018	March 31, 2018
	(U.S. Dollars in thousands)							
Revenues from Proprietary Products	$ 25,175	$ 24,859	$ 27,281	$ 20,381	$ 43,138	$ 9,454	$ 25,978	$ 12,214
Revenues from Distribution	6,896	8,207	7,972	6,416	5,073	5,521	7,864	5,227
Total revenues	32,071	33,066	35,253	26,797	48,211	14,975	33,842	17,441
Cost of revenues from Proprietary Products	14,013	13,234	14,688	10,490	22,290	7,869	16,458	6,179
Cost of revenues from Distribution	5,969	6,968	6,965	5,123	4,665	4,587	6,703	4,246
Total cost of revenues	19,982	20,202	21,653	15,613	26,955	12,456	23,161	10,425
Gross profit	12,089	12,864	13,600	11,184	21,256	2,519	10,681	7,016
Research and development expenses	3,329	3,477	3,487	2,766	2,573	2,323	2,097	2,754
Selling and marketing expenses	929	1,161	1,188	1,092	906	818	936	970
General and administrative expenses	2,343	2,230	2,527	2,094	2,393	1,902	2,166	2,064
Other expense (income)	3	299	5	23	-	-	311	-
Operating income (loss)	5,485	5,697	6,393	5,209	15,384	(2,524)	5,171	1,228
Financial income	259	328	274	285	203	214	184	229
Financial expenses	(76)	(68)	(72)	(77)	(27)	(39)	(46)	(60)
Income (expense) in respect of securities measured at fair value, net	(2)	55	(6)	(52)	(26)	(45)	(9)	(97)
Income (expense) in respect of currency exchange differences and derivatives instruments, net	(148)	25	(216)	(312)	267	3	375	(44)
Income (loss) before taxes on income	5,518	6,037	6,373	5,053	15,801	(2,391)	5,675	1,256
Taxes on income	156	214	230	130	(1,944)	-	(11)	-
Net income (loss)	$ 5,362	$ 5,823	$ 6,143	$ 4,923	$ 17,745	$ (2,391)	$ 5,686	$ 1,256

Liquidity and Capital Resources

Our primary uses of cash are to fund working capital requirements, research and development expenses and capital expenditures. Historically, we have funded our operations primarily through cash flow from operations (including sales of our proprietary products and distribution products), payments received in connection with strategic partnerships (including milestone payments from collaboration agreements), issuances of ordinary shares (including our 2005 initial public offering and listing on the Tel Aviv Stock Exchange, our 2013 initial public offering in the United States and listing on Nasdaq, our 2017 underwritten public offering and our 2020 private placement), and the issuance of convertible debentures and warrants to purchase our ordinary shares. The balance of cash and cash equivalents and short-term investments as of December 31, 2019, 2018 and 2017 totaled $73.9 million, $50.6 million and $43.0 million, respectively. We plan to fund our future operations through continued sales and distribution of our proprietary and distribution products, commercialization and or out-licensing of our pipeline product candidates, and raising additional capital through the issuance of equity or debt.

Our strategic partnership agreement with Takeda includes payments for the achievement of certain milestones. Since inception and through December 31, 2019, we received an aggregate of $39.5 million in payments under these agreements, and there are $5.5 million in payments under these agreements that we could potentially receive if we achieve additional milestones as set forth in such agreements. See “Item 4. Information on the Company—Strategic Partnerships — Takeda (GLASSIA).”

Our capital expenditures for the years ended December 31, 2019, 2018 and 2017 were $2.3 million, $2.9 million and $4.1 million, respectively. Our capital expenditures currently relate primarily to the maintenance and improvements of our facilities. We expect our capital expenditures to remain substantially similar in the near term as such capital expenditures are planned to be attributable mainly to the maintenance and improvements of our facilities.

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

Cash Flows from Operating Activities

Net cash provided by operating activities was $ 27.6 million for the year ended December 31, 2019. This net cash provided by operating activities reflects net income of $22.3 million, $6.3 million of non-cash expenses and an increase in inventories of $14.0 million which are expected to be sold in 2020, a decrease in trade receivables of $5.1 million and an increase in trade payables of $6.3 million.

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

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

Cash Flows from Investing Activities

Net cash used in investing activities was $0.6 million for the year ended December 31, 2019, which comprises of proceeds from short term investment of $1.7 million and purchase of property, plant and equipment of $2.3 million.

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

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

Cash Flows from Financing Activities

Net cash used in financing activities was $1.5 million for the year ended 2019, mainly due to repayments of long-term loans and leases in the amount to $1.5 million.

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

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

Contractual Obligations and Commitments

The following is a summary of our contractual obligations and commitments as of December 31, 2019 (in thousands):

	Total	Less than 1 Year	1 – 3 Years	4-5 Years	More than 5 Years
	(U.S. Dollars in thousands)				
Purchase commitments	31,404	-	-	-	-
Long-term debt obligations (1)	767	506	261	-	-
Leases obligations	5,711	1,198	1,797	1,352	1,364
Total	37,882	1,704	2,058	1,352	1,364

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

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

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

Seasonality

We have experienced in the past, and expect to continue to experience, certain fluctuations in our quarterly revenues. See “Item 5. Operating and Financial Review and Prospects - Quarterly Results of Operations”.

Off-Balance Sheet Arrangements

As of December 31, 2019, 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.

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

Revenue Recognition

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

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

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

For most contracts, revenue recognition occurs at a point in time when control of the asset is transferred to the customer, generally on delivery of the goods. For agreements with a strategic partner, performance obligations are generally satisfied over time, given that the customer either simultaneously receives or consumes the benefits provided by us, or receives assets with no alternative use, for which we have an enforceable right to payment for performance completed to date.

With respect to our agreement with Takeda, we identified the following performance obligations in the contract: (a) the grant of a license to Takeda for distribution of GLASSIA in certain territories and the supply of predetermined minimum quantities; (b) the grant of a license to Takeda for the use our knowledge and patents, and the provision of consulting services to Takeda with respect to the transfer of technology; and (c) the supply of a predetermined quantity of GLASSIA for the purpose of clinical trials performed by Takeda.

For the Takeda agreement, when determining the transaction price we took into consideration the following elements: (a) variable consideration – certain amounts of the promised consideration in the Takeda agreement, such as milestone payments and volume rebates, are variable, and were allocated to a single performance obligation or to a distinct goods or services within it; (b) significant financing component – we concluded that certain advance payments received from Takeda provide us with the benefit of financing. Therefore, we adjusted the transaction price for the effects of the time value of money; and (c) non-cash consideration – we identified raw materials provided by Takeda as non-cash consideration. This consideration is measured at fair value. We allocate the transaction price to the different performance obligation identified. This allocation is based on relative stand-alone selling price. We also concluded that we transfer the goods and services over time. This is because Takeda either receives and consumes the benefits provided by us as it is being performed, or because our performance creates assets with no alternative use and we have an enforceable right to payment for performance completed to date.

Clinical Trial Accruals and Related Expenses

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

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

Inventories

Inventories are measured at the lower of cost and net realizable value. The cost of inventories is comprised of costs required to purchase raw materials and other indirect costs required to manufacture the product (including salaries), in addition, such costs may include the costs of purchase and shipping and handling. Net realizable value is the estimated selling price in the ordinary course of business less the estimated costs of completion and the estimated selling costs.

We periodically evaluate the condition and age of inventories and make provisions for slow-moving inventories accordingly. Unfavorable changes in market conditions may result in a need for additional inventory reserves that could adversely impact our gross margins. Conversely, favorable changes in demand could result in higher gross margins when we sell products.

Inventory that is produced following a change in manufacturing process prior to final approval of regulatory authorities is subject to our estimates as to the probability of receipt of such approval. We periodically reassess the probability of such approval and the remaining shelf life of such inventory. If regulatory approval is not granted, the cost of this inventory will be charged to research and development expenses.

Impairment of Non-financial Assets

We evaluate the need to record an impairment of the carrying amount of non-financial assets whenever events or changes in circumstances indicate that the carrying amount is not recoverable. If the carrying amount of non-financial assets exceeds their recoverable amount, the assets are reduced to their recoverable amount. The recoverable amount is the higher of fair value less costs of sale and value in use. In measuring value in use, the expected future cash flows are discounted using a pre-tax discount rate that reflects the risks specific to the asset. The recoverable amount of an asset that does not generate independent cash flows is determined for the cash-generating unit to which the asset belongs. Impairment losses are recognized in profit or loss.

An impairment loss of an asset, other than goodwill, is reversed only if there have been changes in the estimates used to determine the asset's recoverable amount since the last impairment loss was recognized. Reversal of an impairment loss, as above, will not be increased above the lower of the carrying amount that would have been determined (net of depreciation or amortization) had no impairment loss been recognized for the asset in prior years and its recoverable amount. The reversal of impairment loss of an asset presented at cost is recognized in profit or loss.

We had no impairment of non-financial assets in 2019.

Share-based Payment Transactions

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

The cost of equity-settled transactions is measured at the fair value of the equity instruments granted at grant date. We use the binomial model when estimating the grant date fair value of equity settled share options. We selected the binomial option pricing model as the most appropriate method for determining the estimated fair value of our share-based awards without market conditions. We use the share price at the grant date when estimating the grant date fair value of equity settled restricted shares.

The determination of the grant date fair value of options using an option pricing model is affected by estimates and assumptions regarding a number of complex and subjective variables. These variables include the expected volatility of our share price over the expected term of the options, share option exercise and cancellation behaviors, expected exercise multiple, risk-free interest rates, expected dividends and the price of our ordinary shares on the TASE, which are estimated as follows:

- *Expected Life*. The expected life of the share options is based on historical data, and is not necessarily indicative of the exercise patterns of share options that may occur in the future.

- *Volatility*. The expected volatility of the share prices reflects the assumption that the historical volatility of the share prices on the TASE is reasonably indicative of expected future trends.

- *Risk-free interest rate*. The risk-free interest rate is based on the yields of non-index-linked Bank of Israel treasury bonds with maturities similar to the expected term of the options for each option group.

- *Expected forfeiture rate*. The post-vesting forfeiture rate is based on the weighted average historical forfeiture rate.

- *Dividend yield and expected dividends*. We have not recently declared or paid any cash dividends on our ordinary shares and do not intend to pay any cash dividends. We have therefore assumed a dividend yield and expected dividends of zero.

- *Share price on the TASE*. The price of our ordinary shares on the TASE used in determining the grant date fair value of options is based on the price on the grant date.

If any of the assumptions used in the binomial model change significantly, share-based compensation for future awards may differ materially compared with the awards granted previously.

The cost of equity-settled transactions is recognized in profit or loss, together with a corresponding increase in equity, during the period which the performance and/or service conditions are to be satisfied, ending on the date on which the relevant grantee become fully entitled to the award. The cumulative expense recognized for equity-settled transactions at the end of each reporting period until the vesting date reflects the extent to which the vesting period has expired and our best estimate of the number of equity instruments that will ultimately vest. The expense or income recognized in profit or loss represents the change between the cumulative expense recognized at the end of the reporting period and the cumulative expense recognized at the end of the previous reporting period.

No expense is recognized for awards that do not ultimately vest, except for awards where vesting is conditional upon a market condition, which are treated as vesting irrespective of whether the market condition is satisfied, provided that all other vesting conditions (service and/or performance) are satisfied.

If we modify the conditions on which equity-instruments were granted, an additional expense is recognized for any modification that increases the total fair value of the share-based payment arrangement or is otherwise beneficial to the grantee at the modification date.

If a grant of an equity instrument is cancelled, it is accounted for as if it had vested on the cancellation date, and any expense not yet recognized for the grant is recognized immediately. However, if a new grant replaces the cancelled grant and is identified as a replacement grant on the grant date, the cancelled and new grants are accounted for as a modification of the original grant, as described above.

Post-employment Benefits Liabilities

Our post-retirement benefit plans are normally financed by contributions to insurance companies and classified as defined contribution plans or as defined benefit plans.

We operate a defined benefit plan in respect of severance pay pursuant to the Israeli Severance Pay Law. See Note 2r and Note 16 in our consolidated financial statements included in this Annual Report for more details.

The present value of our severance pay depends on a number of factors that are determined on an actuarial basis using a number of assumptions. The assumptions used in determining the net cost or income for severance pay and plan assets include a discount rate. Any changes in these assumptions will impact the carrying amount of severance pay and plan assets.

Other key assumptions inherent to the valuation include employee turnover, inflation, expected long term returns on plan assets and future payroll increases. The expected return on plan assets is determined by considering the expected returns available on assets underlying the current investments policy. These assumptions are given a weighted average and are based on independent actuarial advice and are updated on an annual basis. Actual circumstances may vary from these assumptions, giving rise to a different severance pay liability.

Accounting for Income Taxes

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

We follow IFRIC 23, “Uncertainty over Income Tax Treatments” (“the Interpretation”) issued by the IASB, The Interpretation clarifies the accounting for recognition and measurement of assets or liabilities in accordance with the provisions of IAS 12, “Income Taxes”, in situations of uncertainty involving income taxes. The Interpretation provides guidance on: (i) considering whether some tax treatments should be considered collectively; (ii) measurement of the effects of uncertainty involving income taxes on the financial statements; and (iii) accounting for changes in facts and circumstances in respect of the uncertainty.

As of December 31, 2019 and 2018, the application of IFRIC 23 did not have a material effect on the financial statements.

Short-term investments

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

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

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

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

Our policy is to record an allowance for expected credit loss (“ECL”) for all debt financial assets not measured at FVPL. ECLs are based on the difference between the contractual cash flows due in accordance with the contract and the cash flows that we actually expect to receive. For other debt financial assets (i.e., debt securities measured at FVOCI), the ECL is based on the 12-month ECL. The 12-month ECL is the portion of lifetime ECLs that results from default events on a financial instrument that are possible within 12 months after the reporting date. As of December 31, 2019, we have not recorded an ECL allowance.

Leases

As of January 1, 2019, we applied IFRS 16, “Leases”. We account for a contract as a lease when the contract terms convey the right to control the use of an identified asset for a period of time in exchange for consideration.

On the inception date of the lease, we determine whether the arrangement is a lease or contains a lease, while examining if it conveys the right to control the use of an identified asset for a period of time in exchange for consideration. In our assessment of whether an arrangement conveys the right to control the use of an identified asset, we assess whether we have the following two rights throughout the lease term:

(a) The right to obtain substantially all the economic benefits from use of the identified asset; and

(b) The right to direct the identified asset’s use.

For leases in which we are the lessee, we recognize on the commencement date of the lease a right-of-use asset and a lease liability, excluding leases whose term is up to 12 months and leases for which the underlying asset is of low value. For these excluded leases, we have elected to recognize the lease payments as an expense in profit or loss on a straight-line basis over the lease term. In measuring the lease liability, we have elected to apply the practical expedient in IFRS 16 and do not separate the lease components from the non-lease components (such as management and maintenance services, etc.) included in a single contract.

On the commencement date, the lease liability includes all unpaid lease payments discounted at the interest rate implicit in the lease, if that rate can be readily determined, or otherwise using our incremental borrowing rate. After the commencement date, we measure the lease liability using the effective interest rate method.

On the commencement date, the right-of-use asset is recognized in an amount equal to the lease liability plus lease payments already made on or before the commencement date and initial direct costs incurred less any lease incentives received. The right-of-use asset is measured applying the cost model and depreciated over the shorter of its useful life or the lease term. We test for impairment of the right-of-use asset whenever there are indications of impairment pursuant to the provisions of IAS 36.

Following the initial application of IFRS 16, on January 1, 2019, we recognized the right of used asset and lease liability in the amount of $4.2 million and $4.7 million, respectively (see Note 2w, and Note 14b in our consolidated financial statements included in this Annual Report).

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 26, 2020.

Name	Age	Position
Executive Officers:		
Amir London	51	Chief Executive Officer
Chaime Orlev	49	Chief Financial Officer
Michal Ayalon, PhD	53	Vice President, Research and Development and IP
Yael Brenner	54	Vice President, Quality
Hanni Neheman	50	Vice President, Marketing & Sales
Eran Nir	47	Vice President, Operations
Orit Pinchuk	55	Vice President, Regulatory Affairs and PVG
Ariella Raban	44	Vice President, Human Resources
Dr. Michal Stein	46	Vice President, Medical Director for Immunology
Dr. Naveh Tov	55	Vice President, Clinical Development and Medical Director for Pulmonary Diseases
Directors:		
Leon Recanati*	71	Chairman, Chairman of Compensation Committee
Lilach Asher Topilsky*	49	Director
Avraham Berger*	68	Director, Chairman of Audit Committee
Amiram Boehm *	48	Director
Ishay Davidi*	57	Director
Karnit Goldwasser*	43	Director
Jonathan Hahn	37	Director, Chairman of the Strategy Committee
David Tsur	70	Director

* Independent director under the Nasdaq listing requirements.

Executive Officers

Amir London has served as our Chief Executive Officer since July 2015. Prior to that, Mr. London served as our Senior Vice President, Business Development since December 2013. Mr. London brings with him over 20 years of senior management and international business development experience. From 2011 to 2013, Mr. London served as the Chief Operating Officer of Fidelis Diagnostics, a U.S.-based provider of innovative in-office medical diagnostic services. Earlier in his career, from 2009 to 2011, Mr. London was the Chief Executive Officer of Promedico, a leading Israeli-based $350 million healthcare distribution company, and the General Manager of Cure Medical, from 2006 to 2009, providing contract manufacturing services for clinical studies, as well as home-care solutions. From 1995 to 2006, Mr. London was a Partner with Tefen, an international publicly-traded operations management consulting firm, responsible for the firm's global biopharma practice. Mr. London holds a B.Sc. degree in Industrial and Management Engineering from the Technion – Israel Institute of Technology.

Chaime Orlev has served as our Chief Financial Officer since December 2017. Prior to that, Mr. Orlev had served in senior finance roles for nearly 20 years, with approximately 12 years spent in the life sciences industry. Most recently, from September 2016 to November 2017, Mr. Orlev served as Chief Financial Officer and Vice President Finance and Administration at Bioblast Pharma Ltd. (Nasdaq: ORPN), a clinical-stage, orphan disease-focused biotechnology company. Prior to that, from 2010, Mr. Orlev served as Vice President Finance and Administration at Chiasma (Nasdaq: CHMA), a clinical-stage biopharmaceutical company focused on treating rare and serious chronic diseases. In this role, Mr. Orlev helped lead the company's 2015 over $100 million initial public offering and listing on Nasdaq, and participated in the negotiations and closing of the licensing agreement for the company's lead product to F. Hoffmann-La Roche. Previously, Mr. Orlev was Chief Financial Officer at Oramed Pharmaceuticals Inc. (Nasdaq: ORMP), which has developed an innovative technology to transform injectable treatments into oral therapies. In this role, he led multiple capital raises. Mr. Orlev is a certified public accountant in Israel, holds an MBA degree from the Leon Recanati Graduate School of Business Administration at the Tel Aviv University and a BA degree in Business Administration from the College of Management in Israel.

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

Yael Brenner has served as our Vice President, Quality since March 2015. Ms. Brenner has more than 20 years of experience in Quality Management, including Quality Assurance and Quality Control managerial positions in the pharmaceutical industry. Prior to joining Kamada, from 2007 to 2015, Ms. Brenner was at Teva Pharmaceuticals Industries, lastly as Senior Director Quality Operations of Teva Kfar Sava Site, managing over 400 employees in Quality Assurance, Quality Control and Regulatory Affairs. Ms. Brenner holds B.Sc. and M.Sc. degrees in Chemistry from the Technion - Israel Institute of Technology, and in addition is a Certified Quality Engineer (CQE) from the American and Israeli Societies for Quality.

Hanni Neheman has served as our Vice President, Marketing & Sales since January 2020. Ms. Neheman joined us in August 2014 and served as Head of Business Operations, Israel. Ms. Neheman has more than 20 years of expertise in different positions in the field of marketing and sales in the pharmaceutical industry. Prior to joining us, Ms. Neheman served as a Commercial Manager at Neopharm Israel. Ms. Neheman holds a B.A degree in Occupational Therapy from the Technion Israel Institute of Technology and Executive M.B.A from Derby University.

Eran Nir has served as our Vice President, Operations since November 1, 2016. Mr. Nir has over 14 years of operations management experience in the pharmaceutical and medical industries. Mr. Nir's recent roles include management of TEVA's Pharmaceutical plant in Jerusalem from 2002 to 2011, VP Operations of Amelia Cosmetics from 2014 to 2015 and management of a medical equipment plant of Philips Medical Systems from 2015 to 2016. Mr. Nir's extensive experience spans across the management of large scale FDA and EMA- approved manufacturing facilities, tech-transfer of new products from development to production and the implementation of world-class operational excellence systems. Mr. Nir holds a B.Sc. degree in Industrial and Management Engineering and a MBA degree in Business Management, both from Ben-Gurion University.

Orit Pinchuk has served as our Vice President, Regulatory Affairs and PVG since October 2014. Ms. Pinchuk has experience of more than 20 years in the pharmaceutical industry, fulfilling key positions that cover, among others, disciplines of Regulatory Affairs and Compliance. Prior to joining Kamada, Ms. Pinchuk was at Teva Pharmaceuticals Industries, from 1993 to 2014, where she served as Director of Compliance and Regulatory Affairs, Operation Israel and Senior Director Regulatory Affairs, Research and Development and Operation Israel. Ms. Pinchuk has extensive experience with FDA, EMA and Canada Health Authorities. Ms. Pinchuk holds a B.Tech degree in Textile Chemistry from Shenkar College for Engineering and Design and M.Sc. degree in Applied Chemistry from the Hebrew University of Jerusalem.

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

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

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

Directors

Leon Recanati has served on our Board of Directors since May 2005 and has served as Chairman since March 2013, and serves as the Chairman of our Compensation Committee. 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, Rainbow Medical Ltd., RelTech Holdings Ltd., Legov Ltd., Insight Capital Ltd., and Shavit Capital Funds. Mr. Recanati currently serves as the Chairman and Chief Executive Officer of GlenRock. Previously, Mr. Recanati was Chief Executive Officer and/or Chairman of IDB Holding Corporation; 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.

Lilach Asher Topilsky has served on our board of directors since December 2019. Ms. Topilsky is a Senior partner in the FIMI Opportunity Funds, Israel's largest group of private equity funds, as of December 2019. Until the end of November 2019, Ms. Asher Topilsky served as the President and CEO of Israel Discount Bank (TASE), one of the leading banking groups in Israel, as the Chairman at IDBNY BANKCORP and as a director at IDB Bank New York, all since February 2014. Ms. Asher Topilsky also served as the Chairman of Mercantile Bank from 2014-2016. Ms. Asher Topilsky currently serves as the Chairman of the board of directors of G1 Ltd. (TASE) and as director at Tel Aviv University. Prior to joining Israel Discount Bank, Ms. Asher Toplisky served as a member of the management of Bank Hapoalim (TASE) as Deputy Chief Executive Officer and Head of Retail Banking Division (2009-2013) and Head of Strategy and Planning Division (2007-2009). Ms. Asher Topilsky also served as a Strategy Consultant at The Boston Consulting Group (BCG, Chicago 1997-1998) and at Shaldor Strategy Consulting (Israel 1995-1996). Ms. Asher Topilsky holds BA degree in Management and Economics from Tel Aviv University and MBA degree from Kellogg School of Management, Northwestern University, Chicago, USA.

Avraham Berger has served on our board of directors since August 2016, and serves as the Chair of our Audit Committee and as a member of our Compensation Committee. Until 2014, Mr. Berger served as a senior partner and Chief Executive Officer of PwC Israel, for more than 20 years. Mr. Berger joined PwC Israel in 1976 and led it from 1991. Mr. Berger has vast experience in mergers and acquisitions and complex public offerings, both in Israel and abroad. Mr. Berger lectures at professional forums and has published several articles in the professional press. Mr. Berger also serves as Chairman of the board of directors of TopAudio Ltd. and serves as director on the board of Weizmann Institute of Science. Mr. Berger holds a BA degree in Accounting and Economics from Tel Aviv University and is a certified public accountant in Israel.

Amiram Boehm has served on our board of directors since December 2019. Mr. Bohem is a Partner in the FIMI Opportunity Funds, Israel's largest group of private equity funds, since 2004. Mr. Boehm served as the Managing Partner and Chief Executive Officer of FITE GP (2004), and serves as a director at Gilat Satellite Communications (NASDAQ), Ham-Let (Israel-Canada) Ltd. (TASE), Hadera Paper Ltd (TASE)., Rekah Pharmaceuticals Ltd. (TASE), TAT Technologies Ltd. (NASDAQ, TASE), PCB Technologies Ltd. (TASE) and DIMAR Ltd, DelekSan Ltd. and Galam Ltd. Mr. Boehm previously served as a director of Ormat Technologies Inc. (NYSE, TASE), Scope Metal Trading Ltd. (TASE), Inter Industries, Ltd. (TASE), Global Wire Ltd. (TASE), Telkoor Telecom Ltd. (TASE) and Solbar Industries Ltd. (previously traded on the TASE) and Novolog Ltd (TASE). Prior to joining FIMI, from 1999 until 2004, Mr. Boehm served as Head of Research of Discount Capital Markets, the investment arm of Israel Discount Bank. Mr. Boehm holds a BA degree in Economics and LLB degree from Tel Aviv University and a Joint MBA degree from Northwestern University and Tel Aviv University.

Ishay Davidi has served on our board of directors since December 2019. Mr. Davidi is the Founder and has served as Chief Executive Officer of the FIMI Opportunity Funds, Israel's largest group of private equity funds, since 1996. Mr. Davidi currently serves as Chairman of the board of directors of Hadera Paper Ltd. (TASE) and Polyram Plastics Ltd., Dimar Cutting Tools Ltd., and as director at Gilat Satellite Communications Ltd. (NASDAQ), Ham-Let (Israel-Canada) Ltd. (TASE), Rekah Pharmaceuticals Ltd. (TASE), Tadir-Gan Precision materials (TASE), C. Mer Industries Ltd. (TASE), GI Ltd., (TASE), SOS Ltd., DelekSan Ltd., Bet Shemesh Engines Holdings (TASE) and P.C.B Technologies Ltd. Mr. Davidi previously served as the Chairman of the board of directors of Inrom Ltd., Retalix Ltd. (previously traded on NASDAQ and TASE) from August 2008 until January 2010, of Tefron Ltd. (New York Stock Exchange and TASE) and of Tadir-Gan Ltd. (TASE), and as a director at Pharm Up Ltd. (TASE), Ormat Industries Ltd. (previously traded on TASE), Retalix, Tadiran Communications Ltd. (TASE), Lipman Electronic Engineering Ltd. (NASDAQ and TASE), Merhav Ceramic and Building Materials Center Ltd. (TASE), TAT Technologies Ltd. (NASDAQ and TASE), Orian C.M. Ltd. (TASE), Ophir Optronics Ltd., Overseas Commerce Ltd Ltd. (TASE), Scope Metals Group Ltd. (TASE) and Formula Systems Ltd. (NASDAQ and TASE). Prior to establishing FIMI, from 1993 until 1996, Mr. Davidi was the Founder and Chief Executive Officer of Tikvah Fund, a private Israeli investment fund. From 1992 until 1993 Mr. Davidi was the Chief Executive Officer of Zer Science Industries Ltd., a developer of diagnostics equipment for the healthcare industry. Mr. Davidi holds a BSc degree in Industrial and Management Engineering from Tel Aviv University and MBA degree from Bar Ilan University.

Karnit Goldwasser has served on our board of directors since December 2019. Ms. Goldwasser serves as an independent consultant and environmental engineer for various agencies and organizations. Ms. Goldwasser is a director at Orian DB Schenker (since September 2017), Delek San Recycling Ltd. (since December 2016) and ELA Recycling Corporation (since April 2015). Ms. Goldwasser served as a director at the government-owned Environmental Services Company Ltd., as chair of the Safety Committee (2010-2016), and as a member of the Tel Aviv-Jaffa City Council, holding the environmental portfolio (2013-2016). Ms. Goldwasser also served as a director in several Tel Aviv-Jaffa municipality corporations: Dan Municipal Sanitation Association, as chair of the audit committee; Tel Aviv-Jaffa Economic Development Authority; and Ganei Yehoshua Co. Ltd. Ms. Goldwasser holds a B.Sc. degree in Environmental Engineering, focusing on chemistry, mathematics and environmental engineering, and M.Sc. degree in Civil Engineering, specializing in Hydrodynamics and Water Resources, both from the Technion – Israel Institute of Technology, and MA degree in Public Policy and Administration from the Lauder School of Government Diplomacy and Strategy, IDC Herzliya. Ms. Goldwasser also completed the Directors Program at LAHAV, School of Management, Tel Aviv University.

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

David Tsur has served as on our board of directors since July 2015, as Active Deputy Chairman on a half-time basis until December 31, 2019, and serves as a member of our Strategy Committee. Prior to that, Mr. Tsur served as our Chief Executive Officer and a director since our inception. Prior to co-founding Kamada in 1990, Mr. Tsur served as Chief Executive Officer of Arad Systems and RAD Chemicals Inc. Mr. Tsur previously served as the Chairman of the Board of Directors of CollPlant Ltd., a company listed on the TASE and OTC market. Mr. Tsur has also held various positions in the Israeli Ministry of Economy and Industry (formerly named the Ministry of Industry and Trade), including Chief Economist and Commercial Attaché in Argentina and Iran. Mr. Tsur holds a BA degree in Economics and International Relations and an MBA degree in Business Management, both from the Hebrew University of Jerusalem.

Under a shareholders' agreement entered into on March 6, 2013, the Recanati Group, on the one hand, and the Damar Group, on the other hand, have each agreed to vote the ordinary shares beneficially owned by them in favor of the election of director nominees designated by the other group as follows: (i) three director nominees, so long as the other group beneficially owns at least 7.5% of our outstanding share capital, (ii) two director nominees, so long as the other group beneficially owns at least 5.0% (but less than 7.5%) of our outstanding share capital, and (iii) one director nominee, so long as the other group beneficially owns at least 2.5% (but less than 5.0%) of our outstanding share capital. In addition, to the extent that after the designation of the foregoing director nominees there are additional director vacancies, each of the Recanati Group and Damar Group have agreed to vote the ordinary shares beneficially owned by them in favor of such additional director nominees designated by the party who beneficially owns the larger voting rights in our company. See "Item 7. Major Shareholders and Related Party Transactions — Related Party Transactions — Shareholder Agreement."

Board of Directors

Under our articles of association, the number of directors on our board of directors must be no less than five and no more than 11. Our board of directors currently consists of eight directors, six of whom qualify as "independent directors" under the Nasdaq listing requirements, such that we comply with the Nasdaq Listing Rule that requires that a majority of our board of directors be comprised of independent directors, within the meaning of Nasdaq Listing Rules.

Our directors are elected by the vote of a majority of the ordinary shares present, in person or by proxy, and voting at a shareholders' meeting. Each director holds office until the first annual general meeting of shareholders following his or her appointment, unless the tenure of such director expires earlier pursuant to the Companies Law or unless he or she is removed from office as described below.

Vacancies on our board of directors, including vacancies resulting from there being fewer than the maximum number of directors permitted by our articles of association, may generally be filled by a vote of a simple majority of the directors then in office.

A general meeting of our shareholders may remove a director from office prior to the expiration of his or her term in office by a resolution adopted by holders of a majority of our shares voting on the proposed removal, provided that the director being removed from office is given a reasonable opportunity to present his or her case before the general meeting.

External Directors

Under the Companies Law, companies incorporated under the laws of the State of Israel that are "public companies," must appoint at least two external directors who meet the qualification requirements in the Companies Law.

However, according to regulations promulgated under the Companies Law, a company whose shares are traded on certain stock exchanges outside Israel (including the Nasdaq Global Select Market, such as our company) that does not have a controlling shareholder and that complies with the requirements of the laws of the foreign jurisdiction where the company's shares are listed, as they apply to domestic issuers, with respect to the appointment of independent directors and the composition of the audit committee and compensation committee, may elect to exempt itself from the requirements of Israeli law with respect to (i) the requirement to appoint external directors and that one external director serve on each committee of the board of directors authorized to exercise any of the powers of the board of directors; (ii) certain limitations on the employment or service of an external director or his or her spouse, children or other relatives, following the cessation of the service as an outside director, by or for the company, its controlling shareholder or an entity controlled by the controlling shareholder; (iii) the composition, meetings and quorum of the audit committee; and (iv) the composition and meetings of the compensation committee. If a company has elected to avail itself from the requirement to appoint external directors and at the time a director is appointed all members of the board of directors are of the same gender, a director of the other gender must be appointed.

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

Audit Committee

We have an audit committee consisting of Mr. Avraham Berger, Ms. Karnit Goldwasser and Mr. Leon Recanati. Mr. Avraham Berger serves as the chairman of the audit committee.

In accordance with regulations promulgated under the Companies Law described above, we elected to "opt out" from the Israeli Companies Law requirement to appoint external directors and related rules concerning the composition of the audit committee and compensation committee. Under such exemption, among other things, the composition of our audit committee must comply with the requirements of SEC and Nasdaq rules.

Under the Exchange Act and Nasdaq listing requirements, we are required to maintain an audit committee consisting of at least three independent directors, each of whom is financially literate and one of whom has accounting or related financial management expertise. Our board of directors has affirmatively determined that each member of our audit committee qualifies as an "independent director" for purposes of serving on an audit committee under the Exchange Act and Nasdaq listing requirements. Our board of directors has determined that Avraham Berger qualifies as an "audit committee financial expert," as defined in Item 407(d)(5) of Regulation S-K. All members of our audit committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and Nasdaq.

Audit Committee Role

Our audit committee generally provides assistance to our board of directors in fulfilling its legal and fiduciary obligations in matters involving our accounting, auditing, financial reporting and internal control functions by reviewing the services of our independent accountants and reviewing their reports regarding our accounting practices and systems of internal control over financial reporting. Our audit committee also oversees the audit efforts of our independent accountants. Our audit committee also acts as a corporate governance compliance committee and oversees the implementation and amendment, from time to time, of our policies for compliance with Israeli and U.S. securities laws and applicable Nasdaq corporate governance requirements, including non-use of inside information, reporting requirements, our engagement with related parties, whistleblower complaints and protection, and is also responsible for the handling of any incidents that may arise in violation of our policies or applicable securities laws. Our board of directors has adopted an audit committee charter setting forth the specific responsibilities of the audit committee consistent with the Companies Law, and the rules and regulations of the SEC and the Nasdaq listing requirements, which include:

- oversight of our independent auditors and recommending the engagement, compensation or termination of engagement of our independent auditors to the board of directors or shareholders for their approval, as applicable, in accordance with the requirements of the Companies Law;
- pre-approval of audit and non-audit services to be provided by the independent auditors;
- reviewing and recommending to the board of directors approval of our quarterly and annual financial reports; and
- overseeing the implementation and amendment of our policies for compliance with Israeli and U.S. securities laws and applicable Nasdaq corporate governance requirements.

Additionally, under the Companies Law, the role of the audit committee includes: (1) determining whether there are delinquencies in the business management practices of our company, including in consultation with our internal auditor or our independent auditor, and making recommendations to the board of directors to improve such practices; (2) determining whether to approve certain related party transactions (including transactions in which an office holder has a personal interest) and whether any such transaction is an extraordinary or material transaction under the Companies Law; (3) determining whether a competitive process must be implemented for the approval of certain transactions with controlling shareholders or in which a controlling shareholder has a personal interest (whether or not the transaction is an extraordinary transaction), under the supervision of the audit committee or other party determined by the audit committee and in accordance with standards determined by the audit committee, or whether a different process determined by the audit committee should be implemented for the approval of such transactions; (4) determining the process for the approval of certain transactions with controlling shareholders that the audit committee has determined are not extraordinary transactions but are not immaterial transactions; (5) where the board of directors approves the work plan of the internal auditor, examining such work plan before its submission to the board of directors and proposing amendments thereto; (6) examining our internal controls and internal auditor's performance, including whether the internal auditor has sufficient resources and tools to dispose of its responsibilities; (7) examining the scope of our auditor's work and compensation and submitting its recommendation with respect thereto to the corporate body considering the appointment thereof (either the board of directors or the shareholders at the general meeting); and (8) establishing procedures for the handling of employees' complaints as to the management of our business and the protection to be provided to such employees.

Compensation Committee

We have a compensation committee consisting of Mr. Leon Recanati, Mr. Avraham Berger, Ms. Karnit Goldwasser and Ms. Lilach Asher-Topilsky. Mr. Recanati serves as the chairman of the compensation committee.

In accordance with regulations promulgated under the Companies Law described above, we elected to "opt out" from the Israeli Companies Law requirement to appoint external directors and related rules concerning the composition of the audit committee and compensation committee. Under such exemption, among other things, the composition of our compensation committee must comply with the requirements of Nasdaq rules. Under Nasdaq listing requirements, we are required to maintain a compensation committee consisting of at least two members, each of whom is an "independent director" under the Nasdaq listing requirements. Our board of directors has affirmatively determined that each member of our compensation committee qualifies as an "independent director" under the Nasdaq listing requirements.

Compensation Committee Role

In accordance with the Companies Law, the roles of the compensation committee are, among others, as follows:

- recommending to the board of directors with respect to the approval of the compensation policy for office holders and, once every three years, regarding any extensions to a compensation policy that was adopted for a period of more than three years;
- reviewing the implementation of the compensation policy and periodically recommending to the board of directors with respect to any amendments or updates of the compensation policy;
- resolving whether or not to approve arrangements with respect to the terms of office and employment of office holders; and
- exempting, under certain circumstances, a transaction with our Chief Executive Officer from the approval of the general meeting of our shareholders.

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

Strategy Committee

Our strategy committee currently consists of Mr. Jonathan Hahn, Ms. Lilach Asher-Topilsky, Mr. Amiram Boehm and Mr. David Tsur. Mr. Jonathan Hahn serves as the chairman of the strategy committee. Our strategy committee is responsible for directing our management in carrying out its various responsibilities related to our company's long-term strategy, financial initiatives and strategic transactions.

Internal Auditor

Under the Companies Law, the board of directors of a public company must appoint an internal auditor recommended by the audit committee. The role of the internal auditor is, among other things, to examine whether a company's actions comply with applicable law and orderly business procedure. Under the Companies Law, the internal auditor may not be an "interested party" or an office holder, or a relative of an interested party or of an office holder, nor may the internal auditor be the company's independent accounting firm or anyone acting on its behalf. An "interested party" is defined in the Companies Law as (i) a holder of 5% or more of the company's outstanding shares or voting rights, (ii) any person or entity (or relative of such person) who has the right to designate one or more directors or to designate the chief executive officer of the company, or (iii) any person who serves as a director or as a chief executive officer of the company. Linur Dloomy of Brightman Almagor Zohar & Co. (a Firm in the Deloitte Global Network) serves as our internal auditor.

Fiduciary Duties and Approval of Specified Related Party Transactions under Israeli Law

Fiduciary Duties of Office Holders

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

An office holder's fiduciary duties consist of a duty of care and a duty of loyalty. The duty of care requires an office holder to act with the level of care with which a reasonable office holder in the same position would have acted under the same circumstances. The duty of care includes, among other things, a duty to use reasonable means, in light of the circumstances, to obtain:

- information on the advisability of a given action brought for his or her approval or performed by the director in his or her capacity as a director; and
- all other important information pertaining to such action.

The duty of loyalty requires an office holder to act in good faith and for the benefit of the company, and includes, among other things, the duty to:

- refrain from any act involving a conflict of interests between the performance of his or her duties to the company and his or her other duties or personal affairs;
- refrain from any activity that is competitive with the business of the company;
- refrain from exploiting any business opportunity of the company to receive a personal gain for himself or herself or others; and
- disclose to the company any information or documents relating to the company's affairs which the office holder received as a result of his or her position as an office holder.

We may approve an act specified above which would otherwise constitute a breach of the office holder's duty of loyalty, provided that the office holder acted in good faith, the act or its approval does not harm the company and the office holder discloses his or her personal interest a sufficient amount of time before the date for discussion of approval of such act.

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

The Companies Law requires that an office holder promptly disclose to the company any "personal interest" that he or she may have, and all related material information or documents relating to any existing or proposed transaction by the company. A "personal interest" is defined under the Companies Law as the personal interest of a person in an action or in a transaction of the company, including the personal interest of such person's relative or of any other corporate entity in which such person and/or such person's relative is a director, general manager or chief executive officer, a holder of 5% or more of the outstanding shares or voting rights, or has the right to appoint at least one director or the general manager, but excluding a personal interest arising solely from ownership of shares in the company. A personal interest includes the personal interest of a person for whom the office holder holds a voting proxy and the personal interest of a person voting as a proxy, even when the person granting such proxy has no personal interest. An interested office holder's disclosure must be made promptly and no later than the first meeting of the board of directors at which the transaction is considered. An office holder is not obliged to disclose such information if the personal interest of the office holder derives solely from the personal interest of his or her relative in a transaction that is not considered as an "extraordinary transaction."

An "extraordinary transaction" is defined under the Companies Law as any of the following:

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

Under the Companies Law, unless the articles of association of a company provide otherwise, a transaction with an office holder or with a third party in which the office holder has a personal interest, and which is not an extraordinary transaction, requires approval by the board of directors. Our articles of association do not provide for a different method of approval. If the transaction considered is an extraordinary transaction with an office holder or third party in which the office holder has a personal interest, then audit committee approval is required prior to approval by the board of directors. For the approval of compensation arrangements with directors and officers who are controlling shareholders, see "— Disclosures of Personal Interests of a Controlling Shareholder and Approval of Certain Transactions," for the approval of compensation arrangements with directors, see "— Compensation of Directors" and for the approval of compensation arrangements with office holders who are not directors, see "— Compensation of Executive Officers."

Subject to certain exceptions, any person who has a personal interest in the approval of a transaction that is brought before a meeting of the board of directors or the audit committee may not be present at the meeting, unless such person is an office holder and invited by the chairman of the board of directors or of the audit committee, as applicable, to present the matter being considered, and may not vote on the matter. In addition, a director who has a personal interest in the approval of a transaction may be present at the meeting and vote on the matter if a majority of the directors or members of the audit committee, as applicable, have a personal interest in the transaction. In such case, shareholder approval is also required.

Disclosure of Personal Interests of a Controlling Shareholder and Approval of Certain Transactions

Pursuant to the Companies Law, the disclosure requirements regarding personal interests that apply to office holders also apply to a controlling shareholder of a public company. For this purpose, a controlling shareholder is a shareholder who has the ability to direct the activities of a company, including a shareholder who owns 25% or more of the voting rights if no other shareholder owns more than 50% of the voting rights. Two or more shareholders with a personal interest in the approval of the same transaction are deemed to be one shareholder.

Extraordinary transactions with a controlling shareholder or in which a controlling shareholder has a personal interest, the terms of services provided by a controlling shareholder or his or her relative, directly or indirectly (including through a corporation controlled by a controlling shareholder), the terms of employment of a controlling shareholder or his or her relative who is employed by the company and who is not an office holder and the terms of service and employment, including exculpation, indemnification or insurance, of a controlling shareholder or his or her relative who is an office holder, require the approval of each of the audit committee or the compensation committee with respect to terms of service and employment by the company as an office holder, employee or service provider, the board of directors and the shareholders, in that order. In addition, the shareholder approval must fulfill one of the following requirements:

- at least a majority of the shares held by shareholders who have no personal interest in the transaction and who are present and voting at the meeting on the matter are voted in favor of approving the transaction, excluding abstentions; or

- the shares voted against the transaction by shareholders who have no personal interest in the transaction who are present and voting at the meeting represent no more than 2% of the voting rights in the company.

Each shareholder voting on the approval of an extraordinary transaction with a controlling shareholder must inform the company prior to voting whether or not he or she has a personal interest in the approval of the transaction, otherwise, the shareholder is not eligible to vote on the proposal and his or her vote will not be counted for purposes of the proposal.

Any extraordinary transaction with a controlling shareholder or in which a controlling shareholder has a personal interest with a term of more than three years requires approval every three years, unless the audit committee determines that the duration of the transaction is reasonable given the circumstances related thereto.

Pursuant to regulations promulgated under the Companies Law, certain transactions with a controlling shareholder or his or her relative, or with directors, relating to terms of service or employment, that would otherwise require approval of the shareholders may be exempt from shareholder approval upon certain determinations of the audit committee and board of directors.

Duties of Shareholders

Under the Companies Law, a shareholder has a duty to refrain from abusing his or her power in the company and to act in good faith and in a customary manner in exercising its rights and performing its obligations to the company and other shareholders, including, among other things, when voting at meetings of shareholders on the following matters:

- an amendment to the company's articles of association;
- an increase in the company's authorized share capital;
- a merger; and
- the approval of related party transactions and acts of office holders that require shareholder approval.

A shareholder also has a general duty to refrain from discriminating against other shareholders.

In addition, certain shareholders have a duty to act with fairness towards the company. These shareholders include any controlling shareholder, any shareholder who knows that his or her vote can determine the outcome of a shareholder vote, and any shareholder that, under a company's articles of association, has the power to appoint or prevent the appointment of an office holder or has another power with respect to the company. The Companies Law does not define the substance of this duty except to state that the remedies generally available upon a breach of contract will also apply in the event of a breach of the duty to act with fairness.

Approval of Significant Private Placements

Under the Companies Law, a significant private placement of securities requires approval by the board of directors and the shareholders by a simple majority. A private placement is considered a significant private placement if it will cause a person to become a controlling shareholder or if all of the following conditions are met:

- the securities issued amount to 20% or more of the company's outstanding voting rights before the issuance;
- some or all of the consideration is other than cash or listed securities or the transaction is not on market terms; and
- the transaction will increase the relative holdings of a shareholder who holds 5% or more of the company's outstanding share capital or voting rights or that will cause any person to become, as a result of the issuance, a holder of more than 5% of the company's outstanding share capital or voting rights.

Compensation of Directors and Executive Officers

Aggregate Compensation of Directors and Officers

The aggregate compensation incurred by us in relation to our executive officers and directors, including share-based compensation, for the year ended December 31, 2019, was approximately $4.0 million. This amount includes approximately $261,903 set aside or accrued to provide pension, severance, retirement or similar benefits or expenses, but does not include business travel, professional and business association dues and expenses reimbursed to executive officers, and other benefits commonly reimbursed or paid by companies in Israel.

From time to time, we grant options and restricted shares to our officers and directors. As of December 31, 2019, options to purchase 803,050 of our ordinary shares granted to our officers and directors as a group were outstanding, of which options to purchase 479,497 of our ordinary shares were vested, with a weighted average exercise price of $13.34 per ordinary share. As of December 31, 2019, 140,015 restricted shares granted to our officers as a group were outstanding. For details regarding the beneficial ownership of our shares by our officers and directors, see "Item 6. Directors, Senior Management and Employees — Share Ownership."

Compensation of Directors

We pay our directors an annual fee and per-meeting fees in the maximum amounts payable from time to time for such fees by us under the Second and Third Addendums, respectively (or, to the extent any director is determined to have financial and accounting expertise and is deemed an expert director (in each case, within the meaning of the Companies Law and the regulations thereunder), under the Fourth Addendum) to the Israeli Companies Regulations (Rules Regarding Compensation and Expense Reimbursement of External Directors), 2000, or the Compensation Regulations. In accordance with the Compensation Regulations, we currently pay all of our directors an annual fee of NIS 85,528 (approximately $23,998), as well as a fee of NIS 3,296 (approximately $925) for each board or committee meeting attended in person, NIS 1,978 (approximately $555) for each board or committee meeting attended via telephone or videoconference and NIS 1,648 (approximately $462) for participation by written consent.

We paid Mr. Tsur, in consideration for his services as Active Deputy Chairman on a half-time basis, in which capacity he served from July 1, 2015 until December 31, 2019, a monthly gross salary of NIS 45,000 (approximately $12,006), in addition to the annual fee and per-meeting fees described above.

There are no arrangements or understandings between us, on the one hand, and any of our directors, on the other hand, providing for benefits upon termination of their service as directors of our company.

To our knowledge, there are no agreements and arrangements between any director and any third party relating to compensation or other payment in connection with their candidacy or service on our Board of Directors.

Compensation of Covered Executives

The following table presents information regarding compensation accrued in our financial statements for our five most highly compensated office holders (within the meaning of the Companies Law), namely our Chief Executive Officer, Vice President, Clinical Development and Medical Director for Pulmonary Diseases, Chief Financial Officer, Vice President, Regulatory Affairs and PVG and Vice President, Operations, during or with respect to the year ended December 31, 2019. Each such office holder was covered by our directors' and officers' liability insurance policy and was entitled to indemnification and exculpation in accordance with indemnification and exculpation agreements, our articles of association and applicable law.

Name and Position	**Salary**	**Bonus[1]**	**Value of Options Granted[2]**	**Other[3]**	**Total**
			(in thousands)		
Amir London *Chief Executive Officer*	$ 332,662	$ 188,552	$ 190,966	$ 25,752	$ 737,932
Dr. Naveh Tov *Vice President, Clinical Development and Medical Director for Pulmonary Diseases*	$ 232,921	$ 72,907	$ 27,804	$ 19,055	$ 352,687
Chaime Orlev *Chief Financial Officer*	$ 232,656	$ 44,848	$ 28,096	$ 17,041	$ 322,641
Orit Pinchuk Vice President, Regulatory Affairs and PVG	$ 206,077	$ 66,846	$ 27,512	$ 18,945	$ 319,381
Eran Nir *Vice President, Operations*	$ 209,465	$ 42,020	$ 30,433	$ 24,535	$ 306,453

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

(2) The value of options is the expense recorded in our financial statements for the period ended December 31, 2019 with respect to all options granted to such executive officer.

(3) Cost of use of company car.

Agreements with Five Most Highly Compensated Office Holders

We have entered into agreements with each of our five most highly compensated office holders (within the meaning of the Companies Law), listed below. The terms of employment or service of such office holders are directed by our compensation policy. See above "— Compensation Policy." Each of these agreements contains provisions regarding non-competition, confidentiality of information and assignment of inventions. The non-competition provision applies for a period that is generally 12 months following termination of employment. The enforceability of covenants not to compete in Israel and the United States is subject to limitations. Such office holders are entitled to an annual bonus subject to the fulfillment of certain targets determined for each year by the compensation committee and board of directors. In addition, all such executive officers are entitled to a company car, as well as sick pay, convalescence pay, manager's insurance and a study fund ("*keren hishtalmut*"), all in accordance with Israeli law, and annual leave.

Amir London, Chief Executive Officer. Mr. London has served as our Chief Executive Officer since July 2015. Prior to that and effective as of December 1, 2013, Mr. London served as our Vice President, Business Development. Mr. London's engagement terms as our Chief Executive Officer have been approved by our Compensation Committee, the Board of Directors and our shareholders. According to the terms of the agreement, either party may terminate the agreement at any time upon three months' prior written notice to the other party, and we may terminate the agreement immediately for cause in accordance with Israeli law.

Dr. Naveh Tov, Vice President, Clinical Development and Medical Director for Pulmonary Diseases. Effective as of July 2016, we entered into an employment agreement with Dr. Naveh Tov with respect to his employment as our Vice President, Clinical Development and Medical Director for Pulmonary Diseases. Either party may terminate the agreement at any time upon three months' prior written notice to the other party, and we may terminate the agreement immediately for cause in accordance with Israeli law.

Chaime Orlev, Chief Financial Officer. Effective as of October 1, 2017, we entered into an employment agreement with Mr. Chaime Orlev with respect to his employment as our Chief Financial Officer. Either party may terminate the agreement at any time upon three months' prior written notice to the other party, and we may terminate the agreement immediately for cause in accordance with Israeli law.

Orit Pinchuk Vice President, Regulatory Affairs and PVG. Effective as of January 1, 2014,,we entered into an employment agreement with Ms. Orit Pinchuk with respect to her employment as our *Vice President, Regulatory Affairs and PVG*. 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.

Eran Nir, Vice President, Operations. Effective as of November 1, 2016, we entered into an employment agreement with Mr. Eran Nir with respect to his employment as our Vice President, Operations. Either party may terminate the agreement at any time upon two months' prior written notice to the other party, and we may terminate the agreement immediately for cause in accordance with Israeli law.

Other Executive Officers

We have entered into written employment agreements with the rest of our executive officers. The terms of employment of our executive office holders are directed by our compensation policy. See "— Compensation Policy." Each of these agreements contains provisions regarding non-competition, confidentiality of information and assignment of inventions. The non-competition provision applies for a period that is generally 12 months following termination of employment. The enforceability of covenants not to compete in Israel and the United States is subject to limitations. In addition, we are required to provide up to three months' notice prior to terminating the employment of such executive officers, other than in the case of a termination for cause. Each of our employment agreements with such executive officers provides for annual bonuses, which are subject to the fulfillment of certain targets determined for each year, and the executive officers are also entitled to special bonuses upon the achievement of certain company milestones.

Compensation of Directors and Executive Officers

Compensation Policy.

Under the Companies Law, a public company is required to adopt a compensation policy, which sets forth the terms of service and employment of office holders, including the grant of any benefit, payment or undertaking to provide payment, any exemption from liability, insurance or indemnification, and any severance payment or benefit. Such compensation policy must comply with the requirements of the Companies Law. The compensation policy must be approved at least once every three years, first, by our board of directors, upon recommendation of our compensation committee, and second, by the shareholders by a special majority. Our current compensation policy was approved by our shareholders on August 30, 2016 and was amended by our shareholders on November 30, 2017, December 20, 2018 and December 24, 2019. Our compensation committee and board of directors have approved an amended compensation policy for executive officers and amended compensation policy for directors, which are subject to the approval of our shareholders at an extraordinary general meeting of shareholders to be held on March 25, 2020.

Compensation of Directors

Under the Companies Law, the compensation (including insurance, indemnification, exculpation and compensation) of our directors requires the approval of our compensation committee, the subsequent approval of the board of directors and, unless exempted under the regulations promulgated under the Companies Law, the approval of the shareholders at a general meeting. The approval of the compensation committee and board of directors must be in accordance with the compensation policy. In special circumstances, the compensation committee and board of directors may approve a compensation arrangement that is inconsistent with the company's compensation policy, provided that they have considered the same considerations and matters required for the approval of a compensation policy in accordance with the Companies Law, in which case the approval of the company's shareholders must be by a special majority (referred to as the "Special Majority for Compensation") that requires that either:

- a majority of the shares held by shareholders who are not controlling shareholders and shareholders who do not have a personal interest in such matter and who are present and voting at the meeting, are voted in favor of approving the compensation package, excluding abstentions; or

- the total number of shares voted by non-controlling shareholders and shareholders who do not have a personal interest in such matter that are voted against the compensation package does not exceed 2% of the aggregate voting rights in the company.

Where the director is also a controlling shareholder, the requirements for approval of transactions with controlling shareholders apply, as described above under "— Disclosure of Personal Interests of a Controlling Shareholder and Approval of Certain Transactions."

Compensation of Officers Other than the Chief Executive Officer

Pursuant to the Companies Law, the compensation (including insurance, indemnification and exculpation) of a public company's office holders (other than directors, which is described above, and the chief executive officer, which is described below) generally requires approval first by the compensation committee and second by the company's board of directors, according to the company's compensation policy. In special circumstances the compensation committee and board of directors may approve a compensation arrangement that is inconsistent with the company's compensation policy, provided that they have considered the same considerations and matters required for the approval of a compensation policy in accordance with the Companies Law and such arrangement must be approved by the company's shareholders by the Special Majority for Compensation.

However, if the shareholders of the company do not approve a compensation arrangement with an executive officer that is inconsistent with the company's compensation policy, the compensation committee and board of directors may, in special circumstances, override the shareholders' decision, subject to certain conditions.

Under the Companies Law, an amendment to an existing arrangement with an office holder (other than the chief executive officer) who is not a director requires only the approval of the compensation committee, if the compensation committee determines that the amendment is not material in comparison to the existing arrangement. However, according to regulations promulgated under the Companies Law, an amendment to an existing arrangement with an office holder (who is not a director) who is subordinate to the chief executive officer shall not require the approval of the compensation committee, if (i) the amendment is approved by the chief executive officer and the company's compensation policy determines that a non-material amendment to the terms of service of an office holder (other than the chief executive officer) will be approved by the chief executive officer and (ii) the engagement terms are consistent with the company's compensation policy.

Compensation of Chief Executive Officer

The compensation (including insurance, indemnification and exculpation) of a public company's chief executive officer generally requires the approval of first, the company's compensation committee; second, the company's board of directors; and third (except for limited exceptions), the company's shareholders by the Special Majority for Compensation. If the shareholders of the company do not approve the compensation arrangement with the chief executive officer, the compensation committee and board of directors may override the shareholders' decision, subject to certain conditions. The compensation committee and board of directors approval should be in accordance with the company's compensation policy; however, in special circumstances, they may approve compensation terms of a chief executive officer that are inconsistent with such policy provided that they have considered the same considerations and matters required for the approval of a compensation policy in accordance with the Companies Law and that shareholder approval was obtained by the Special Majority for Compensation. Under certain circumstances, the compensation committee and board of directors may waive the shareholder approval requirement in respect of the compensation arrangements with a candidate for chief executive officer if they determine that the compensation arrangements are consistent with the company's stated compensation policy.

However, an amendment to an existing arrangement with an executive officer (who is not a director) requires only the approval of the compensation committee, if the compensation committee determines that the amendment is not material in comparison to the existing arrangement. Furthermore, according to regulations promulgated under the Companies Law, the renewal or extension of an existing arrangement with a chief executive officer shall not require shareholder approval if (i) the renewal or extension is not beneficial to the chief executive officer as compared to the prior arrangement or there is no substantial change in the terms and other relevant circumstances; and (ii) the engagement terms are consistent with the company's compensation policy and the prior arrangement was approved by the shareholders by the Special Majority for Compensation.

Where the office holder is also a controlling shareholder, the requirements for approval of transactions with controlling shareholders apply, as described above under "— Disclosure of Personal Interests of a Controlling Shareholders and Approval of Certain Transactions."

Exculpation, Insurance and Indemnification of Office Holders

Under the Companies Law, a company may not exculpate an office holder from liability for a breach of the duty of loyalty. An Israeli company may exculpate an office holder in advance from liability to the company, in whole or in part, for damages caused to the company as a result of a breach of duty of care, but only if a provision authorizing such exculpation is included in the company's articles of association. Our articles of association include such a provision. However, we may not exculpate an office holder for an action or transaction in which a controlling shareholder or any other office holder (including an office holder who is not the office holder we have undertaken to exculpate) has a personal interest (within the meaning of the Companies Law). We may also not exculpate in advance a director from liability arising out of a prohibited dividend or distribution to shareholders.

Under the Companies Law, a company may indemnify an office holder for the following liabilities, payments and expenses incurred for acts performed by him or her, as an office holder, either pursuant to an undertaking given by the company in advance of the act or following the act, provided its articles of association authorize such indemnification:

- a monetary liability imposed on him or her in favor of another person pursuant to a judgment, including a settlement or arbitrator's award approved by a court. However, if an undertaking to indemnify an office holder with respect to such liability is provided in advance, then such an undertaking must be limited to events which, in the opinion of the board of directors, can be foreseen based on the company's activities when the undertaking to indemnify is given, and to an amount, or according to criteria, determined by the board of directors as reasonable under the circumstances. Such undertaking shall detail the foreseen events and amount or criteria mentioned above;

- reasonable litigation expenses, including reasonable attorneys' fees, incurred by the office holder (1) as a result of an investigation or proceeding instituted against him or her by an authority authorized to conduct such investigation or proceeding, provided that (i) no indictment was filed against such office holder as a result of such investigation or proceeding; and (ii) no financial liability was imposed upon him or her as a substitute for the criminal proceeding as a result of such investigation or proceeding or, if such financial liability was imposed, it was imposed with respect to an offense that does not require proof of criminal intent (*mens rea*); and (2) in connection with a monetary sanction; and

- reasonable litigation expenses, including attorneys' fees, incurred by the office holder or imposed by a court in proceedings instituted against him or her by the company, on its behalf, or by a third party, or in connection with criminal proceedings in which the office holder was acquitted, or as a result of a conviction for an offense that does not require proof of criminal intent (*mens rea)*.

In addition, under the Companies Law, a company may insure an office holder against the following liabilities incurred for acts performed by him or her as an office holder, to the extent provided in the company's articles of association:

- a breach of a duty of loyalty to the company, provided that the office holder acted in good faith and had a reasonable basis to believe that the act would not harm the company;

- a breach of duty of care to the company or to a third party, to the extent such a breach arises out of the negligent conduct of the office holder; and

- a monetary liability imposed on the office holder in favor of a third party.

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

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

For the approval of exculpation, indemnification and insurance of office holders who are directors, see "— Compensation of Directors," for the approval of exculpation, indemnification and insurance of office holders who are not directors, see "—Compensation of Executive Officers" and for the approval of exculpation, indemnification and insurance of office holders who are controlling shareholders, see "— Fiduciary Duties and Approval of Specified Related Party Transactions under Israeli Law — Disclosure of Personal Interests of a Controlling Shareholder and Approval of Certain Transactions."

Our articles of association permit us to exculpate, indemnify and insure our office holders to the fullest extent permitted under the Companies Law (other than indemnification for litigation expenses in connection with a monetary sanction); provided that we may not exculpate an office holder for an action or transaction in which a controlling shareholder or any other office holder (including an office holder who is not the office holder we have undertaken to exculpate) has a personal interest (within the meaning of the Companies Law).

We have entered into indemnification and exculpation agreements with each of our current office holders exculpating them from a breach of their duty of care to us to the fullest extent permitted by the Companies Law (provided that we may not exculpate an office holder for an action or transaction in which a controlling shareholder or any other office holder (including an office holder who is not the office holder we have undertaken to exculpate) has a personal interest (within the meaning of the Companies Law)) and undertaking to indemnify them to the fullest extent permitted by the Companies Law (other than indemnification for litigation expenses in connection with a monetary sanction), to the extent that these liabilities are not covered by insurance. This indemnification is limited to events determined as foreseeable by our board of directors based on our activities, as set forth in the indemnification agreements. Under such agreements, the maximum aggregate amount of indemnification that we may pay to all of our office holders together is (i) for office holders who joined our company before May 31, 2013, the greater of 30% of the shareholders equity according to our most recent financial statements (audited or reviewed) at the time of payment and NIS 20 million, and (ii) for office holders who joined our company after May 31, 2013, 25% of the shareholders equity according to our most recent financial statements (audited or reviewed) at the time of payment.

We are not aware of any pending or threatened litigation or proceeding involving any of our office holders as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any office holder.

Employees

As of December 31, 2019, we employed 429 employees, according to the following division: 224 in Operations, 108 in Quality, 20 in Research and Development, 17 in Regulation, 4 in Business Development, 10 in Medical & Clinical, 9 in sales, Israel, 15 in Human Resources & Administration and 22 in Finance (our Procurement Department merged into the Finance department). As of December 31, 2018, we employed 408 employees, according to the following division: 202 in Operations, 104 in Quality, 20 in Research and Development, 17 in Regulation, 19 in Business Development, 8 in Medical & Clinical, 14 in Human Resources & Administration and 24 in Finance (our Procurement Department merged into the Finance department). As of December 31, 2017, we employed 413 employees, according to the following division: 199 in Operations, 104 in Quality, 21 in Research and Development, 20 in Regulation, 16 in Business Development, 12 in Medical & Clinical, 16 in Human Resources & Administration and 25 in Finance (our Procurement Department merged into the Finance department).

We signed a collective bargaining agreement with the Histadrut (General Federation of Labor in Israel) and the employees' committee established by our employees at our Beit Kama facility in December 2013, which expired in December 2017. In July 2018, during the course of our negotiations with the Histadrut and the employees' committee on the extension of the collective bargaining agreement beyond the December 2017 expiration, the employee's committee commenced a labor strike, which continued for approximately one month. In November 2018, we signed a new collective bargaining agreement with the employees' committee and the Histadrut, which will expire in December 2021. Approximately 60% of our employees, all of whom are located at our Beit Kama facility, currently work under the collective bargaining agreement signed in November 2018. The collective bargaining agreement governs certain aspects of our employee-employer relations, such as: firing procedures, annual salary raise, eligibility for certain compensation terms and welfare.

Israeli labor laws govern the length of the workday, minimum wages for employees, procedures for hiring and dismissing employees, determination of severance pay, annual leave, sick days, advance notice of termination of employment, equal opportunity and anti-discrimination laws and other conditions of employment. Subject to certain exceptions, Israeli law generally requires severance pay upon the retirement, death or dismissal of an employee, and requires us and our employees to make payments to the National Insurance Institute, which is similar to the U.S. Social Security Administration. Our employees have defined benefit pension plans that comply with the applicable Israeli legal requirements.

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

Share Ownership

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

The percentage of beneficial ownership of our ordinary shares is based on 44,523,970 ordinary shares outstanding as of February 26, 2020 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.

	Ordinary Shares Beneficially Owned	
Name	**Number**	**Percentage**
Executive Officers		
Amir London (1)	219,500	*
Chaime Orlev (2)	15,906	*
Michal Ayalon (3)	5,000	-
Yael Brenner (4)	45,575	*
Hanni Neheman (5)	17,427	*
Eran Nir (6)	26,737	*
Orit Pinchuk (7)	48,075	*
Ariella Raban (8)	23,062	*
Dr. Michal Stein (9)	16,947	*
Dr. Naveh Tov (10)	44,562	*

Name	Ordinary Shares Beneficially Owned	
	Number	Percentage
Directors		
Leon Recanati(11)	3,634,373	8.15%
Lilach Asher Topilsky	-	-
Avraham Berger(12)	11,875	*
Amiram Boehm	-	-
Ishay Davidi(13)	9,407,623	21.13%
Karnit Goldwasser	-	-
Jonathan Hahn(14)	2,064,751	4.63%
David Tsur(15)	937,537	2.10%
Directors and executive officers as a group (18 persons)(16)	16,518,949	37.08%

* Less than 1% of our ordinary shares.

(1) Includes 15,375 ordinary shares, 2,625 restricted shares and options to purchase 201,500 ordinary shares exercisable within 60 days of the date of this Annual Report, at a weighted average exercise price of NIS 23.87 (or $6.91) per share, which expire between May 15, 2020 and June 20, 2025. Does not include unvested options to purchase 72,000 ordinary shares and 24,000 unvested restricted shares that are not exercisable within 60 days of this Annual Report.

(2) Includes 3,741 ordinary shares, 233 restricted shares and options to purchase 11,931 ordinary shares exercisable within 60 days of the date of this Annual Report, at a weighted average exercise price of NIS 18.28 (or $5.29) per share, which expire between May 12, 2024 and December 20, 2025. Does not include unvested options to purchase 22,968 ordinary shares and 7,656 unvested restricted shares that are not exercisable within 60 days of this Annual Report.

(3) Includes 1,250 ordinary shares, options to purchase 3,750 ordinary shares exercisable within 60 days of the date of this Annual Report, at exercise price of NIS 20.30(or $5.80) per share, which expire at August 01, 2025. Does not include unvested options to purchase 22,450 ordinary shares and 7,483 unvested restricted shares that are not exercisable within 60 days of this Annual Report.

(4) Includes 4,692 ordinary shares, 358 restricted shares and options to purchase 40,525 ordinary shares exercisable within 60 days of the date of this Annual Report, at a weighted average exercise price of NIS 18.67 (or $5.40) per share, which expire between October 27, 2021 and December 20, 2025. Does not include unvested options to purchase 20,875 ordinary shares and 7,083 unvested restricted shares that are not exercisable within 60 days of this Annual Report.

(5) Includes 1,078 ordinary shares, 76 restricted shares and options to purchase 16,273 ordinary shares exercisable within 60 days of the date of this Annual Report, at a weighted average exercise price of NIS 17.70 (or $5.12) per share, which expire between October 27, 2021 and December 20, 2025. Does not include unvested options to purchase 6,976 ordinary shares and 2,263 unvested restricted shares that are not exercisable within 60 days of this Annual Report.

(6) Includes 6,448 ordinary shares, 233 restricted shares and options to purchase 20,056 ordinary shares exercisable within 60 days of the date of this Annual Report, at a weighted average exercise price of NIS 21.29 (or $6.16) per share, which expire between January 31, 2024 and December 20, 2025. Does not include unvested options to purchase 22,844 ordinary shares and 7,614 unvested restricted shares that are not exercisable within 60 days of this Annual Report.

(7) Includes 4,692 ordinary shares, 358 restricted shares and options to purchase 43,025 ordinary shares exercisable within 60 days of the date of this Annual Report, at an exercise price of NIS 35.38 (or $10.24) per share, which expire between October 27, 2021 and December 20, 2025. Does not include unvested options to purchase 20,875 ordinary shares and 7,083 unvested restricted shares that are not exercisable within 60 days of this Annual Report.

(8) Includes 2,499 ordinary shares, 313 restricted shares and options to purchase 20,250 ordinary shares exercisable within 60 days of the date of this Annual Report, at an exercise price of NIS 18.07 (or $5.23) per share, which expire between May 14, 2020 and December 20, 2025. Does not include unvested options to purchase 20,950 ordinary shares and 6,921 unvested restricted shares that are not exercisable within 60 days of this Annual Report.

(9) Includes 4,001 ordinary shares, 233 restricted shares and options to purchase 12,713 ordinary shares exercisable within 60 days of the date of this Annual Report, at an exercise price of NIS 20.81 (or $6.02) per share, which expire between January 31, 2024 and December 20, 2025. Does not include unvested options to purchase 22,187 ordinary shares and 7,396 unvested restricted shares that are not exercisable within 60 days of this Annual Report.

(10) Includes 6,449 ordinary shares, 494 restricted shares and options to purchase 37,619 ordinary shares exercisable within 60 days of the date of this Annual Report, at an exercise price of NIS 28.25 (or $8.17) per share, which expire between May 14, 2020 and December 20, 2025. Does not include unvested options to purchase 21,281 ordinary shares and 7,354 unvested restricted shares that are not exercisable within 60 days of this Annual Report

(11) Mr. Recanati holds 677,479 ordinary shares directly and 2,895,644 ordinary shares indirectly through Gov Financial Holdings Ltd., a company organized under the laws of the State of Israel ("**Gov**"). Gov is wholly-owned by Mr. Recanati, the Chairman of our Board of Directors, who exercises sole voting and investment power over the shares held by Gov. In addition, includes options to purchase 61,250 ordinary shares directly held by Mr. Recanati that are exercisable within 60 days of the date of the table, at a weighted average exercise price of NIS 43.53 (or $12.6) per share, which expire between May 14, 2020 and June 20, 2025. Does not include unvested options to purchase 13,750 ordinary shares that are not exercisable within 60 days of the date of the table.

(12) Subject to options to purchase 11,875 ordinary shares that are currently exercisable or exercisable within 60 days of the date of the table, at a weighted average exercise price of NIS 19.23 (or $5.56) per share, which expire between March 2, 2023 and June 20, 2025. Does not include unvested options to purchase 13,125 ordinary shares that are not exercisable within 60 days of the date of the table.

(13) Based solely upon, and qualified in its entirety with reference to, Amendment No. 1 to Schedule 13D filed with the SEC on January 21, 2020. According to the Statement, (i) the FIMI Funds are comprised of FIMI Opportunity Fund 6, L.P. and FIMI Israel Opportunity Fund 6, Limited Partnership (the "FIMI Funds"), (ii) FIMI 6 2016 Ltd. ("FIMI 6") serves as the managing general partner of the FIMI Funds, (iii) Or Adiv Ltd., a company controlled by Mr. Ishay Davidi, controls FIMI 6 and (iv) FIMI 6, Or Adiv Ltd. and Mr. Ishay Davidi share voting and dispositive power with respect to the shares beneficially owned by the FIMI Funds.

(14) Mr. Jonathan Hahn directly holds 119,558 ordinary shares. In addition, Mr. Hahn holds 25% of the shares of Sinara, which holds 100% of the shares of Damar, which directly holds 1,908,318 ordinary shares. Also includes options to purchase 36,875 ordinary shares directly held by Mr. Jonathan Hahn that are exercisable within 60 days of the date of the table, at a weighted average exercise price of NIS 39.62 (or $11.46) per share, which expire between May 14, 2020 and June 20, 2025. Does not include unvested options to purchase 13,125 ordinary shares held by Mr. Jonathan Hahn that are not exercisable within 60 days of the date of the table.

(15) Mr. David Tsur directly holds 771,287 ordinary shares. In addition, includes options to purchase 166,250 ordinary shares directly held by Mr. Tsur that are exercisable within 60 days of the date of the table, at a weighted average exercise price of NIS 53.15 (or $15.38) per share, which expire between May 14, 2020 and June 20, 2025. Does not include unvested options to purchase 13,750 ordinary shares that are not exercisable within 60 days of the date of the table.

(16) See footnotes (1)-(15) for certain information regarding beneficial ownership.

Equity Compensation Plans

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

In July 2011, we adopted our 2011 Israeli Share Option Plan and in September 2016, we amended and renamed it as the 2011 Israeli Share Award Plan (the "2011 Plan"). Under the 2011 Plan, we are authorized to grant options and restricted shares to directors, officers, employees, consultants and service providers of our company and subsidiaries. The 2011 Plan is intended to enhance our ability to attract and retain desirable individuals by increasing their ownership interests in us. The 2011 Plan, which is effective until July 23, 2021, is designed to reflect the provisions of the Israeli Tax Ordinance, which affords certain tax advantages to Israeli employees, officers and directors that are granted options in accordance with its terms. The 2011 Plan may be administered by our board of directors either directly or upon the recommendation of the compensation committee.

We have granted options to our employees, officers and directors under the 2011 Plan. Each option granted under the 2011 Plan entitles the grantee to purchase one of our ordinary shares. In general, the exercise price of each option granted under the 2011 Plan is equal to the average closing price of our ordinary shares on the TASE during the 30-TASE trading days immediately prior to board approval of the grant of such options. The exercise price of options granted to directors and officers under the 2011 Plan prior to January 1, 2020, is generally 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 plus 5%. Subject to shareholder approval of the amended compensation policies for our directors and officers being presented for approval at the extraordinary general meeting of shareholder to be held on March 25, 2020, the exercise price of options granted to directors and officers under the 2011 Plan shall generally be equal to the higher of (i) the average closing price of our ordinary shares on the TASE during the 30-TASE trading days immediately prior to board approval of the grant of such options; and (ii) the closing price of our ordinary shares on the TASE on the date of the approval of the grant of options**.** Options granted under the 2011 Plan are exercised by way of cashless exercise and accordingly, the grantee is not required to pay the exercise price when exercising the options and instead, receives, upon exercise and sale of such number of ordinary shares, an amount which is equal to the difference between the total market value of the ordinary shares on the date of exercise and sale underlying the exercised options and the total exercise price for such options. The actual number of shares issued pursuant to the cashless exercise of the options is equal to the number of shares subject to the option less the number of shares tendered back to the company to pay the exercise price.

The options granted under the 2011 Plan prior to January 1, 2020, generally vest during a four-year period following the date of the grant in 13 installments: 25% of the options vest on the first anniversary of the grant date and 6.25% of the remaining options vest at the end of each quarter thereafter. Effective as of January 1, 2020, options will generally vest in four equal installments, 25% each on each of the four anniversaries of the date of grant. Options granted under the 2011 Plan are generally exercisable for 6.5 years following the date of grant and all unexercised options will expire immediately thereafter. Options that have vested prior to the end of a grantee's employment or services agreement with us may generally be exercised within 90 days from the end of such grantee's employment or services with us, unless such relationship was terminated for cause. Options which are not exercised during such 90-day period expire at the end of the period, unless all of the 90-day period is a black-out period during which time the options may not be exercised, in which case our Chief Executive Officer or Chief Financial Officer is entitled to extend the exercise period for specified periods. Options that have not vested on the date of the end of a grantee's employment or services agreement with us, and, in the event of termination of employment or services for cause, all unexercised options (whether vested or not), expire immediately upon termination.

Beginning in 2016, we have also granted restricted shares to our officers. The restricted shares awarded under the 2011 Plan generally vest over a period of four years in 13 installments: 25% of the restricted shares vest on the first anniversary of the grant date and 6.25% of the remaining restricted shares vest at the end of each quarter thereafter.

In the event of certain transactions, such as our being acquired, or a merger or reorganization or a sale of all or substantially all of our assets, awards then outstanding under the 2011 Plan shall be assumed or substituted for shares or other securities of the surviving or acquiring entity as were distributed to our shareholders in connection and the transaction, subject to an appropriate adjustment to the exercise price (if applicable). The board or the compensation committee may determine that the terms of certain awards under the 2011 Plan include a provision that their vesting schedules will be accelerated such that they will be exercisable prior to the closing of such a transaction, if the awards are not assumed or substituted by the successor company.

Options and restricted shares granted to our employees under the 2011 Plan were granted pursuant to the provisions of Section 102 of the Israeli Income Tax Ordinance, under the capital gains alternative. In order to comply with the capital gains alternative, all such options and restricted shares under the 2011 Plan are granted or issued to a trustee and are to be held by the trustee for at least two years from the date of grant. Under the capital gains alternative, we are not allowed an Israeli tax deduction for the grant of the options or issuance of the shares issuable thereunder.

As of December 31, 2019, an aggregate of 1,050,298 ordinary shares were reserved for future issuance under the 2011 Plan (subject to certain adjustments specified in the 2011 Plan), and options to purchase 2,336,554 ordinary shares were outstanding under the 2011 Plan, of which options to purchase 1,412,023 ordinary shares were vested as of such date, and 145,897 restricted shares were outstanding under the 2011 Plan. Any ordinary shares underlying options that expire prior to exercise or restricted shares that are forfeited under the 2011 Plan will become again available for issuance under the 2011 Plan.

Item 7. Major Shareholders and Related Party Transactions

Major Shareholders

The following table sets forth information with respect to the beneficial ownership of our ordinary shares by each person known to us to own beneficially more than 5% of our ordinary shares.

The percentage of beneficial ownership of our ordinary shares is based on 44,523,970 ordinary shares outstanding as of February 26, 2020. 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
FIMI Funds(1)	9,407,623	21.13%
Leon Recanati(2)	3,634,373	8.15%
Hahn Family(3)	2,252,833	5.06%

(1) Based solely upon, and qualified in its entirety with reference to, Amendment No. 1 to Schedule 13D filed with the SEC on January 21, 2020. According to the Statement, (i) the FIMI Funds are comprised of FIMI Opportunity Fund 6, L.P. and FIMI Israel Opportunity Fund 6, Limited Partnership (the "FIMI Funds"), (ii) FIMI 6 2016 Ltd. ("FIMI 6") serves as the managing general partner of the FIMI Funds, (iii) Or Adiv Ltd., a company controlled by Mr. Ishay Davidi, controls FIMI 6 and (iv) FIMI 6, Or Adiv Ltd. and Mr. Ishay Davidi share voting and dispositive power with respect to the shares beneficially owned by the FIMI Funds.

(2) Mr. Recanati holds 677,479 ordinary shares directly and 2,895,644 ordinary shares indirectly through Gov Financial Holdings Ltd., a company organized under the laws of the State of Israel ("Gov"). Gov is wholly-owned by Mr. Recanati, the Chairman of our Board of Directors, who exercises sole voting and investment power over the shares held by Gov. In addition, includes options to purchase 61,250 ordinary shares directly held by Mr. Recanati that are exercisable within 60 days of the date of the table, at a weighted average exercise price of NIS 44.29 (or $12.8) per share, which expire between May 14, 2020 and June 20, 2025. Does not include unvested options to purchase 13,750 ordinary shares that are not exercisable within 60 days of the date of the table.

(3) Based solely upon Amendment No. 6 to Schedule 13G filed with the SEC on February 13, 2020, Damar Chemicals Inc., a company registered in Panama ("Damar"), directly holds 1,908,318 ordinary shares. According to the Statement, Damar is wholly-owned by Sinara Financing S.A. ("Sinara"), which is jointly owned by Mr. Jonathan Hahn, Ms. Tamar Hahn, Mr. Nicolas Hahn and the Fundacion Martinez, and Mr. Jonathan Hahn has the power to vote the shares held by Damar. In addition, according to the Statement, Mr. Jonathan Hahn directly holds 119,558 ordinary shares, Ms. Tamar Hahn directly holds 94,040 ordinary shares and Mr. Nicolas Rodolfo Hahn directly holds 94,041ordinary shares. Also includes options to purchase 36,875 ordinary shares directly held by Mr. Jonathan Hahn that are exercisable within 60 days of the date of the table, at a weighted average exercise price of NIS 39.67 (or $11.58) per share, which expire between May 14, 2020 and June 20, 2025. Does not include unvested options to purchase 13,125 ordinary shares held by Mr. Jonathan Hahn that are not exercisable within 60 days of the date of the table.

To our knowledge, based on information provided to us by our transfer agent in the United States, as of February 25, 2020, we had one shareholder of record who was registered with an address in the United States, holding approximately 23.03% 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 beneficial ownership percentage held by our major shareholders during the past three years have been the following: From January 1, 2017 to the date of this Annual Report, the beneficial ownership percentage of Hahn family decreased by 4.94% from 10.00% to 5.06%. Mr. Leon Recanati's beneficial ownership percentage decreased by 2.75% from 10.9% to 8.15% during such period. The Phoenix Holdings Group beneficial ownership percentage decreased by 0.91% from 7.83% to 6.92% during such period. The DS Apex group's beneficial ownership percentage decreased to less than 5% during such period. The Brosh Capital Partners group's beneficial ownership percentage increased from less than 5% to 7.68% during such period and decreased to less than 5% during such period. The FIMI Funds beneficial ownership percentage increased from less than 5% to 21.13% during such period. Meitav Dash Investments Ltd.'s beneficial ownership percentage decreased to less than 5% during such period.

None of our shareholders has different voting rights from other shareholders. We are not aware of any arrangement that may, at a subsequent date, result in a change of control of our company.

Related Party Transactions

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

In August 2011, we entered into a distribution agreement with Tuteur that amends and restates a distribution agreement we entered into in November 2001. Tuteur is a company organized under the laws of Argentina and was formerly controlled by Mr. Ralf Hahn, the former Chairman of our board of directors. Mr. Hahn's son, Mr. Jonathan Hahn, a director, is currently the President and a director of Tuteur. The amended agreement was made as an arm's length transaction, in connection with the expected completion of GLASSIA's registration in Argentina and the commencement of its marketing in Argentina. On August 19, 2014, we entered into an amendment to the distribution agreement in order to add KamRho(D) as an additional product to be distributed by Tuteur and expanded the territories to include Bolivia. On January 21, 2019, we entered into an additional amendment to the distribution agreement in order to change the terms of payments by Tuteur, change the terms of shipment, appoint a sub-distributor in Paraguay and to extend a fixed discount for the GLASSIA, per vial, sale price in exchange for obtaining a bank guarantee from Tuteur to cover any future supply of products Pursuant to the distribution agreement, as amended, Tuteur serves as the exclusive distributor of GLASSIA and KamRho(D), in Argentina, Paraguay and Bolivia. Tuteur is obligated under the agreement to commence marketing, sales and distribution of the products within each country covered by the agreement within two months after the grant of regulatory approval in each such country. Commencing the second year following the date that Tuteur commences sales of the product in Argentina, Tuteur will be obligated to purchase minimum amounts of products in the territories, in the total annual amount of not less than $1,006,800.

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

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

Khairi S.A.

On June 4, 2016, we entered into a distribution agreement with Khairi S.A. ("Khairi") for the distribution by Khairi of GLASSIA and KamRho(D) in Uruguay, which expired on December 31, 2019. 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 was an arm's length transaction, based on the terms of the distribution agreement previously signed with Tuteur. Mr. Leon Recanati (the Chairman of our board of directors), Mr. Jonathan Hahn (a director) and his siblings and Mr. Reuven Behar (who served as a director from April 2013 until May 2016) are shareholders of Khairi. Mr. Reuven Behar serves as the chairman of the board of directors of Khairi. In 2018, we received regulatory approval to market our GLASSIA product in Uruguay through Khairi and first shipment was performed. Our audit committee and board of directors approved the engagement of Khairi in accordance with the Companies Law.

Indemnification Agreements

We have entered into indemnification and exculpation agreements with each of our current officers and directors, exculpating them from a breach of their duty of care to us to the fullest extent permitted by the Companies Law (provided that we may not exculpate an office holder for an action or transaction in which a controlling shareholder or any other office holder (including an office holder who is not the office holder we have undertaken to exculpate) has a personal interest (within the meaning of the Companies Law)) and undertaking to indemnify them to the fullest extent permitted by the Companies Law (other than indemnification for litigation expenses in connection with a monetary sanction), including with respect to liabilities resulting from our initial public offering in the United States, to the extent such liabilities are not covered by insurance. See "Item 6. Directors, Senior Management and Employees — Exculpation, Insurance and Indemnification of Office Holders."

Employment Agreements

We have entered into employment agreements with our executive officers and key employees, which are terminable by either party for any reason. The employment agreements contain standard provisions, including assignment of invention provisions and non-competition clauses. See "Item 6. Directors, Senior Management and Employees — Employment Agreements with Executive Officers."

Shareholders' Agreement

Under a shareholders' agreement entered into on March 4, 2013, the Recanati Group, on the one hand, and the Damar Group, on the other hand, have each agreed to vote the ordinary shares beneficially owned by them in favor of the election of director nominees designated by the other group as follows: (i) three director nominees, so long as the other group beneficially owns at least 7.5% of our outstanding share capital, (ii) two director nominees, so long as the other group beneficially owns at least 5.0% (but less than 7.5%) of our outstanding share capital, and (iii) one director nominee, so long as the other group beneficially owns at least 2.5% (but less than 5.0%) of our outstanding share capital. In addition, to the extent that after the designation of the foregoing director nominees there are additional director vacancies, each of the Recanati Group and Damar Group have agreed to vote the ordinary shares beneficially owned by them in favor of such additional director nominees designated by the party who beneficially owns the larger voting rights in our company.

FIMI Private Placement

On January 20, 2020, we entered into a securities purchase agreement with the FIMI Funds to purchase an aggregate of 4,166,667 ordinary shares at a price of $6.00 per share, for an aggregate $25 million gross proceeds. Concurrently, we entered into a registration rights agreement with the FIMI Funds, pursuant to which the FIMI Funds are entitled to customary demand registration rights (effective six months following the closing of the transaction) and piggyback registration rights with respect to our shares held by them. Upon the closing of the private placement, the beneficial ownership of the FIMI Funds increased from approximately 12.15% to 21.13%. Ishay Davidi, Lilach Asher Topilsky and Amiram Boehm, members of our board of directors, are partners of the FIMI Funds. For details regarding the beneficial ownership of the FIMI Funds and Messrs. Davidi and Boehm and Ms. Asher Topilsky see "Item 7. Major Shareholders and Related Party Transactions — Major Shareholders" and "Item 6. Directors, Senior Management and Employees — Share Ownership."

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."

Item 10. Additional Information

A. Share Capital

Not applicable.

B. Memorandum and Articles of Association

Establishment and Purposes of the Company

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

Ordinary Shares

Voting

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

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

Transfer of Shares

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

Election of Directors

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

Dividend and Liquidation Rights

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

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

Shareholder Meetings

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

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

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

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

Quorum

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

Resolutions

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

Access to Corporate Records

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

Acquisitions Under Israeli Law

Full Tender Offer

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

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

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

Special Tender Offer

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

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

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

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

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

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

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

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

Merger

The Companies Law permits merger transactions if approved by each party's board of directors and, unless certain requirements described under the Companies Law are met, a majority of each party's shareholders. Under our articles of association, a merger shall require the approval of 66.6% of the voting rights represented at a meeting of our shareholders and voting on the matter, in person or by proxy, and any amendment to such provision shall require the approval of 60% of the voting rights represented at a meeting of our shareholders and voting on the matter, in person or by proxy.

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

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

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

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

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

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

Anti-takeover Measures

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

Tax Law

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

Modification of Class Rights

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

Transfer Agent and Registrar

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

C. Material Contracts

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

D. Exchange Controls

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

E. Taxation

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

Israeli Tax Considerations and Government Programs

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

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

General Corporate Tax Structure in Israel

Israeli companies are generally subject to corporate tax, which has decreased in recent years, from a rate of 26.5% in 2014 and 2015 to 25% in 2016 and to 24% in 2017, and further decreased to 23% in 2018 and thereafter. However, the effective corporate tax rate payable by a company that derives income from an Approved Enterprise, a Privileged Enterprise or a Preferred Enterprise (as discussed below) may be considerably less. Capital gains generated by an Israeli company are generally subject to tax at the corporate tax rate.

Law for the Encouragement of Industry (Taxes), 1969

The Law for the Encouragement of Industry (Taxes), 1969 (the “Encouragement of Industry Law”), provides several tax benefits to “Industrial Companies.” Pursuant to the Encouragement of Industry Law, a company qualifies as an Industrial Company if it is a resident of Israel and at least 90% of its income in any tax year (exclusive of income from certain defense loans) is generated from an “Industrial Enterprise” that it owns and is located in Israel or in the “Area”, in accordance with its definition under section 3A of the Israeli Income Tax Ordinance. An Industrial Enterprise is defined as an enterprise whose principal activity, in a given tax year, is industrial activity.

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

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

We believe that we may qualify as an Industrial Company within the meaning of the Encouragement of Industry Law; however, there is no assurance that we qualify or will continue to qualify as an Industrial Company or that the benefits described above will be available in the future.

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/Preferred Enterprise status under the Investment Law, and the benefits available at that time. Below is a short description of the different benefits available to us under the Investment Law:

Approved Enterprise

One of our facilities was granted Approved Enterprise status by the Investment Center, which made us eligible for a grant and certain tax benefits under the "Grant Track." The approved investment program provided us with a grant in the amount of 24% of our approved investments, in addition to certain tax benefits, which applied to our turnover resulting from the operation of such investment program, for a period of up to ten consecutive years from the first year in which we generated taxable income. The tax benefits under the Grant Track include accelerated depreciation and amortization for tax purposes as well as a tax exemption for the first two years of the benefit period and the taxation of income generated from an Approved Enterprise at a reduced corporate tax rate of 10%-25%, 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 expired at the end of 2017.

Privileged Enterprise

We obtained a tax ruling from the Israel Tax Authority according to which, among other things, our activity has been qualified as an "industrial activity", as defined in the Investment Law and is also eligible to tax benefits as a Privileged Enterprise under the "Tax Benefit Track," which 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 2020 and 2023.

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

A taxpayer owning a Privileged Enterprise may be entitled to an exemption from corporate tax on undistributed income for a period of two to ten years, depending on the location of the Privileged Enterprise within Israel, as well as a reduced corporate tax rate of 10% to 25% for the remainder of the benefit period, depending on the level of foreign investment in each year. In addition, the Privileged Enterprise is entitled to claim accelerated depreciation for manufacturing assets used by the Privileged Enterprise.

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

Preferred Enterprise

An amendment to the Investment Law that became effective on January 1, 2011 (“Amendment No. 68”) changed the benefit alternatives available to companies under the Investment Law and introduced new benefits for income generated by a “Preferred Company” through its “Preferred Enterprises” (as such terms are defined in the Investment Law). The definition of a Preferred Company includes a company incorporated in Israel that is not wholly-owned by a governmental entity, and that, among other things, owns a Preferred Enterprise and is controlled and managed from Israel. The tax benefits granted to a Preferred Company are determined depending on the location of its Preferred Enterprise within Israel. Amendment No. 68 imposes a reduced flat corporate tax rate which is not program-dependent and applies to the Preferred Company’s “preferred income” which is generated by its Preferred Enterprise.

According to the Investment Law, a Preferred Company is subject to reduced corporate tax rate of 10% for preferred income attributed to Preferred Enterprises located in areas in Israel designated as Development Zone A and 15% for those located elsewhere in Israel in the tax years 2011-2012, and 7% for Development Zone A and 12.5% for the rest of Israel in the tax year 2013, and 9% for Development Zone A and 16% for the rest of Israel in the tax years 2014 until 2016. Under an amendment to the Investment Law that became effective on January 1, 2017, the corporate tax rate applying to income attributed to Preferred Enterprise located in Development Zone A was reduced to 7.5% while the reduced corporate tax rate for the rest of Israel remains 16%. Income derived by a Preferred Company from a “Special Preferred Enterprise” (as such term is defined in the Investment Law) would be entitled, during a benefits period of 10 years, to further reduced tax rates of 5% if the Special Preferred Enterprise is located in Development Zone A, or 8% if the Special Preferred Enterprise is located elsewhere in Israel.

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

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

The provisions of Amendment No. 68 do not apply to existing Privileged Enterprises or Approved Enterprises, which will continue to be entitled to the tax benefits under the Investment Law as in effect prior to Amendment No. 68. Nevertheless, a company owning such enterprises may choose to apply Amendment No. 68 to its existing enterprises while waiving benefits provided under the Investment Law as in effect prior to Amendment No. 68. Once a company elects to be classified as a Preferred Enterprise under the provisions of Amendment No. 68, the election cannot be rescinded and such company will no longer enjoy the tax benefits of its Approved/Privileged Enterprises.

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

New Tax benefits under the 2017 Amendment that became effective on January 1, 2017

An amendment to the Investment Law was enacted as part of the Economic Efficiency Law that was published on December 29, 2016, and is effective as of January 1, 2017 (the "2017 Amendment"). The 2017 Amendment provides new tax benefits for two types of "Technology Enterprises", as described below, and is in addition to the other existing tax beneficial programs under the Investment Law.

The 2017 Amendment provides that a technology company satisfying certain conditions will qualify as a "Preferred Technology Enterprise" and will thereby enjoy a reduced corporate tax rate of 12% on income that qualifies as "Preferred Technology Income", as defined in the Investment Law. The tax rate is further reduced to 7.5% for a Preferred Technology Enterprise located in Development Zone A. In addition, a Preferred Technology Company will enjoy a reduced corporate tax rate of 12% on capital gain derived from the sale of certain "Benefitted Intangible Assets" (as defined in the Investment Law) to a related foreign company if the Benefitted Intangible Assets were acquired from a foreign company on or after January 1, 2017 for at least NIS 200 million, and the sale receives prior approval from the National Authority for Technological Innovation ("NATI").

The 2017 Amendment further provides that a technology company satisfying certain conditions will qualify as a "Special Preferred Technology Enterprise" and will thereby enjoy a reduced corporate tax rate of 6% on "Preferred Technology Income" regardless of the company's geographic location within Israel. In addition, a Special Preferred Technology Enterprise will enjoy a reduced corporate tax rate of 6% on capital gain derived from the sale of certain "Benefitted Intangible Assets" to a related foreign company if the Benefitted Intangible Assets were either developed by the Special Preferred Technology Enterprise or acquired from a foreign company on or after January 1, 2017, and the sale received prior approval from NATI. A Special Preferred Technology Enterprise that acquires Benefitted Intangible Assets from a foreign company for more than NIS 500 million will be eligible for these benefits for at least ten years, subject to certain approvals as specified in the Investment Law.

Dividends distributed by a Preferred Technology Enterprise or a Special Preferred Technology Enterprise, paid out of Preferred Technology Income, are generally subject to withholding tax at source at the rate of 20% or such lower rate as may be provided in an applicable tax treaty (subject to the receipt in advance of a valid certificate from the Israel Tax Authority allowing for a reduced tax rate). However, if such dividends are paid to an Israeli company, no tax is required to be withheld. If such dividends are distributed to a foreign company and other conditions are met, the withholding tax rate will be 4%.

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

The Encouragement of Industrial Research, Development and Technological Innovation in the Industry Law, 5744-1984 (formerly known as The Encouragement of Industrial Research and Development Law, 5744-1984)

We have received grants from the Government of the State of Israel through the Israel Innovation Authority of the Israeli Ministry of Economy and Industry (the "IIA") (formerly known as the Office of the Chief Scientist of the Israeli Ministry of Economy (the "OCS")), for the financing of a portion of our research and development expenditures pursuant to the Encouragement of Research, Development and Technological Innovation in the Industry Law 5744-1984 (formerly known as the Encouragement of Industrial and Development Law, 5744-1984) (the "Research Law") and related regulations. We previously received funding from the IIA for five research and development programs, in the aggregate amount of approximately $1.7 million as of December 31, 2019, which amount has accrued aggregate interest of approximately $8,252 as of such date, and we had paid aggregate royalties to the IIA for these programs in the amount of approximately $1.0 million and had a contingent liability to the IIA in the amount of approximately $0.7 million (excluding any interest thereon) as of December 31, 2019.

Under the Research Law, research and development programs which meet specified criteria and are approved by the IIA (formerly the OCS) are eligible for grants. Under the Research Law, as currently in effect, the grants awarded are typically up to 50% of the project's expenditures. The grantee is required to pay royalties to the State of Israel from the sale of products developed under the program. Regulations under the Research Law, as currently in effect, generally provide for the payment of royalties of 3% to 5% on sales of products and services based on technology developed using grants, until 100% (which may be increased under certain circumstances) of the U.S. dollar-linked value of the grant is repaid, with interest at the rate of 12-month LIBOR. The terms of the IIA grants generally require that products developed with such grants be manufactured in Israel and that the technology developed thereunder may not be transferred outside of Israel, unless approval is received from the IIA and additional payments are made to the State of Israel. However, this does not restrict the export of products that incorporate the funded technology. The royalty repayment ceiling can reach up to three times the amount of the grant received if manufacturing is moved outside of Israel, and if the funded technology itself is transferred outside of Israel, the royalty ceiling can reach up to six times the amount of grants (plus interest). Even following the full repayment of any IIA grants, we must nevertheless continue to comply with the requirements of the Research Law. If we fail to comply with any of the conditions and restrictions imposed by the Research Law, or by the specific terms under which we received the grants, we may be required to refund any grants previously received together with interest and penalties, and, in certain circumstances, may be subject to criminal charges.

Taxation of Our Shareholders

The Israeli Income Tax Ordinance applies Israeli tax on a worldwide basis with respect to Israeli residents, and on an Israeli source income, with respect to non-Israeli residents. Dividends distributed (or deemed distributed) by an Israeli resident company to a holder in respect of its securities and consideration received by a holder (or deemed received) in connection with the sale or other disposition of securities of an Israeli resident company are considered to be an Israeli source income.

Capital gains

Under present Israeli tax legislation, the tax rate applicable to real capital gain derived by Israeli resident corporations from the sale of shares of an Israeli company is the general corporate tax rate (which was 26.5% in 2015, reduced to 25% in 2016 and 24% in 2017 and reduced to 23% in 2018 and thereafter).

Generally, as of January 1, 2006, the tax rate applicable to real capital gain derived by Israeli individuals from the sale of shares which had been purchased on or after January 1, 2003, whether or not listed on a stock exchange, is 25%, unless such shareholder claims a deduction for interest and linkage differences expenses in connection with the purchase and holding of such shares. Additionally, if such a shareholder is considered a "Substantial Shareholder" (*i.e.*, a person who holds, directly or indirectly, alone or together with another, 10% or more of any of the company's "means of control" (including, among other things, the right to receive profits of the company, voting rights, the right to receive the company's liquidation proceeds and the right to appoint a director)) at the time of sale or at any time during the preceding 12-month period, such gain will be taxed at the rate of 30%. Individual shareholders dealing in securities in Israel are taxed at their marginal tax rates applicable to business income (up to 47% from 2017).

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

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

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

Dividends

Our company is obligated to withhold tax, at the rate of 20%, upon the distribution of a dividend attributed to an Approved/Privileged Enterprise's income, subject to a reduced tax rate under the provisions of an applicable double tax treaty, provided that a certificate from the Israel Tax Authority allowing for a reduced withholding tax rate is obtained in advance. If the dividend is distributed from income not attributed to an Approved/Privileged Enterprise, the following withholding tax rates will apply: (i) Israeli resident corporations — 0%, (ii) Israeli resident individuals — 25% (or 30% in the case of a Substantial Shareholder) and (iii) non-Israeli residents (whether an individual or a corporation), so long as the shares are registered with a nominee company — 25%, subject to a reduced tax rate under the provisions of an applicable double tax treaty, provided that a certificate from the Israel Tax Authority allowing for a reduced withholding tax rate is obtained in advance. Generally, unless the recipient of the dividend is a U.S. corporate resident which holds at least 10% of the share capital of the Company, the withholding rate will not be reduced under the Israel-U.S.A. Double Tax Treaty.

Excess Tax

An additional tax liability at the rate of 3% in 2017 onwards is added to the applicable tax rate on the annual taxable income of individuals (whether any such individual is an Israeli resident or non-Israeli resident) exceeding NIS 641,880 in 2018, NIS 649,560 in 2019 and NIS 651,600 in 2020.

Estate and gift tax

Israeli law presently does not impose estate or gift taxes.

United States Federal Income Taxation

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

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

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

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

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

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

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

Distributions

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

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

Sale, Exchange or Other Disposition of Ordinary Shares

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

Passive Foreign Investment Company Considerations

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

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

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

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

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

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

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

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

Based on the financial information currently available to us and the nature of our business, we do not expect that we will be classified as a PFIC for the taxable year ended December 31, 2019 However, this determination could be subject to change. If, contrary to our expectations, we were to be classified as a PFIC, U.S. Holders of ordinary shares may be required to file form 8621 with respect to their ownership of our ordinary shares in the year in which we were a PFIC. U.S. Holders of our ordinary shares should consult their tax advisors in this regard.

Backup Withholding and Information Reporting Requirements

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

Additional Medicare Tax

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

Foreign Asset Reporting

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

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

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

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

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

I. Subsidiary Information

Not applicable.

Item 11. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

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

Foreign Currency Risk

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

For the years ended December 31, 2019, 2018 and 2017, we have witnessed high volatility in the U.S. dollar exchange rate. This fact impacts our revenues from the Distribution segment, where prices are denominated in or linked to the NIS upon delivery of product while our expenses for the purchase of raw materials and imported goods in the Distribution segment are in U.S. dollars and part of our development and marketing expenses are paid in NIS.

We attempt to mitigate our currency exposure by matching assets denominated in NIS currency with liabilities denominated in NIS. In the Distribution segment, we attempt to mitigate foreign currency exposure by matching Euro denominated expenses with Euro denominated revenues. Additionally, we used, and from time to time, will continue to use, currency hedging transactions using financial derivatives and forward currency contracts. We attempt to enter into forward currency contracts with critical terms that match those of the underlying exposure. As of December 31, 2019, we had open transactions in derivatives in the amount of approximately $17.1 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, 2017	(6.3)
Year ended December 31, 2018	8.1
Year ended December 31, 2019	(7.8)

As of December 31, 2019, we had excess liabilities over assets denominated in NIS in the amount of $0.5 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 income.

As of December 31, 2019, we had foreign currency exposures to currencies other than U.S. dollars (mainly in EUR) amounting to $11.0 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 $0.05 million, $1.2 million and $1.3 million as of December 31, 2019, 2018 and 2017, 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, 2019, we have used a significant portion of the net proceeds of our initial public offering. We intend to use the remaining net proceeds we received from our initial public offering as disclosed in our Registration Statement on Form F-1.

Item 15. Controls and Procedures

(a) *Disclosure Controls and Procedures*. Our management, under the supervision and with the participation of our Chief Executive Officer and our Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2019, pursuant to Rule 13a-15 under the Exchange Act. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer (the principal executive and principal financial officer, respectively) have concluded that our disclosure controls and procedure are effective to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure, and is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms.

(b) *Report* of *Management on Internal Control over Financial Reporting*. Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our management has assessed the effectiveness of internal control over financial reporting based on the Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this assessment, our management has concluded that our internal control over financial reporting as of December 31, 2019 was effective.

(c) *Attestation Report of the Registered Public Accounting Firm*. Our independent registered public accounting firm, Kost Forer Gabbay & Kasierer, a member of Ernst & Young Global, has audited the consolidated financial statements included in this annual report on Form 20-F, and as part of its audit, has issued its audit report on the effectiveness of our internal control over financial reporting as of December 31, 2019. The report of Kost Forer Gabbay & Kasierer is included with our consolidated financial statements included elsewhere in this annual report and is incorporated herein by reference.

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

Item 16A. Audit Committee Financial Expert

Our board of directors has determined that Avraham Berger is an "independent" director for purposes of serving on an audit committee under the Exchange Act and Nasdaq listing requirements and qualifies as an "audit committee financial expert," as defined in Item 407(d)(5) of Regulation S-K.

Item 16B. Code of Ethics

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

Item 16C. Principal Accountant Fees and Services

During the years ended December 31, 2019 and 2018, we were billed the following aggregate fees for the professional services rendered by Kost Forer Gabbay & Kasierer, a member of Ernst & Young Global, independent registered public accounting firm:

	Year Ended December 31,	
	2019	**2018**
Audit Fees(1)	$ 245,000	$ 260,000
Tax Fees (2)	10,000	14,702
Other (3)	72,027	39,728
Total	$ 327,027	$ 314,430

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

(2) Tax services rendered by our auditors in 2019 and 2018 were for compliance with tax regulation.

(3) Mainly includes services in connection with risk analysis, SEC correspondence and policy implementation of new regulation.

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

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, 2019, neither the company nor any affiliated purchaser (as defined in the Exchange Act) purchased any of the company's ordinary shares.

Item 16F. Change in Registrant's Certifying Accountant

None.

Item 16G. Corporate Governance

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

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

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

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

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

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

Item 16H. Mine Safety Disclosure

Not applicable.

PART III

Item 17. Financial Statements

Consolidated Financial Statements are set forth under Item 18.

Item 18. Financial Statements

Our Consolidated Financial Statements beginning on pages F-1 through F-67, as set forth in the following index, are hereby incorporated herein by reference. These Consolidated Financial Statements are filed as part of this Annual Report.

Item 19. Exhibits

Exhibit No.	Description
1.1	Amended Articles of Association of the Registrant (incorporated by reference to Appendix A2 to the Proxy Statement for the 2016 Annual General Meeting of Shareholders, filed as Exhibit 99.1 to Form 6-K filed with the Securities and Exchange Commission on July 26, 2016).
1.2	Memorandum of Association of the Registrant, as currently in effect (as translated from Hebrew) (incorporated by reference to Exhibit 3.1 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on May 15, 2013).
2.1	Form of Certificate for Ordinary Shares (incorporated by reference to Exhibit 4.1 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on May 15, 2013).
4.1†	Exclusive Manufacturing, Supply and Distribution Agreement, dated as of August 23, 2010, by and between Kamada Ltd. and Baxter Healthcare Corporation (incorporated by reference to Exhibit 10.1 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on May 15, 2013).
4.2†	Technology License Agreement, dated as of August 23, 2010, by and between Kamada Ltd. and Baxter Healthcare S.A. (incorporated by reference to Exhibit 10.2 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on May 15, 2013).
4.3†	Amended and Restated Fraction IV-1 Paste Supply Agreement, dated as of August 23, 2010, by and between Kamada Ltd. and Baxter Healthcare Corporation (incorporated by reference to Exhibit 10.3 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on April 11, 2013).
4.4†	First Amendment to the Amended and Restated Fraction IV-1 Paste Supply Agreement, dated as of May 10, 2011, by and between Kamada Ltd. and Baxter Healthcare Corporation (incorporated by reference to Exhibit 10.4 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on April 11, 2013).

4.5†	Second Amendment to the Amended and Restated Fraction IV-1 Paste Supply Agreement, dated as of June 22, 2011, by and between Kamada Ltd. and Baxter Healthcare Corporation (incorporated by reference to Exhibit 10.5 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on April 11, 2013).
4.6†	License Agreement, dated as of November 16, 2006, by and between PARI GmbH and Kamada Ltd. (incorporated by reference to Exhibit 10.7 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on April 11, 2013).
4.7†	Amendment No. 1 to License Agreement, dated as of August 9, 2007, by and between PARI GmbH and Kamada Ltd. (incorporated by reference to Exhibit 10.8 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on April 11, 2013).
4.8†	Addendum No. 1 to License Agreement, dated as of February 21, 2008, by and between PARI Pharma GmbH and Kamada Ltd. (incorporated by reference to Exhibit 10.9 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on April 11, 2013).
4.9†	Supply and Distribution Agreement, dated as of July 18, 2011, by and between Kamada Ltd. and Kedrion S.p.A. (incorporated by reference to Exhibit 10.10 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on April 11, 2013).
4.10†	Distribution Agreement, dated as of August 2, 2011, by and between Kamada Ltd. and TUTEUR S.A.C.I.F.I.A. (incorporated by reference to Exhibit 10.11 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on April 11, 2013).
4.11	English translation of form of Indemnification Agreement with the Registrant's directors and officers (incorporated by reference to Exhibit 10.15 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on May 15, 2013).
4.12	English translation of amendment to form of Indemnification Agreement with the Registrant's directors and officers (incorporated by reference to Appendixes A3 and A4 of the Proxy filed as Exhibit 99.1 to Form 6-K filed with the Securities and Exchange Commission on May 22, 2015).
4.13	English summary of two lease agreements dated June 20, 2002, by and between the Israel Lands Administration and Kamada Nehasim (2001) Ltd., as such agreements were amended by lease agreement dated January 30, 2011, by and between the Israel Lands Authority and Kamada Assets (2001) Ltd. (incorporated by reference to Exhibit 10.16 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on April 11, 2013).
4.14†	Fraction IV-1 Paste Supply Agreement, dated December 3, 2012, by and between Baxter Healthcare S.A. and Kamada Ltd. (incorporated by reference to Exhibit 10.18 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on April 11, 2013).
4.15	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).
4.16	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).
4.17†	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).
4.18†	First Amendment to the Technology License Agreement, dated as of May 14, 2013, by and between Kamada Ltd. and Baxter Healthcare SA (incorporated by reference to Exhibit 10.23 of the Registration Statement on Form F-1 filed with the Securities and Exchange Commission on May 28, 2013).
4.19†	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).
4.20†	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).

4.21†	Third Amendment to the Amended and Restated Fraction IV-1 Paste Supply Agreement executed on July 19, 2015 by and between Kamada Ltd. and Baxalta US Inc. (incorporated by reference to Exhibit 4.29 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 25, 2016).
4.22†	Fourth Amendment to the Exclusive Manufacturing, Supply and Distribution Agreement, dated as of October, 2015, by and between Kamada Ltd. and Baxalta US Inc. (incorporated by reference to Exhibit 4.30 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 25, 2016).
4.23†	Second Amendment to the Technology License Agreement, dated as of August 25, 2015, by and between Kamada Ltd. and Baxalta GmbH. (incorporated by reference to Exhibit 4.31 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 25, 2016).
4.24†	Fifth Amendment to the Exclusive Manufacturing, Supply and Distribution Agreement, dated as of October 5, 2016, by and between Kamada Ltd. and Shire plc. (incorporated by reference to Exhibit 4.28 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on March 1, 2017)
4.25	Compensation Policy for Executive Officers and Directors
4.26	Kamada Ltd. 2011 Israeli Share Award Plan (incorporated by reference to Exhibit 4.2 to the Form S-8 filed with the Securities and Exchange Commission on February 9, 2017).
4.27†	1st Addendum to Supply And Distribution Agreement dated October 15, 2016 between Kamada Ltd., and Kedrion S.p.A. (incorporated by reference to Exhibit 4.32 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on March 1, 2017).
4.28†	2nd Addendum to Supply And Distribution Agreement dated October 11, 2018 between Kamada Ltd., and Kedrion S.p.A. (incorporated by reference to Exhibit 4.29 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 27, 2019)
4.29†	Termination Agreement dated as of November 14, 2017 by and between Kamada Ltd. and Chiesi Farmaceutici S.p.A. (incorporated by reference to Exhibit 4.29 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on March 6, 2018).
4.30†	Sixth Amendment to the Exclusive Manufacturing, Supply and Distribution Agreement, dated as of August 30, 2019, by and between Kamada Ltd. and Baxalta US Inc.
4.31†	Clinical Study Supply Agreement, dated as of May 5, 2019, by and between PARI GmbH and Kamada Ltd.
4.32†	Binding Term Sheet between partner and Kamada Ltd., dated December 6, 2019.
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.

SIGNATURES

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

KAMADA LTD.

By: /s/ Chaime Orlev
Chaime Orlev
Chief Financial Officer

Date: February 26, 2020

Kamada Ltd.

Consolidated Financial Statements as of December 31, 2019

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Building a better working world

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of KAMADA LTD.

Opinion on the Financial Statements

We have audited the accompanying Consolidated Statements of Financial Position of Kamada Ltd and subsidiaries (the Company) as of December 31, 2019 and 2018, the related consolidated statements of comprehensive income, shareholders' equity and cash flows for each of the three years in the period ended December 31, 2019, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2019, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission 2013 framework and our report dated February 26, 2020 expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

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

We have served as the Company's auditor since 2005.
Tel-Aviv, Israel
February 26, 2020

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Building a better working world

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of KAMADA LTD.

Opinion on Internal Control Over Financial Reporting

We have audited Kamada Ltd's and subsidiaries internal control over financial reporting as of December 31, 2019, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), (the COSO criteria). In our opinion, Kamada Ltd. (and subsidiary) (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2019, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Consolidated Statements of Financial Position of the Company as of December 31, 2019 and 2018, the related consolidated statements of comprehensive income, shareholders' equity and cash flows for each of the three years in the period ended December 31, 2019, and the related notes and our report dated February 26, 2020 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

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

Tel-Aviv, Israel
February 26, 2020

Consolidated Statements of Financial Position

	Note	As of December 31, 2019	2018
		U.S. Dollars in thousands	
Assets			
Current Assets			
Cash and cash equivalents	5	$ 42,662	$ 18,093
Short-term investments	6	31,245	32,499
Trade receivables, net	7	23,210	27,674
Other accounts receivables	8	3,272	3,308
Inventories	9	43,173	29,316
Total Current Assets		143,562	110,890
Non-Current Assets			
Property, plant and equipment, net	10	24,550	25,004
Right-of-use assets	14b	4,022	-
Other long term assets	11	352	174
Deferred taxes	21	1,311	2,048
Total Non-Current Assets		30,235	27,226
Total Assets		$ 173,797	$ 138,116
Liabilities			
Current Liabilities			
Current maturities of bank loans	14a	$ 489	$ 452
Current maturities of lease liabilities	14b	1,020	110
Trade payables	12	24,830	17,285
Other accounts payables	13	5,811	5,261
Deferred revenues	17	589	461
Total Current Liabilities		32,739	23,569
Non-Current Liabilities			
Bank loans	14a	257	688
Lease liabilities	14b	3,981	28
Deferred revenues	17	232	668
Employee benefit liabilities, net	16	1,269	787
Total Non-Current Liabilities		5,739	2,171
Shareholder's Equity	19		
Ordinary shares		10,425	10,409
Additional paid in capital net		180,819	179,147
Capital reserve due to translation to presentation currency		(3,490)	(3,490)
Capital reserve from hedges		8	(57)
Capital reserve from financial assets measured at fair value through other comprehensive income		145	34
Capital reserve from share-based payments		8,844	9,353
Capital reserve from employee benefits		(359)	4
Accumulated deficit		(61,073)	(83,024)
Total Shareholder's Equity		135,319	112,376
Total Liabilities and Shareholder's Equity		$ 173,797	$ 138,116

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

Consolidated Statements of Profit or Loss and Other Comprehensive Income

	Note	For the Year Ended December 31, 2019	2018	2017
		U.S. Dollars in thousands, except for share and per share data		
Revenues from proprietary products	1a	$ 97,696	$ 90,784	$ 79,559
Revenues from distribution		29,491	23,685	23,266
Total revenues	22a,b	127,187	114,469	102,825
Cost of revenues from proprietary products		52,425	52,796	51,335
Cost of revenues from distribution		25,025	20,201	19,402
Total cost of revenues	22c	77,450	72,997	70,737
Gross profit		49,737	41,472	32,088
Research and development expenses	22d	13,059	9,747	11,973
Selling and marketing expenses	22e	4,370	3,630	4,398
General and administrative expenses	22f	9,194	8,525	8,273
Other expense		330	311	-
Operating income		22,784	19,259	7,444
Financial income	22g	1,146	830	500
Expense in respect of securities measured at fair value, net	22g	(5)	(178)	(80)
Income (expenses) in respect of currency exchange differences and derivatives instruments, net	22g	(651)	602	(612)
Financial expense	22g	(293)	(172)	(82)
Income before tax on income		22,981	20,341	7,170
Taxes on income	21	730	(1,955)	269
Net Income		$ 22,251	$ 22,296	$ 6,901
Other Comprehensive Income:				
Amounts that will be or that have been reclassified to profit or loss when specific conditions are met				
Gain (loss) from securities measured at fair value through other comprehensive income		143	51	(23)
Gain (loss) on cash flow hedges		92	(176)	329
Net amounts transferred to the statement of profit or loss for cash flow hedges		(23)	70	(256)
Items that will not be reclassified to profit or loss in subsequent periods:				
Remeasurement gain (loss) from defined benefit plan		(388)	340	(256)
Tax effect		(11)	(9)	-
Total comprehensive income		$ 22,064	$ 22,572	$ 6,695
Earnings per share attributable to equity holders of the Company:	23			
Basic net earnings per share		$ 0.55	$ 0.55	$ 0.18
Diluted net earnings per share		$ 0.55	$ 0.55	$ 0.18

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

Consolidated Statements of Changes in Equity

	Share capital	Additional paid in capital	Capital reserve From securities measured at fair value through other Comprehensive income	Capital reserve due to translation to presentation currency	Capital reserve from hedges	Capital reserve from share based payments	Capital reserve from employee benefits	Accumulated deficit	Total equity
	U.S. Dollars in thousands								
Balance as of December 31, 2016	$ 9,320	$ 162,671	$ 19	$ (3,490)	$ (27)	$ 9,795	$ (81)	$ (111,464)	$ 66,743
Net income	-	-	-	-	-	-	-	6,901	6,901
Other comprehensive income (loss)	-	-	(23)	-	73	-	(256)	-	(206)
Total comprehensive income (loss)	-	-	(23)	-	73	-	(256)	6,901	6,695
Exercise and forfeiture of share-based payment into shares	3	712	-	-	-	(712)	-	-	3
Issuance of ordinary shares, net of issuance costs	1,077	14,491	-	-	-	-	-	-	15,568
Cost of share-based payment	-	-	-	-	-	483	-	-	483
Balance as of December 31, 2017	$ 10,400	$ 177,874	$ (4)	$ (3,490)	$ 46	$ 9,566	$ (337)	$ (104,563)	$ 89,492
Cumulative effect of Initial application of IFRS 15	-	-	-	-	-	-	-	(757)	(757)
Balance as at January 1, 2018 (after initially application of IFRS 15)	10,400	177,874	(4)	(3,490)	46	9,566	(337)	(105,320)	88,735
Net income	-	-	-	-	-	-	-	22,296	22,296
Other comprehensive income (loss)	-	-	50	-	(106)	-	340	-	284
Tax effect			(12)		3	-	1		(8)
Total comprehensive income (loss)	-	-	38	-	(103)	-	341	22,296	22,572
Exercise and forfeiture of share-based payment into shares	9	1,161	-	-	-	(1,161)	-	-	9
Cost of share base payment	-	-	-	-	-	948	-	-	948
Tax effect	-	112	-	-	-	-	-	-	112
Balance as of December 31, 2018	$ 10,409	$ 179,147	$ 34	$ (3,490)	$ (57)	$ 9,353	$ 4	$ (83,024)	$ 112,376
Cumulative effect of initially application of IFRS 16	-	-	-	-	-	-	-	(300)	(300)
Balance as at January 1, 2019 (after Initial application of IFRS 16)	10,409	179,147	34	(3,490)	(57)	9,353	4	(83,324)	112,076
Net income								22,251	22,251
Other comprehensive income (loss)	-	-	143	-	69	-	(388)	-	(176)
Tax effect	-	-	(32)	-	(4)	-	25	-	(11)
Total comprehensive income (loss)	-	-	111	-	65	-	(363)	22,251	22,064
Exercise and forfeiture of share-	16	1,672	-	-	-	(1,672)	-	-	16

based payment into shares									
Cost of share-based payment	-	-	-	-	-	1,163	-	-	1,163
Balance as of December 31, 2019	$ 10,425	$ 180,819	$ 145	$ (3,490)	$ 8	$ 8,844	$ (359)	$ (61,073)	$ 135,319

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

Consolidated Statements of Cash Flows

	Note	For the year ended December 31, 2019	2018	2017
		U.S. Dollars in thousands		
Cash Flows from Operating Activities				
Net income		$ 22,251	$ 22,296	$ 6,901
Adjustments to reconcile net income to net cash provided by operating activities:				
Adjustments to the profit or loss items:				
Depreciation and amortization	10	4,519	3,703	3,523
Financial expense (income), net		(197)	(1,082)	274
Cost of share-based payment	20	1,163	948	483
Taxes on income	21	730	(1,955)	269
Loss (gain) from sale of property and equipment		(2)	55	(52)
Change in employee benefit liabilities, net		94	(16)	166
		6,307	1,653	4,663
Changes in asset and liability items:				
Decrease (increase) in trade receivables, net		5,117	2,311	(9,967)
Decrease (increase) in other accounts receivables		(214)	(1,336)	328
Decrease (increase) in inventories		(13,857)	(8,246)	4,524
Decrease in deferred expenses		399	235	594
Increase (decrease) in trade payables		6,259	(1,116)	(838)
Increase (decrease) in other accounts payables		863	(658)	71
Decrease in deferred revenues		(283)	(5,256)	(2,930)
		(1,716)	(14,066)	(8,218)
Cash paid during the year for:				
Interest paid		(243)	(54)	(21)
Interest received		1,106	739	399
Taxes paid		(134)	(22)	(116)
		729	663	262
Net cash provided by operating activities		$ 27,571	$ 10,546	$ 3,608

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

Consolidated Statements of Cash Flows

	Note	For the year ended December 31, 2019	2018	2017
		U.S. Dollars in thousands		
Cash Flows from Investing Activities				
Investment in short term investments, net		$ 1,727	$ (2,322)	$ (11,501)
Purchase of property and equipment and intangible assets	10	(2,300)	(2,884)	(4,167)
Proceeds from sale of property and equipment		9	30	60
Net cash used in investing activities		(564)	(5,176)	(15,608)
Cash Flows from Financing Activities				
Proceeds from exercise of share base payments		16	9	3
Receipt of long-term loans		-	-	279
Repayment of lease liabilities		(1,070)	(136)	(111)
Repayment of long-term loans		(476)	(460)	(419)
Proceeds from issuance of ordinary shares, net		-	-	15,568
Net cash provided by (used in) financing activities		(1,530)	(587)	15,320
Exchange differences on balances of cash and cash equivalent		(908)	629	(607)
Increase in cash and cash equivalents		24,569	5,412	2,713
Cash and cash equivalents at the beginning of the year		18,093	12,681	9,968
Cash and cash equivalents at the end of the year		$ 42,662	$ 18,093	$ 12,681
Significant non-cash transactions				
Right-of-use asset recognized with corresponding lease liability	14b	5,035	-	282
Purchase of property and equipment		$ 992	$ 720	$ 1,681

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

NOTE 1: - GENERAL

a. General description of the Company and its activity

Kamada Ltd. ("the Company") is a plasma-derived biopharmaceutical company focused on orphan indications, with an existing marketed product portfolio and a late-stage product pipeline. The Company uses its proprietary platform technology and know-how for the extraction and purification of proteins from human plasma to produce Alpha-1 Antitrypsin (AAT) in a highly-purified, liquid form, as well as other plasma-derived immune globulins. The Company's flagship product is Glassia® ("Glassia"), the first liquid, ready-to-use, intravenous plasma-derived AAT product approved by the U.S. FDA. The Company markets Glassia in the U.S. through a strategic partnership with Takeda Pharmaceuticals Company Limited ("Takeda") and in other counties through local distributors. The Company's second leading product is KamRab®, a rabies immune globulin (Human) for post-exposure prophylaxis against rabies infection. KamRab is FDA approved and is being marketed in the U.S. under the brand name KedRab through a strategic partnership with Kedrion S.p.A ("Kedrion"). In addition to Glassia and KedRab, the Company has a product line of four other plasma-derived pharmaceutical products administered by injection or infusion, that are marketed through distributors in more than 15 countries, including Israel, Russia, Brazil, India and other countries in Latin America and Asia. The Company has late-stage products in development, including an inhaled formulation of AAT for the treatment of AAT deficiency. In addition, the Company's intravenous AAT is in development for other indications, such as GvHD and prevention of lung transplant rejection. The Company leverages its expertise and presence in the plasma-derived protein therapeutics market by distributing more than 20 complementary products in Israel that are manufactured by third parties.

Pursuant to the agreement with Takeda (as detailed on Note 17) the Company will continue to produce Glassia for Takeda through 2021. Takeda is planning to complete the technology transfer of Glassia, and pending FDA approval, will initiate its own production of Glassia for the U.S. market in 2021. Accordingly, following the transition of manufacturing to Takeda, the Company will terminate the manufacturing and sale of Glassia to Takeda resulting in a significant reduction in revenues. Pursuant to the agreement, upon initiation of sales of Glassia manufactured by Takeda, Takeda will pay royalties to the Company at a rate of 12% on net sales through August 2025, and at a rate of 6% thereafter until 2040, with a minimum of $5 million annually, for each of the years from 2022 to 2040.

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

Proprietary Products	Development, manufacturing, sales and distribution of plasma-derived protein therapeutics.
Distribution	Distribute imported drug products in Israel, which are manufactured by third parties.

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

The Company has three wholly-owned subsidiaries – Kamada Inc. and Kamada Ireland limited which are not active and Kamada Biopharma Limited. 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 International Accounting Standard ("IAS") 24.
USD/$	-	U.S. dollar.
NIS	-	New Israeli Shekel
EUR	-	Euro

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES

a. Basis of presentation of financial statements

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

2. Measurement basis:

The Company's consolidated Financial Statements are prepared on a cost basis, except for financial instruments (including derivatives) at fair value through profit or loss and other comprehensive income such as marketable securities financial assets.

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, 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. Non-monetary assets and liabilities denominated in foreign currency and measured at fair value are translated into the functional currency using the exchange rate prevailing at the date when the fair value was determined.

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

e. Cash and cash equivalents

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

f. Short-term deposits

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

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, 2019 the Company recognized an allowance for doubtful accounts at an amount of $67 thousands.

The Company did not recognize an allowance in respect of groups of customers that are collectively assessed for impairment since it did not identify any groups of customers which bear similar credit risks. Impaired receivables are derecognized when they are assessed as uncollectible.

h. Inventories

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

Cost of inventories is determined as follows:

Raw materials	At cost using the first-in, first-out method. Fair value of raw material received at no charge is not included in the inventory value.
Work in process	Costs of raw materials, direct and indirect costs including labor, other materials and other indirect manufacturing costs allocated to the in process manufactured batches through the end of the reporting period. The allocation of indirect costs is accounted for on a quarterly basis by dividing the total quarterly indirect manufacturing cost to the batches manufactured during that quarter based on predetermined allocation factors.
Finished products	Costs of raw materials, direct and indirect costs including labor, other materials and other indirect manufacturing costs allocated to the manufactured finished products through completion of manufacturing process.
Purchased products	At cost using the first-in, first-out method.

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

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

i. Research and development costs

Research expenditures are recognized in profit or loss when incurred and include preclinical and clinical costs (as well as cost of materials associated with the development of new products or existing products for new therapeutic indications). In addition, these costs include additional product development activities with respect to approved and distributed products as well as post marketing commitment research and development activities.

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

j. Revenue recognition

On January 1, 2018, the Company initially adopted IFRS 15, "Revenue from Contracts with Customers" ("the Standard"). The Company elected to apply the provisions of the Standard using the modified retrospective method with the application of certain practical expedients and without restatement of comparative data. The accounting policy for revenue recognition applied from January 1, 2018, is as follows:

The Company recognizes revenue when the customer obtains control over the promised goods or services. Revenues are recognized at an amount that reflects the consideration to which an entity expects to be entitled in exchange for transferring goods or services to a customer. The Company includes variable consideration, such as milestone payments or volume rebates, in the transaction price only when it is highly probable that its inclusion will not result in a significant revenue reversal in the future when the uncertainty has been subsequently resolved

In determining the amount of revenue from contracts with customers, the Company evaluates whether it is a principal or an agent in the arrangement. The Company is a principal when the Company controls the promised goods or services before transferring them to the customer. In these circumstances, the Company recognizes revenue for the gross amount of the consideration.

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

Identifying the contract

The Company account for a contract with a customer only when all of the following criteria are met:

a) The parties to the contract have approved the contract (in writing, orally or in accordance with other customary business practices) and are committed to perform their respective obligations;

b) The Company can identify each party's rights regarding the goods or services to be transferred;

c) The Company can identify the payment terms for the goods or services to be transferred;

d) The contract has commercial substance (i.e. the risk, timing or amount of the entity's future cash flows is expected to change as a result of the contract); and

e) It is probable that the Company will collect the consideration to which it will be entitled in exchange for the goods or services that will be transferred to the customer

For the purpose of paragraph (e) the Company examines, inter alia, the percentage of the advance payments received and the spread of the contractual payments, past experience with the customer and the status and existence of sufficient collateral.

Combination of contracts

The Company accounts for multiple contracts as a single contract when all the contracts are signed at or near the same time with the same customer or with related parties of the customer, and when one of the following criteria is met:

a) The contracts are negotiated as a package with a single commercial objective.

b) The amount of consideration to be paid in one contract depends on the consideration of another contract.

c) The goods or services that the Company will provide according to the contracts represent a single performance obligation for the Company.

Identifying performance obligations

On the contract's inception date the Company assesses the goods or services promised in the contract with the customer and identifies the performance obligations in it.

The Company identifies the performance obligations when the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer and the Company promise to transfer the good or service to the customer is separately identifiable from other promises in the contract.

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

Determining the transaction price

The transaction price is the amount of the consideration that is expected to be received based on the contract terms. The Company takes into account the effects of all the following elements when determining the transaction price:

a) Variable consideration – The Company determines the transaction price separately for each contract with a customer. When exercising this judgment, the Company evaluates the effect of each variable amount in the contract, taking into consideration discounts, penalties, variations, claims, and non-cash consideration. The Company includes the estimated variable consideration in the transaction price only to the extent it is highly probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty is resolved. The Company updates the estimated transaction price to represent faithfully the circumstances present at the end of the reporting period and the changes in circumstances during the reporting period.

b) Existence of a significant financing component – the Company adjusts the amount of the promised consideration in respect of the effects of the time value of money when certain advance payments provide the Company with a significant financing benefit. The financing component is recognized as interest expenses over the period, which are calculated according to the effective interest method.

c) Non-cash consideration - Non-cash consideration is measured at the fair value for goods receivable on a contract's inception.

d) Consideration payable to customers- The Company accounts for payments made to a customer as a reduction of the revenues from the customer when the Company recognizes revenue from the transfer of goods or services to the customer or the Company pays the consideration or promises to pay the consideration in accordance with the Company's customary business practices. When the consideration payable to a customer is a payment for a distinct good or service from the customer, then the Company accounts for the purchase of the good or service in the same way it accounts for other purchases from suppliers.

Allocating the transaction price

For contracts that consist of more than one performance obligation, at contract inception the Company allocates the contract transaction price to each performance obligation identified in the contract on a relative stand-alone selling price basis. The stand-alone selling price is the price at which the Company would sell the promised goods or services separately to a customer. When the stand-alone selling price is not directly observable by reference to similar transactions with similar customers, the Company applies suitable methods for estimating the stand-alone selling price including: the adjusted market assessment approach, the expected cost plus a margin approach and the residual approach. The Company may also use a combination of these approaches to allocate the transaction price in the contract.

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

Satisfaction of performance obligations

The Company recognizes revenue from contracts with customers when the control over the goods or services is transferred to the customer.

For most contracts, revenue recognition occurs at a point in time when control of the asset is transferred to the customer, generally on delivery of the goods. For agreements with a strategic partner, performance obligations are generally satisfied over time, given that the customer both simultaneously receives and consumes the benefits provided by the Company, or receives assets with no alternative use, for which the Company has an enforceable right to payment for performance completed to date. The method for measuring the progress of performance obligations that are satisfied over time usually based upon the deliverables forming part of performance obligations.

Contract modifications

A contract modification is a change in the scope or price (or both) of a contract that was approved by the parties to the contract. A contract modification can be approved in writing, orally or be implied by customary business practices. A contract modification can take place also when the parties to the contract have a disagreement regarding the scope or price (or both) of the modification or when the parties have approved the modification in scope of the contract but have not yet agreed on the corresponding price modification.

When a contract modification has not yet been approved by the parties, the Company continues to recognize revenues according to the existing contract, while disregarding the contract modification, until the date the contract modification is approved or the contract modification is legally enforceable.

The Company accounts for a contract modification as an adjustment of the existing contract since the remaining goods or services after the contract modification are not distinct and therefore constitute a part of one performance obligation that is partially satisfied on the date of the contract modification. The effect of the modification on the transaction price and on the rate of progress towards full satisfaction of the performance obligation is recognized as an adjustment to revenues (increase or decrease) on the date of the contract modification, meaning on a catch-up basis.

When a contract modification increases the scope of the contract as a result of adding distinct goods or services and the contract price changes by an amount reflecting the stand-alone selling prices of the additional goods or services, the Company accounts for the contract modification as a separate contract.

The Company generate revenue mainly from sale of products to strategic partners and distributors as well as from the licensing of our technology and distribution rights.

The Company identifies the goods and services it promises in its contracts with customers and analyzes whether each good or service promised is distinct. The Company further groups a series of distinct goods or services to a single performance obligation.

The Company’s conclusion depends on the specific facts and circumstances pertaining to a contract.

In the majority of contracts, revenue recognition occurs at a point in time when control of our product is transferred to the customer, generally on delivery of the goods.

With regards to certain contract with our strategic partner the Company analyzed the following:

The Company identified few performance obligations which include:

a. Grant of a license for distribution one of the Company’s products in certain territories and the supply of predetermined minimum quantities.
b. The supply of a predetermined quantity of the Company’s product for the purpose of clinical trials performed conducted by strategic partner.
c. Grant of a license for the use of the Company’s knowledge and patents, and the provision of consulting services with respect to the transfer of technology.

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

Subsequently, the Company determines the transaction price. The transaction price is the amount of the consideration that is expected to be received based on the contract terms. The Company takes into account the effects of all the following elements when determining the transaction price

a. Variable consideration – certain amounts of the promised consideration such as milestone payments and volume rebates. The Company includes the estimated variable consideration in the transaction price only to the extent it is highly probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty is resolved.
b. Significant financing component – Advance payments received provide with the benefit of financing. Accordingly the Company adjusted the transaction price for the effects of the time value of money.
c. Non-cash consideration – Raw materials provided as non-cash consideration. This consideration is measured at fair value.
d. Consideration payable to customers- The Company accounts for payments made to a customer as a reduction of the revenues from the customer when the Company recognizes revenue from the transfer of goods or services to the customer or the Company pays the consideration or promises to pay the consideration in accordance with the Company's customary business practices.

The Company allocates the transaction price to the different performance obligation identified. This allocation is based on relative stand-alone selling price. For certain amounts of variable consideration the Company allocated to a certain performance obligation or to a distinct goods or services within it.

For each performance obligation identified, the Company recognizes revenue when (or as) it satisfies the performance obligation. The performance obligations are satisfied over time, as the customer both simultaneously receives and consumes the benefits provided by the Company, or receives assets with no alternative use, for which the Company has an enforceable right to payment for performance completed to date. The method for measuring the progress in performance obligations that are satisfied over time usually based upon the deliverables forming part of those performance obligations.

Deferred revenues

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

The accounting policy for revenue recognition applied until December 31, 2017

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.

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

k. Taxes on income

Taxes on income in profit or loss comprise of current and deferred taxes. Current or deferred taxes are recognized in profit or loss, except to the extent that the tax arises from items which are recognized directly in other comprehensive income or 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 carryforward losses and 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. Deductible carryforward losses and temporary differences for which deferred tax assets had not been recognized are reviewed at the end of each reporting period and a respective deferred tax asset is recognized to the extent that their utilization is probable.

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.

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

3. IFRIC 23, "Uncertainty over Income Tax Treatments":

In June 2017, the IASB issued IFRIC 23, "Uncertainty over Income Tax Treatments" ("the Interpretation"). The Interpretation clarifies the accounting for recognition and measurement of assets or liabilities in accordance with the provisions of IAS 12, "Income Taxes", in situations of uncertainty involving income taxes. The Interpretation provides guidance on (i) considering whether some tax treatments should be considered collectively, (ii) measurement of the effects of uncertainty involving income taxes on the financial statements and (iii) accounting for changes in facts and circumstances in respect of the uncertainty.

As of December 31, 2019 and 2018, the application of IFRIC 23 did not have a material effect on the financial statements.

l. Leases

As of January 1, 2019 the Company initially applied IFRS 16, "Leases" ("the Standard").

The Company chose to apply the provisions of the Standard using the modified retrospective approach without restatement of comparative data.

The accounting policy for leases applied effective from January 1, 2019, is as follows:

The Company accounts for a contract as a lease when the contract terms convey the right to control the use of an identified asset for a period of time in exchange for consideration.

On the inception date of the lease, the Company determines whether the arrangement is a lease or contains a lease, while examining if it conveys the right to control the use of an identified asset for a period of time in exchange for consideration. In its assessment of whether an arrangement conveys the right to control the use of an identified asset, the Company assesses whether it has the following two rights throughout the lease term:

a) The right to obtain substantially all the economic benefits from use of the identified asset; and

b) The right to direct the identified asset's use.

The Company as a lessee:

For leases in which the Company is the lessee, the Company recognizes on the commencement date of the lease a right-of-use asset and a lease liability, excluding leases whose term is up to 12 months and leases for which the underlying asset is of low value. For these excluded leases, the Company has elected to recognize the lease payments as an expense in profit or loss on a straight-line basis over the lease term. In measuring the lease liability, the Company has elected to apply the practical expedient in the Standard and does not separate the lease components from the non-lease components (such as management and maintenance services, etc.) included in a single contract.

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

On the commencement date, the lease liability includes all unpaid lease payments discounted at the interest rate implicit in the lease, if that rate can be readily determined, or otherwise using the Company's incremental borrowing rate. After the commencement date, the Company measures the lease liability using the effective interest rate method.

On the commencement date, the right-of-use asset is recognized in an amount equal to the lease liability plus lease payments already made on or before the commencement date and initial direct costs incurred less any lease incentives received. The right-of-use asset is measured applying the cost model and depreciated over the shorter of its useful life or the lease term. The Company tests for impairment of the right-of-use asset whenever there are indications of impairment pursuant to the provisions of IAS 36.

Depreciation of right-of-use asset

After lease commencement, a right-of-use asset is measured on a cost basis less accumulated depreciation and accumulated impairment losses and is adjusted for re-measurements of the lease liability. Depreciation is calculated on a straight-line basis over the useful life or contractual lease period, whichever earlier, as follows:

	%	Mainly %
Land and Buildings	10	10
Vehicles	20-33	33
office equipment (i.e. printing and photocopying machines)	20	20

Lease extension and termination options:

A non-cancellable lease term includes both the periods covered by an option to extend the lease when it is reasonably certain that the extension option will be exercised and the periods covered by a lease termination option when it is reasonably certain that the termination option will not be exercised.

In the event of any change in the expected exercise of the lease extension option or in the expected non-exercise of the lease termination option, the Company re-measures the lease liability based on the revised lease term using a revised discount rate as of the date of the change in expectations. The total change is recognized in the carrying amount of the right-of-use asset until it is reduced to zero, and any further reductions are recognized in profit or loss.

Subleases:

In a transaction in which the Company is a lessee of an underlying asset (head lease) and the asset is subleased to a third party, the Company assesses whether the risks and rewards incidental to ownership of the right-of-use asset have been transferred to the sub-lessee, among others, by evaluating the sublease term with reference to the useful life of the right-of-use asset arising from the head lease.

When substantially all the risks and rewards incidental to ownership of the right-of-use asset have been transferred to the sub- lessee, the Company accounts for the sublease as a finance lease, otherwise it is accounted for as an operating lease. If the sublease is classified as a finance lease, the leased asset is derecognized on the commencement date and a new asset, "finance lease receivable" is recognized at an amount equivalent to the present value of the lease payments, discounted at the interest rate implicit in the lease. Any difference between the carrying amount of the leased asset before the derecognition and the carrying amount of the finance lease receivable is recognized in profit or loss.

Lease modification:

If a lease modification does not reduce the scope of the lease and does not result in a separate lease, the Company re-measures the lease liability based on the modified lease terms using a revised discount rate as of the modification date and records the change in the lease liability as an adjustment to the right-of-use asset.

If a lease modification reduces the scope of the lease, the Company recognizes a gain or loss arising from the partial or full reduction of the carrying amount of the right-of-use asset and the lease liability. The Company subsequently remeasures the carrying amount of the lease liability according to the revised lease terms, at the revised discount rate as of the modification date and records the change in the lease liability as an adjustment to the right-of-use asset.

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

For additional information regarding right-of-use assets and lease liabilities and refer to Note 14.

The accounting policy for leases applied until December 31, 2018, is as follows:

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

The Company as lessee:

1. Finance lease

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

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

2. Operating lease

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

m. Property, plant and equipment

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

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

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

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

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

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

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

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

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

n. Impairment of non-financial assets

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

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

An impairment loss of an asset, is reversed only if there have been changes in the estimates used to determine the asset's recoverable amount since the last impairment loss was recognized. Reversal of an impairment loss, as above, shall not be increased above the lower of the carrying amount that would have been determined (net of depreciation or amortization) had no impairment loss been recognized for the asset in prior years and its recoverable amount. The reversal of impairment loss of an asset presented at cost is recognized in profit or loss.

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

o. Financial instruments

On January 1, 2018, the Company initially adopted IFRS 9, "Financial Instruments" ("the Standard"). The Company elected to apply the provisions of the Standard retrospectively without restatement of comparative data.

The accounting policy for financial instruments applied commencing from January 1, 2018, is as follows:

1. Financial assets

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

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

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

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

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

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

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

Impairment of financial assets

The Company evaluates at the end of each reporting period the loss allowance for financial debt instruments which are not measured at fair value through profit or loss. The Company distinguishes between two types of loss allowances:

a) Debt instruments whose credit risk has not increased significantly since initial recognition, or whose credit risk is low - the loss allowance recognized in respect of this debt instrument is measured at an amount equal to the expected credit losses within 12 months from the reporting date (12-month ECLs); or

b) Debt instruments whose credit risk has increased significantly since initial recognition, and whose credit risk is not low - the loss allowance recognized is measured at an amount equal to the expected credit losses over the instrument's remaining term (lifetime ECLs).

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

The Company has short-term financial assets such as trade receivables in respect of which the Company applies a simplified approach and measures the loss allowance in an amount equal to the lifetime expected credit losses.

An impairment loss on debt instruments measured at amortized cost is recognized in profit or loss with a corresponding loss allowance that is offset from the carrying amount of the financial asset, whereas the impairment loss on debt instruments measured at fair value through other comprehensive income is recognized in profit or loss with a corresponding loss allowance that is recorded in other comprehensive income and not as a reduction of the carrying amount of the financial asset in the statement of financial position.

The Company applies the low credit risk simplification in the Standard, according to which the Company assumes the debt instrument's credit risk has not increased significantly since initial recognition if on the reporting date it is determined that the instrument has a low credit risk, for example when the instrument has an external rating of "investment grade".

In addition, the Company considers that when contractual payments in respect of a debt instrument are more than 30 days past due, there has been a significant increase in credit risk, unless there is reasonable and supportable information that demonstrates that the credit risk has not increased significantly.

The Company considers a financial asset in default when contractual payments are more than 90 days past due. However, in certain cases, the Company considers a financial asset to be in default when external or internal information indicates that the Company is unlikely to receive the outstanding contractual amounts in full.

The Company considers a financial asset that is not measured at fair value through profit or loss as credit-impaired when one or more events that have a detrimental impact on the estimated future cash flows of that financial asset have occurred. The Company takes into consideration the following events as evidence that a financial asset is credit impaired:

a) significant financial difficulty of the issuer or borrower;

b) a breach of contract, such as a default or past due event;

c) a concession granted to the borrower due to the borrower's financial difficulties that would otherwise not be granted;

d) it is probable that the borrower will enter bankruptcy or financial reorganization;

e) the disappearance of an active market for that financial asset because of financial difficulties; or

f) the purchase or origination of a financial asset at a deep discount that reflects the incurred credit losses.

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

ECLs are based on the difference between the contractual cash flows due in accordance with the contract and all the cash flows that the Company expects to receive. For other debt financial assets (i.e., debt securities at FVOCI), the ECL is based on the 12-month ECL. The 12-month ECL is the portion of lifetime ECLs that results from default events on a financial instrument that are possible within 12 months after the reporting date. As of December 31, 2019 there is no ECL allowance.

2. Financial liabilities

Financial liabilities within the scope of IFRS 9 are initially measured at fair value less transaction costs that are directly attributable to the issue of the financial liability.

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

a) Financial liabilities measured at amortized cost

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

b) Financial liabilities measured at fair value

Derivatives are classified as fair value through profit and loss unless they are designated as effective hedging instruments. Transaction costs are recognized in profit or loss.

After initial recognition, changes in fair value are recognized either in profit or loss for non-hedge accounting derivatives or in other comprehensive income for hedge accounting derivatives.

p. Fair value measurement

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

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

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

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.

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

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).

1. 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.

2. De-recognition of financial instruments

a. Financial assets

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

b. Financial liabilities

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

q. Derivative financial instruments designated as hedges

The Company enters into contracts for derivative financial instruments such as forward currency contracts and cylinder strategy in respect of foreign currency to hedge risks associated with foreign exchange rates fluctuations and cash flows risk. Such derivative financial instruments are carried as financial assets when the fair value is positive and as financial liabilities when the fair value is negative.

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

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

Any gains or losses arising from changes in the fair value of derivatives that do not qualify for hedge accounting are recorded immediately in profit or loss.

Cash flow hedges

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

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

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

r. Provisions

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

s. Employee benefit liabilities

The Company has several employee benefit plans:

1. Short-term employee benefits

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

2. Post-employment benefits

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

The Company has defined contribution plans pursuant to Section 14 to the Israeli Severance Pay Law under which the Company pays fixed contributions to certain employees under Section 14 and will have no legal or constructive obligation to pay further contributions.

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 Israeli Severance Pay Law. According to the Law, employees are entitled to severance pay upon dismissal or retirement. The liability for termination of employment is measured using the projected unit credit method. The actuarial assumptions include expected salary increases and rates of employee's turnover based on the estimated timing of payment. The amounts are presented based on discounted expected future cash flows using a discount rate determined by reference to market yields at the reporting date on high quality corporate bonds that are linked to the Consumer Price Index with a term that is consistent with the estimated term of the severance pay obligation.

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

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

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

t. Share-based payment transactions

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

Equity-settled transactions

The cost of equity-settled transactions (options and restricted shares) with employees and Board of Directors members is measured at the fair value of the equity instruments granted at grant date. The fair value of options is determined using a standard option pricing model. The fair value of restricted shares is determined using the share price at the grant date.

The cost of equity-settled transactions is recognized in profit or loss together with a corresponding increase in shareholder's equity during the period which the performance and/or service conditions are to be satisfied ending on the date on which the relevant employees become entitled to the award ("the vesting period"). The cumulative expense recognized for equity-settled transactions at the end of each reporting period until the vesting date reflects the extent to which the vesting period has expired and the Company's best estimate of the number of equity instruments that will ultimately vest.

No expense is recognized for awards that do not ultimately vest.

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

u. Earnings (loss) per Share

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

v. Reclassification of prior years' amounts

Certain amounts in prior years' financial statements have been reclassified to conform to the current year's presentation. The reclassification had no effect on previously reported net loss or shareholders' equity.

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

w. Changes in accounting policies - initial application of new financial reporting and accounting standards and amendments to existing financial reporting and accounting standards:

Initial application of IFRS 16, "Leases"

In January 2016, the IASB issued IFRS 16, "Leases" ("the Standard"), which provides guidance on the recognition, measurement, presentation and disclosure of leases and supersedes IAS 17, "Leases" ("the old Standard"), IFRIC 4, "Determining Whether an Arrangement Contains a Lease", and SIC-15, "Operating Leases - Incentives". According to the Standard, a lease is a contract, or part of a contract, that conveys the right to use an asset for a period of time in exchange for consideration.

The Standard has been applied for the first time in these financial statements. As permitted by the Standard, the Company elected to apply the provisions of the Standard using the modified retrospective method. The Company recognized lease liabilities on the initial application date of the Standard in respect of leases previously classified as operating leases according to IAS 17. The amount of the liability as of the date of initial application of the Standard was measured using the Company's incremental borrowing rate of interest on the date of initial application of the Standard.

Certain right-of-use assets were measured as if the Standard has been applied from the commencement date of the lease but for the purpose of calculation, the lessee's incremental borrowing rate on the date of initial adoption was used, while the carrying amount of other right-of-use assets are identical to the carrying amount of the lease liability. For details of the accounting policy applied from the date of initial application of the Standard, see Note 14b.

The main effect of the initial application of the Standard relates to existing leases in which the Company is the lessee. According to the Standard, as explained in Note 14b, the Company recognizes a lease liability and a corresponding right-of-use asset for each lease in which it is the lessee, excluding certain exceptions. This accounting treatment is different than the accounting treatment applied under the old Standard according to which the lease payments in respect of leases for which substantially all the risks and rewards incidental to ownership of the leased asset were not transferred to the lessee were recognized as an expense in profit or loss on a straight-line basis over the lease term.

Following are data relating to the initial application of the Standard as of January 1, 2019, in respect of leases existing as of that date:

	According to the previous accounting policy	Difference	According to the current accounting policy
	U.S Dollars in thousands		
As of January 1, 2019			
Non-current assets:			
Right-of-use assets	$ -	$ 4,161	$ 4,161
Liabilities			
Current maturities of leases	110	810	920
Leases	28	3,907	3,935
Other accounts payables	$ 5,261	$ (255)	$ 5,006
Shareholder's Equity			
Accumulated deficit	$ 112,376	$ (300)	$ 112,076

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (CONT.)

The lease liabilities as at January 1, 2019 can be reconciled to the operating lease commitments as of December 31, 2018 as follows:

	U.S Dollars In thousands
Future minimum payments for non-cancellable leases as per IAS 17 according to the financial statements as of December 31, 2018	$ 5,434
Weighted average incremental borrowing rate as at January 1, 2019 (1)	3.06%-4.6%
Discounted operating lease commitment at January 1, 2019	4,685
Add:	
Leases of other equipment	32
Leases that were previously identified as leases under IAS 17	138
Lease liabilities as at January 1, 2019	$ 4,855

(1) The weighted average incremental borrowing rate was evaluated based on credit risk, terms of the leases and other economic variables. The weighted average incremental borrowing rate was used to discount future lease payments in the calculation of the lease liability on the date of initial adoption of the Standard.

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

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

a. Judgments

- Determining the fair value of share-based payment transactions

  The fair value of share-based payment transactions is determined upon initial recognition by an acceptable option pricing model. The inputs to the model include share price, exercise price and assumptions regarding expected volatility, expected life of share option and expected dividend yield.

- Discount rate for a lease liability

  When the Company is unable to readily determine the discount rate implicit in a lease in order to measure the lease liability, the Company uses an incremental borrowing rate. That rate represents the rate of interest that the Company would have to pay to borrow over a similar term and with similar security, the funds necessary to obtain an asset of similar value to the right-of-use asset in a similar economic environment. When there are no financing transactions that can serve as a basis, the Company determines the incremental borrowing rate based on its credit risk, the lease term and other economic variables deriving from the lease contract's conditions and restrictions. In certain situations, the Company is assisted by an external valuation expert in determining the incremental borrowing rate.

- Revenue

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

- Inventory

  Work in process and Finished Good including direct and indirect costs. The allocation of indirect costs is accounted for on a quarterly basis by dividing the total quarterly indirect manufacturing cost to the batches manufactured during that quarter based on predetermined allocation factors. The criteria for allocation of indirect manufacturing expense to manufactured batches which eventually effect our inventory value is subject to Company judgment.

b. Estimates and assumptions

The preparation of the financial statements requires management to make estimates and assumptions that have an effect on the application of the accounting policies and on the reported amounts of assets, liabilities, revenues and expenses. Changes in accounting estimates are reported in the period of the change in estimate.

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

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

- 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.

- Lease extension and/or termination options

  In evaluating whether it is reasonably certain that the Company will exercise an option to extend a lease or not exercise an option to terminate a lease, the Company considers all relevant facts and circumstances that create an economic incentive for the Company to exercise the option to extend or not exercise the option to terminate such as: significant amounts invested in leasehold improvements, the significance of the underlying asset to the Company's operation and whether it is a specialized asset, the Company's past experience with similar leases, etc.

  After the commencement date, the Company reassesses the term of the lease upon the occurrence of a significant event or a significant change in circumstances that affects whether the Company is reasonably certain to exercise an option or not exercise an option previously included in the determination of the lease term, such as significant leasehold improvements that had not been anticipated on the lease commencement date, sublease of the underlying asset for a period that exceeds the end of the previously determined lease period, etc.

- Provisions for clinical trial and related expenses

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

- Capitalization of materials for clinical trials and inventory designated for R&D activities

  The Company recognizes inventory produced for commercial sale, including costs incurred prior to regulatory approval but subsequent to the filing of a regulatory request when the Company has determined that the inventory has probable future economic benefit. Inventory is not recognized prior to completion of a phase III clinical trial. For products with an approved indication, raw materials and purchased drug product associated with development programs are included in inventory and charged to research and development expense when consumed. For products without an approved indication, drug product is charged to research and development expense.

- Impairment of inventories with realizable value lower than cost or which are slow moving

  Inventories are measured at the lower of cost and net realizable value. The cost of inventories comprises costs of purchase of raw and other materials and costs incurred in bringing the inventories to their present location and condition. Net realizable value is the estimated selling price in the ordinary course of business, net of selling expenses. The estimation of realizable value can effect on the inventory value at the period end.

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

  Deferred tax assets are recognized for unused carryforward tax losses and deductible temporary differences to the extent that it is probable that taxable profit will be available against which the losses can be utilized. Significant management judgment is required to determine the amount of deferred tax assets that can be recognized, based upon the timing and level of future taxable profits, its source and the tax planning strategy. For information regarding deferred taxes recognition, please refer to note 21.

- Impairment test for the production facility

  The Company performed an impairment test of its production facility. The Company calculated the recoverable amount of the production facility to determine whether the book value exceeds its recoverable amount. The impairment test was based on a Discount Cash Flow ("DCF") model using the Company's long term forecast. As of December 31, 2019 no impairment was recorded as the recoverable amount exceeded the book value.

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

- Legal claims

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

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

Amendments to IFRS 9, IFRS 7 and IAS 39:

In September 2019, the IASB published an amendment to IFRS 9, "Financial Instruments", IFRS 7, "Financial Instruments: Disclosures" and IAS 39," Financial Instruments: Recognition and Measurement" ("the Amendment").

In view of global regulatory changes, numerous countries have considered introducing a reform in the benchmark Interbank Offered Rates ("IBORs") (LIBOR, the London Interbank Offered Rate, being one of the most common examples) and switching to a risk-free interest rate alternative ("RFRs") which extensively rely on data of specific transactions. The IBOR reform leads to uncertainty regarding the dates and amounts to be attributed to future cash flows relating to both hedging instruments and hedged items that rely on existing IBORs.

According to the existing accounting guidance of IFRS 9 and IAS 39, entities that have entered into the above hedges are facing uncertainty as a result of the IBOR reform which is likely to affect their ability to continue meeting the effective hedging requirements underlying existing transactions as well as the hedging requirements of future transactions. In order to resolve this uncertainty, the IASB issued the Amendment to offer transitional reliefs for entities that apply IBOR-based hedge accounting. The Amendment represents phase one in the reform that will include additional amendments in the future.

The Amendment also permits certain reliefs in applying the hedge accounting effectiveness tests during the period of transition from IBORs to RFRs. These reliefs assume that the benchmark interest underlying the hedge will not change as a result of the expected interest reform. The reliefs will be effective indefinitely, until the occurrence of one of the events specified in the Amendment. The Amendment also requires entities to provide specific disclosures of the application of any reliefs.

The Amendment is to be applied retrospectively for annual periods beginning on or after January 1, 2020. Early adoption is permitted.

The Company believes that the adoption of the Amendment will not have an effect on its financial statements since it does not currently enter into substantial IBOR-based hedges.

NOTE 5: - CASH AND CASH EQUIVALENTS

	December 31,	
	2019	2018
	U.S. Dollars in thousands	
Cash and deposits for immediate withdrawal	$ 25,559	$ 18,018
Cash equivalents in USD deposits (1)	17,017	-
Cash equivalents in NIS deposits (2)	86	75
Total Cash and Cash Equivalents	$ 42,662	$ 18,093

(1) The deposits bear interest of 2.0%-2.4% per year, as of December 31, 2019.
(2) The deposits bear interest of 0.02% per year, as of December 31, 2019 and 0.16% per year, as of December 31, 2018.

NOTE 6: - SHORT-TERM INVESTMENTS

	December 31,	
	2019	2018
	U.S. Dollars in thousands	
Fair value through other comprehensive income	$ 12,832	$ 10,325
Bank deposits in USD (1)	18,413	22,174
Total Short-Term Investments	$ 31,245	$ 32,499

(1) The deposits bear interest of 2.5%-3.3% and 2.6%-3.5% per year, as of December 31, 2019 and 2018, respectively.

NOTE 7: - TRADE RECEIVABLES, NET

	December 31,	
	2019	2018
	U.S. Dollars in thousands	
Open accounts:		
In NIS	$ 8,357	$ 6,780
In USD	14,920	20,814
	$ 23,277	$ 27,594
Checks receivable	-	80
	$ 23,277	$ 27,674
Less allowance for doubtful accounts(1)	(67)	-
Total Trade receivables, net	$ 23,210	$ 27,674

(1) Allowance for doubtful accounts:

December 31, 2018	-
Provision for the year	(67)
December 31, 2019	(67)

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

	Past due trade receivables with aging of						
	Neither past due nor impaired	Up to 30 Days	31-60 Days	61-90 Days	91-120 Days	Over 121 days	Total
December 31, 2019	$ 22,617	$ 469	$ 25	$ 33	$ 65	$ 68(1)	$ 23,277
December 31, 2018	$ 27,215	$ 337	$ 15	$ 15	$ 6	$ 6	$ 27,594

(1) $67 thousands of the over 121 days balance is provided for as allowance for doubtful accounts.

NOTE 8: - OTHER ACCOUNTS RECEIVABLES

	December 31,	
	2019	2018
	U.S. Dollars in thousands	
Government authorities	$ 1,838	$ 1,552
Prepaid expenses	1,240	1,086
Accrued interest	70	66
Accrued income	101	193
Materials for clinical trials and inventory designated for R&D activities	-	399
Other	8	12
Derivatives financial instruments mainly measured at fair value through other comprehensive income	15	-
Total Other Accounts Receivables	$ 3,272	$ 3,308

NOTE 9: - INVENTORIES

	December 31,	
	2019	2018
	U.S. Dollars in thousands	
Finished products	$ 12,016	$ 7,023
Purchased products	10,412	4,813
Work in progress	9,043	4,792
Raw materials	11,702	12,688
Total Inventories	$ 43,173	$ 29,316

(1) The inventories balance as of December 31, 2019 and December 31, 2018 is presented net of impairment of inventories in the amount of $334 thousands and $61 thousands, respectively.

NOTE 10: - PROPERTY, PLANT AND EQUIPMENT

a. Composition and movement:

2019

	Land and Buildings (1)	Machinery and Equipment (1)	Vehicles	Computers, Software, Equipment and Office Furniture	Leasehold Improvements	Total
	U.S. Dollars in thousands					
Cost						
Balance at January 1, 2019	$ 29,167	$ 30,386	$ 85	$ 6,493	$ 1,141	$ 67,272
Additions	1,101	1,302	-	699	14	3,116
Sale and write-off	-	(148)	-	(391)	-	(539)
Balance as of December 31, 2019	30,268	31,540	85	6,801	1,155	69,849
Accumulated Depreciation						
Balance as of January 1, 2019	15,076	21,679	63	5,247	203	42,268
Depreciation	1,232	1,575	5	636	115	3,563
Sale and write-off	-	(142)	-	(390)	-	(532)
Balance as of December 31, 2019	16,308	23,112	68	5,493	318	45,299
Depreciated cost as of December 31, 2019	$ 13,960	$ 8,428	$ 17	$ 1,308	$ 837	$ 24,550

(1) Including labor costs charged in 2019 to the cost of facilities, machinery and equipment in the amount of $493 thousands.

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

2018

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

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

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

b. As for liens, refer to Note 18.

c. Leasing rights of land from the Israel land administration.

	December 31,	
	2019	2018
	U.S. Dollars in thousands	
Under finance lease	$ 992	$ 1,004

A Company's subsidiary capitalized leasing rights from the Israel Land Administration for an area of 16,880 m² in Beit Kama, Israel, on which the Company's manufacturing plant and other buildings are located. The sum attributed to capitalized rights is presented under property, plant and equipment and is depreciated over the leasing period, which includes the option period.

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

NOTE 11: - OTHER LONG TERM ASSETS

	December 31,	
	2019	2018
	U.S. Dollars in thousands	
Distribution right (1)	298	123
Long term pre-paid expenses	54	51
Total Other Long Term Assets	$ 352	$ 174

(1) During 2018 and 2019 the Company entered into agreements for the distribution right of certain therapeutic products to be distributed in Israel, subject to Israeli Ministry of Health ("IL MOH") marketing approval. Pursuant to the agreements, the Company was required to make certain upfront and milestone payments. These payments are accounted for as long term assets through obtaining IL MOH marketing authorization and it will be amortized during the product's economic useful life. As of December 31, 2019 no amortization was recorded.

NOTE 12: - TRADE PAYABLES

	December 31,	
	2019	2018
	U.S. Dollars in thousands	
Open debts mainly in USD	$ 7,847	$ 7,256
Open debts in EUR	11,426	4,206
Open debts in NIS	5,557	5,822
Sub-Total	24,830	17,284
Notes payable	-	1
Total Trade Payables	$ 24,830	$ 17,285

NOTE 13: - OTHER ACCOUNTS PAYABLES

	December 31,	
	2019	2018
	U.S. Dollars in thousands	
Employees and payroll accruals	$ 5,669	$ 4,708
Derivatives financial instruments mainly measured at fair value through other comprehensive income	-	64
Accrued Expenses and Others	142	489
Total Other Accounts Payables	$ 5,811	$ 5,261

NOTE 14: - LOANS AND LEASES

a. Bank loans

	December 31,	
	2019	2018
	U.S. Dollars in thousands	
Bank loans	746	688
Less current maturities of bank loans	257	452
Total Long term bank loans	$ 489	$ 1,140

Bank loans
The bank loans are payable over 60 equal monthly installments. The loans bear fixed interest rate in the range of 3.15% -3.55%. No new bank loans received in 2019. See Note 18 regarding pledge information related to the bank loans.

b. Leases

The Company applies IFRS 16, Leases, as from January 1, 2019. The Company has lease agreements with respect to the following items:

1. Office and storage spaces:

   The Company has engaged in lease agreements for office and storage spaces for total of 10 years which includes lease extension for three year that will expire in 2026.

2. Vehicles:

   The Company leases vehicles for mainly for three-year periods from several different leasing companies.

3. Office equipment (i.e. printing and photocopying machines):

   The Company leases office equipment (i.e. printing and photocopying machines) for five year periods.

Right-of-use assets composition and Changes in leas liabilities

	Right-of-use-assets				
	Rented Offices	Vehicles	Computers, Software, Equipment and Office Furniture	Total	Lease Liabilities (2)
	U.S Dollars in thousands				
As of January 1, 2019(1)	$ 3,466	$ 663	$ 32	$ 4,161	$ 4,855
Additions to right -of -use assets	-	874		874	870
Write-off	-	(57)		(57)	(60)
Depreciation expense	(433)	(517)	(6)	(956)	-
Exchange rate differences	-	-		-	406
Repayment of lease liabilities	-	-		-	(1,070)
As of December 31, 2019	$ 3,033	$ 989	$ 26	$ 4,022	$ 5,001

(1) Following the initial application of IFRS 16, on January 1, 2019, the Company recorded operating lease commitment classified as a lease liability at the amount of $4,717 thousands with respect to office and storage spaces, vehicles and certain office equipment (i.e. printing and photocopying machines) at the amount of $4,022, $663 and $32 thousands, respectively. Also refer to Note 2ii.

(2) The weighted average incremental borrowing rate used to discount future lease payments in the calculation of the lease liability was in the range of 3.06%-4.6% evaluated based on credit risk, terms of the leases and other economic variables.

NOTE 14: - LOANS AND LEASES (CONT.)

Below is the Consolidated Statements of Profit or Loss and Other Comprehensive Income impact for the year ended December 31, 2019

	Expense decrease (increase) For the year ended on December 31, 2019
	U.S Dollars in thousands
Operating lease expense	$ 1,182
Depreciation of right of use assets	(956)
Operating income	226
Finance expense	(212)
Net Income (loss)	$ 14

Below is the Consolidated Statements of cash flow impact for the year ended December 31, 2019

	According to the previous accounting policy	Difference	According to the current accounting policy
		U.S Dollars in thousands	
For the year ended on December 31, 2019			
Cash flows from operating activities	$ 26,501	$ 1,070	$ 27,571
Cash flows from financing activities	$ (460)	$ (1,070)	$ (1,530)

Maturity analysis of the Company's lease liabilities (including interest)

	Less than one year	1 to 2	2 to 3	3 to 5	6 and thereafter	Total
Lease liabilities (including interest)	$ 1,198	$ 1,000	$ 797	$ 1,352	1,364	$ 5,711

Lease extension

The Company has leases that include extension options. These options provide flexibility in managing the leased assets and align with the Company's business needs.

The Company exercises significant judgement in deciding whether it is reasonably certain that the extension options will be exercised.

Office and storage spaces leases have extension options for additional three years. The Company have reasonably certain that the extension option will be exercised in order to avoid a significant adverse impact to its operating activities.

NOTE 15: - FINANCIAL INSTRUMENTS

a. Classification of financial assets and liabilities

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

	December 31,	
	2019	2018
	U.S. Dollars in thousands	
Financial assets		
Financial assets at fair value through profit or loss:		
Foreign exchange forward contracts	$ 2	$ -
Financial assets at fair value through other comprehensive income:		
Cash flow hedges	13	
Marketable debt securities	12,832	10,324
Financial assets at cost:		
Cash and cash equivalent	42,662	18,093
Short term bank deposits	18,413	22,175
Total assets measured at fair value through other comprehensive income	$ 73,920	$ 50,592
Total financial assets	$ 73,920	$ 50,592
Financial liabilities		
Financial assets at fair value through profit or loss:		
Foreign exchange forward contracts	$ -	$ 6
Financial liabilities at fair value through other comprehensive income:		
Cash flow hedges	$ -	$ 58
Financial liabilities measured at amortized cost:		
Bank loans	746	1,140
Leases	5,001	138
Total Financial liabilities measured at amortized cost:	$ 5,747	$ 1,278
Total financial and lease liabilities	$ 5,747	$ 1,342

NOTE 15: - FINANCIAL INSTRUMENTS (CONT.)

b. Financial risk factors

The Company's activities expose it to various financial risks, such as market risk (foreign currency risk, interest rate risk and price risk), credit risk and liquidity risk. The Company's investment policy focuses on activities that will preserve the Company's capital. The Company utilized derivatives to hedge certain exposures to risk.

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

1. Market risks

a) Foreign exchange risk

The Company operates in an international environment and is exposed to foreign exchange risk resulting from the exposure to different currencies, mainly the NIS and EUR. Foreign exchange risks arise from recognized assets and liabilities denominated in a foreign currency other than the functional currency, such as trade and other accounts receivables, trade and other accounts payables, loans and capital leases.

As of December 31, 2019 and 2018, the Company has a position in financial derivatives intended to hedge changes in the exchange rate of the USD vs. the NIS and the EUR (see also Note 15f. below).

b) Price risk

As of December 31, 2019 and 2018, the Company has financial instruments, classified as financial assets measured at fair value through other comprehensive income for which the Company is exposed to risk of fluctuations in the security price that is determined by reference to the quoted market price.

2. Credit risk

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

a) Cash, cash equivalent and short term investments:

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

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

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

b) Trade receivables:

The Company regularly monitors the credit extended to its customers and their general financial condition, and, when necessary, requires collateral as security for the debt such as letters of creditor and down payments. In addition, the Company partially insures its overseas sales with foreign trade risk insurance. Refer to Note 7 for additional information.

NOTE 15: - FINANCIAL INSTRUMENTS (CONT.)

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

The Company's maximum exposure to credit risk for the components of the statement of financial position as of December 31, 2019 and 2018 is the carrying amount of trade receivables.

c) Foreign currency derivative contracts:

The Company is exposed to foreign currency exchange movements, primarily in USD vs. NIS and EUR. Consequently, it enters into various foreign currency exchange contracts with major financial institutions (see also Note 15f. below).

3. Liquidity risk

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

December 31, 2019

	Less than one year	1 to 2	2 to 3	3 to 5	6 and thereafter	Total
Trade payables	$ 24,830	-	-	-	-	$ 24,830
Other accounts payables	5,811	-	-	-	-	5,811
bank loans (including interest)	506	227	34	-	-	767
Lease liabilities (including interest)	1,198	1,000	797	1,352	1,364	5,711
	$ 32,345	$ 1,227	$ 831	$ 1,352	$ 1,364	$ 37,119

NOTE 15: - FINANCIAL INSTRUMENTS (CONT.)

December 31, 2018

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

Changes in liabilities arising from financing activities

	January 1, 2019	Cumulative effect of initially applying IFRS 16 (1)	Payments	Foreign exchange movement	New loans and leases	Write off	December 31, 2019
	U.S. Dollars in thousands						
Bank loans	$ 1,140	-	(475)	81	-	-	$ 746
Leases	138	4,717	(1,070)	406	870	(60)	5,001
Total	$ 1,278	$ 4,717	$ (1,545)	$ 487	$ 870	$ (60)	$ 5,747

(1) Following the initial application of IFRS 16, on January 1, 2019, the Company recorded discounted operating lease commitment classified as a lease at the amount of $4,717 thousands with respect to office and storage spaces, vehicles and certain office equipment (i.e. printing and photocopying machines) at the amount of $4,023, $663 and $31 thousands, respectively.

c. Fair value

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

	Carrying Amount		Fair Value	
	December 31,		December 31,	
	2019	2018	2019	2018
	U.S. Dollars in thousands			
Financial liabilities				
Bank loans	746	1,140	754	1,139
Leases	5,001	138	5,583	136
Total Financial liabilities	$ 5,747	$ 1,278	$ 6,337	$ 1,275

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

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

NOTE 15: - FINANCIAL INSTRUMENTS (CONT.)

d. Classification of financial instruments by fair value hierarchy

Financial assets (liabilities) measured at fair value:

Financial assets (liabilities) measured at fair value:	**Level 1**	**Level 2**
	U.S. Dollars in thousands	
December 31, 2019		
Debt securities (corporate and government) measured at fair value through other comprehensive income	$ 4,289	8,543
Derivatives instruments	-	15
	$ 4,289	$ 8,558

	Level 1	**Level 2**
	U.S. Dollars in thousands	
December 31, 2018		
Debt securities (corporate and government) measured fair value through other comprehensive income	$ 1,588	8,736
Derivatives instruments	-	(64)
	$ 1,588	$ 8,672

During 2019 and 2018 there was no transfer due to the fair value measurement of any financial instrument from Level 1 to Level 2, and furthermore, there were no transfers to or from Level 3 due to the fair value measurement of any financial instrument.

Sensitivity tests and principal work assumptions

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

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

NOTE 15: - FINANCIAL INSTRUMENTS (CONT.)

	December 31,	
	2019	2018
	U.S. Dollars in thousands	
Sensitivity test to changes in market price of listed Securities		
Gain (loss) from change:		
5% increase in market price	$ 642	$ 519
5% decrease in market price	$ (642)	$ (519)
Sensitivity test to changes in foreign currency:		
Gain (loss) from change:		
5% increase in NIS	$ (24)	$ (21)
5% decrease in NIS	$ 24	$ 21
5% increase in Euro	$ (552)	$ (197)
5% decrease in Euro	$ 552	$ 197

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

	December 31,	
	2019	2018
	U.S. Dollars in thousands	
In NIS:		
Bank loans measured at amortized cost	$ 746	$ 1,140
Leases measured at amortized cost	4,973	-
	$ 5,719	$ 1,140
In USD:		
Leases measured at amortized cost	$ 28	$ 138

f. Derivatives and hedging:

Derivatives instruments not designated as hedging

The Company has foreign currency forward contracts designed to protect it from exposure to fluctuations in exchange rates, mainly of NIS and EUR, in respect of its trade receivables, trade payables and inventory. Foreign currency forward contracts are not designated as cash flow hedges, fair value or net investment in a foreign operation. These derivatives are not considered as hedge accounting. As of December 31, 2019 the fair value of the derivative instruments not designated as hedging was an asset of $2 thousands. The open transactions for those derivatives were in an amount of $6,316 thousands.

Cash flow hedges:

As of December 31, 2019, 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, 2019 the fair value of the derivative instruments designated as hedge accounting was an asset of $13 thousands. The open transactions for those derivatives were in an amount of $371 thousands.

Cash flow hedges of the expected salaries expenses in December 31, 2019 was estimated as highly effective and accordingly a net unrecognized income was recorded in other comprehensive income in the amount of $65 thousands net.

NOTE 16: - EMPLOYEE BENEFIT LIABILITIES, NET

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

Post-employment benefits:

According to the labor laws and Severance Pay Law in Israel, the Company is required to pay compensation to an employee upon dismissal or retirement or to make current contributions in defined contribution plans pursuant to Section 14 of the Severance Pay Law, as specified below. The Company's liability is accounted for as a post-employment benefit only for employees not under Section 14. The computation of the Company's employee benefit liability is made in accordance with a valid employment contract or a collective bargaining agreement based on the employee's salary and employment terms which establish the entitlement to receive the compensation.

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

1. Defined contribution deposit:

   The Company's agreements with part of its employees are in accordance with section 14 of the Israeli Severance Pay Law. Contributions made by the Company in accordance with Section 14 release the Company from any future severance liabilities in respect of those employees. The expenses for the defined benefit deposit in 2019, 2018 and 2017 were $1,102 thousands, $992 thousands and $884 thousands, respectively.

2. Defined benefit plans:

   The Company accounts for the payment of compensation as a defined benefit plan for which an employee benefit liability is recognized and for which the Company deposits amounts in a long-term employee benefit fund and in qualifying insurance policies.

3. Expenses recognized in comprehensive income (loss):

	Year Ended December 31,		
	2019	2018	2017
	U.S. Dollars in thousands		
Current service cost	$ 282	$ 292	$ 356
Interest expenses, net	24	25	23
Current service cost (income) due to the transfer of real yield from the compensation component to the royalties' component in executive insurance policies before 2004	(1)	3	(7)
Total employee benefit expenses	305	320	372
Actual return on plan assets	$ 158	$ 171	$ 119

NOTE 16: - EMPLOYEE BENEFIT LIABILITIES, NET (CONT.)

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

	Year Ended December 31,		
	2019	2018	2017
	U.S. Dollars in thousands		
Cost of revenues	$ 201	$ 175	$ 211
Research and development	62	50	57
Selling and marketing	16	75	73
General and administrative	26	20	31
	$ 305	$ 320	$ 372

4. The plan liabilities, net:

	December 31,	
	2019	2018
	U.S. Dollars in thousands	
Defined benefit obligation	$ 5,058	$ 4,987
Fair value of plan assets	(3,789)	(4,200)
Total liabilities, net	$ 1,269	$ 787

5. Changes in the present value of defined benefit obligation

	2019	2018
	U.S. Dollars in thousands	
Balance at January 1,	$ 4,987	$ 5,907
Interest costs	133	110
Current service cost	282	292
Benefits paid	(1,180)	(645)
Demographic assumptions	40	(29)
Financial assumptions	292	(223)
Past Experience	108	(2)
Currency Exchange	396	(423)
Balance at December 31,	$ 5,058	$ 4,987

6. Plan assets

a) Plan assets

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

NOTE 16: - EMPLOYEE BENEFIT LIABILITIES, NET (CONT.)

b) Changes in the fair value of plan assets

	2019	2018
	U.S. Dollars in thousands	
Balance at January 1,	$ 4,200	$ 4,763
Expected return	108	85
Contributions by employer	179	182
Benefits paid	(1,081)	(564)
Demographic assumptions	(4)	5
Financial assumptions	(2)	(2)
Past Experience	58	82
Current service cost due to the transfer of real yield from the compensation component to the royalties component in executive insurance policies before 2004	1	(3)
Currency exchange	330	(348)
Balance at December 31,	$ 3,789	$ 4,200

7. The principal assumptions underlying the defined benefit plan

	2019	2018	2017
		%	
Discount rate of the plan liability	2.79	2.02	2.27
Future salary increases	3.1	3.6	4

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

In the event that the discount rate would be one percent higher or lower, and all other assumptions were held constant, the defined benefit obligation would decrease by $288 thousands or increase by $343 thousands, respectively.

In the event that the expected salary growth would increase or decrease by one percent, and all other assumptions were held constant, the defined benefit obligation would increase by $326 thousands or decrease by $276 thousands, respectively.

NOTE 17: - CONTINGENT LIABILITIES AND COMMITMENTS

a. On August 23, 2010, the Company entered into a 30 years collaboration agreement with Baxter Healthcare Corporation ("Baxter") with respect to obtaining the distribution rights for Glassia. During 2015, Baxter assigned all its rights under the collaboration agreement to Baxalta US Inc. ("Baxalta") which was acquired during 2016 by Shire plc ("Shire"), which is now part of Takeda ("Takeda" and in these consolidated financial statements Baxter, Baxalta and Shire will be referred to as "Takeda").

The collaboration agreement consists of three main agreements (1) An Exclusive Manufacturing, Supply and Distribution agreement for Glassia in the United States, Canada, Australia and New Zealand (the "Territory" and the "Distribution Agreement", respectively); (2) Technology License Agreement for the use of the Company's knowhow and patents for the production, continued development and sale of Glassia by Takeda (the "License Agreement") in the Territory; and (3) A Paste Supply Agreement for the supply by Takeda of plasma derived fraction IV-1 to be used by the Company for the production of Glassia (the "Raw Materials Supply Agreement").

Pursuant to the agreements, the Company was entitled to certain upfront and milestone payments at a total amount of $45 million, and for a minimum commitment of Takeda to acquire Glassia produced by the Company over the first five years of the term of the Distribution Agreement. In addition, upon initiation of sales of Glassia manufactured by Takeda the Company will be entitled to royalty payments at a rate of 12% on net sales of Glassia through August 2025, and at a rate of 6% thereafter until 2040, with a minimum of $5 million annually (the "Royalty Payments").

As of December 31, 2019, the Company received a total of $39.5 million on account of the agreed upfront and milestone payments from Takeda pursuant to the Distribution and License Agreements as amended. Prior to the October 2016 amendment of the Distribution Agreement, the net proceeds on account of the upfront the milestone payments received were recorded as deferred revenues and were recognized as revenues based on the actual sales of Glassia on a pro-rata basis. Following October 2016, the balance of the deferred revenues was recognized on a straight - line basis according to Takeda's updated minimum purchase commitment through December 31, 2018, which was the term of the supply commitment period prior to the October 2016 amendment. Non-refundable revenues due to the achievement of milestones are recognized upon reaching the milestone. The Company is entitled to the remaining unpaid balance of the millstone payments totaling $5.5 million which will be paid upon the achievement of such milestones.

Between 2013 and 2019, the parties amended the License Agreement and the Distribution Agreement to extend the supply of Glassia by the Company to Takeda and increase Takeda's minimum purchase commitment. Pursuant to the recent amendment of the Distribution Agreement entered into during August 2019, the maximum commitment by the Company to manufacture and sale Glassia to Takeda and the minimum commitment of Takeda to acquire Glassia manufactured by the Company is currently extended through the end of 2021. The Company projects that total revenues from sales of Glassia to Takeda for the year 2020 will be approximately $65 million and for the year 2021 between $25 million to $50 million. See note 22a for information regarding 2019 revenues from sales to Takeda.

Takeda is planning to complete the technology transfer of Glassia, and pending FDA approval, will initiate, during 2021 its own production of Glassia for distribution in the U.S. market. Accordingly, following the transition of manufacturing to Takeda, the Company will terminate the manufacturing and sale of Glassia to Takeda resulting in a significant reduction in revenues. Upon initiation of sales of Glassia manufactured by Takeda, Takeda will pay the Company the Royalty Payments as defined above.

Pursuant to the Distribution Agreement, Takeda is responsible to conduct any required additional clinical studies required to obtain or maintain Glassia's marketing authorization in the Territory. Under certain condition, the Company will be required to participate in the funding of these clinical studies in a total amount not to exceed $10 million.

NOTE 17: - CONTINGENT LIABILITIES AND COMMITMENTS (CONT.)

Pursuant to the Raw Material Supply Agreement Takeda undertook to provide the Company, free of charge, all quantities of plasma derived fraction IV-1 required by the Company for manufacturing Glassia to be sold to Takeda for distribution in the Territory. The Company accounts for the fair value of the plasma derived fraction IV-1 used and sold as revenues and charges the same fair value to cost of revenue. In addition, the Company has the right to acquire from Takeda plasma derived fraction IV-1 for its continued development and for the production, sale and distribution of Glassia by the Company outside the Territory.

b. In November 2006, the Company entered into an agreement with PARI GmbH in connection with a supply by the third party of a certain medical devise required for the development of a Company's Inhaled AAT product. Pursuant to the agreement, the Company was licensed to use developments made by the third party. Furthermore, the third party will provide the Company certain quantities of devices for carrying out clinical trials, free of charge. In the event that the development is successful and the underlining product obtains required marketing authorization, the Company will pay the third party royalties based on sales of the devices through the later of the device patents expiration period or 15 years from the first commercial sale of the Company's the Inhaled AAT product.

On expiration of the royalty period, the license will become non-exclusive and the Company shall be entitled to use the rights granted to it pursuant to the agreement without paying royalties or any other compensation. In addition, and according to a mechanism set in the agreement, the third party would be required to pay royalties to the Company of the total net sales of the device exceeding a certain amount, through the later of the device patents expiration period or 15 years from the first commercial sale of the Company's Inhaled AAT product.

In February 2008, the parties executed an amendment to the agreement according to which the exclusive global license granted to the Company was expanded to two additional indications. The royalties are applicable to all indications mentioned above.

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

In May 2019, the Company signed a Clinical Study Supply Agreement ("CSSA") with such third party for the supply of the required quantities of controller kits and the web portal associated with the third party's device required for Company's continued clinical trials with respect the its Inhaled AAT product. The CSSA is a supplement agreement to the agreement and will expire upon the expiration or termination of the agreement.

NOTE 17: - CONTINGENT LIABILITIES AND COMMITMENTS (CONT.)

c. In July 2011, the Company entered into a strategic collaboration agreement with Kedrion Biopharma for clinical development, marketing, distribution and sales in the United States of KedRab, the Company's rabies immune globulin (Human). The product, KedRab, is manufactured and marketed by the Company in other countries. The Company obtained U.S marketing approval from the FDA for KedRab in August 2017. Launch of the product in the US was initiated in the beginning of 2018.

In October 2016 the parties entered into an amendment to the agreement pursuant to which the parties agreed to conduct a required post-marketing-commitment clinical study which was initiated in March 2017 and is planned to finalize in 2020. The cost of the study is equally shared between the parties.

d. In July 2019, the Company entered into a 7-year Master Clinical Services Agreement with a third party for the provision of certain clinical research services and other tasks to be performed by such third party, in connection with the Company's Phase III clinical study for its inhaled AAT product.

e. In December 2019, the Company entered into a binding term sheet for a 12-year contract manufacturing agreement with a third party to manufacture an FDA-approved and commercialized specialty hyper-immune globulin product. Following the execution of the required technology transfer from the current manufacturer, and pending obtaining all required FDA approvals, the Company is expected to commence commercial manufacturing of the product in early 2023.

f. In December 2019, the Company entered into an agreement with Alvotech, a global biopharmaceutical company, to commercialize Alvotech's portfolio of six biosimilar product candidates in Israel, upon receipt of regulatory approval from the Israeli Ministry of Health ("IMOH"). Pursuant to the agreement the Company is obligated to pay Alvotech certain milestone payments to Alvotech, in advance of the launch of the six biosimilar in Israel.

NOTE 18: - GUARANTEES AND CHARGES

a. The Company provided a bank guarantees in the amount of $ 255 thousands in favor of the Lessor of its leased office facility in Rehovot, Israel, and for other obligation, as guarantee for meeting its obligations under the lease agreement.

b. The Company pledged specific purchased assets as collateral against loans, in the original amount of NIS 8,355 thousands ($ 2,176 thousands) received to fund the purchase of such assets.

NOTE 19: - EQUITY

a. share capital

	December 31, 2019		December 31, 2018	
	Authorized	Outstanding	Authorized	Outstanding
Ordinary shares of NIS 1 par value	70,000,000	40,353,101	70,000,000	40,295,078

b. Movement in share capital:

Issued and outstanding share capital:

	Number of shares
Balance as of January 1, 2018	40,262,819
Issue of shares	-
Exercise of options into shares	8,686
Exercise of restricted shares	23,573
Balance as of December 31, 2018	40,295,078
Issue of shares	
Exercise of options into shares	13,133
Exercise of restricted shares	44,890
Balance as of December 31, 2019	40,353,101

Ordinary shares of NIS 1 par value

c. Rights attached to Shares

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

d. Share options and restricted shares

During 2019 and 2018, 67,470 and 53,584 share options, respectively, were exercised, on a cash-less basis, into 13,133 and 8,686 ordinary shares of NIS 1 par value each and 44,892 and 23,572 restricted shares were vested for total consideration of $16 thousand and $9 thousands, respectively.

For additional information regarding options and restricted shares granted to employees and management in 2019, refer to Note 20 below.

e. Capital management in the Company

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

f. Issuance of ordinary shares by the Company

Refer to Note 25 e 3 for information regarding the issuance of ordinary shares as of February 10, 2020

NOTE 20: - SHARE-BASED PAYMENT

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

Pursuant to the 2011 Plan, granted share options and RS generally vest over a four-year period following the date of the grant in 13 installments: 25% of the options vest on the first anniversary of the grant date and 6.25% options vest at the end of each quarter thereafter.

a. Expense recognized in the financial statements

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

	For the Year Ended December 31		
	2019	2018	2017
	U.S. Dollar in thousands		
Cost of revenues	$ 364	$ 401	$ 179
Research and development	254	224	138
Selling and marketing	63	51	48
General and administrative	482	272	118
Total share-based compensation	$ 1,163	$ 948	$ 483

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

On June 20, 2019 the Company's Board of Directors approved the grant of options to purchase 90,000 Ordinary Shares of the Company at an exercise price of NIS 21.34 per share and 30,000 RS to the Company's CEO. The initial fair value of the options and of the RSs estimated based on the Binomial Model was $154 thousands and $165 thousands, respectively. The grant of the equity instruments to the Company's CEO is subject to the approval of the General Meeting of Shareholders of the Company that is expected to take place during March 2020

c. Share options and Restricted shares granted to Employees and Management

1. During 2019 the Company's Board of Directors approved the grant of 443,000 options to employees and members of the Company's management. The fair value of the options calculated on the date of grant using the binomial option valuation model was estimated at $778 thousands.

NOTE 20: - SHARE-BASED PAYMENT (CONT.)

2. During 2019, the Company's Board of Directors approved the grant of 69,725 RSs to the Company's employees and management. The RSs do not have exercise price. The fair value of the RSs was estimated based on the market price of the share on the grant date at $381 thousands.

d. Share options granted to members of the Board of Directors

On January 20, 2020, the Company's Board of Directors approved the grant of 212,800 options to Board of Directors. The fair value of the options calculated on the date of grant using the binomial option valuation model was estimated at $391 thousands. The grant of the options to the Board of Directors is subject to the approval of the General Meeting of Shareholders of the Company that is expected to take place by March 2020.

e. Change of Awards during the Year

The following table lists the number of share options, the weighted average exercise prices of share options and changes in share options grants during the year:

	2019		2018		2017	
	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	2,445,597	29.99	2,572,372	32.47	2,487,236	35.20
Granted	443,800	20.64	617,825	19.02	458,950	21.10
Exercised	(67,470)	32.30	(53,584)	15.77	(10,659)	18.19
Forfeited	(485,373)	16.98	(691,016)	30.51	(363,155)	35.70
Outstanding at end of year	2,336,554	27.87	2,445,597	29.99	2,572,372	32.47
Exercisable at end of year	1,412,023	33.17	1,406,048	38.02	1,755,253	38.69
The weighted average remaining contractual life for the share options		3.39		3.63		3.22

The range of exercise prices for share options outstanding as of December 31, 2018 and 2019 were NIS 15- NIS 57. Exercise is by cashless method.

NOTE 20: - SHARE-BASED PAYMENT (CONT.)

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

	Number of RSs		
	2019	**2018**	**2017**
Outstanding at beginning of year	139,706	76,512	27,333
Granted	69,725	96,308	58,835
End of restriction period	(18,643)	(23,572)	(7,656)
Forfeited	(44,892)	(9,542)	(2,000)
Outstanding at end of year	145,896	139,706	76,512
The weighted average remaining contractual life for the restricted share	2.78	3.21	3.54

g. Measurement of the fair value of share options:

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

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

	2019	**2018**	**2017**
Dividend yield (%)	-	-	-
Expected volatility of the share prices (%)	23-41	25-39	37-45
Risk-free interest rate (%)	0.3 – 1.7	0.2-2.0	0.1-1.83
Contractual term of up to (years)	6.5	6.5	6.5
Exercise multiple	2	2	2
Weighted average share prices (NIS)	19.17-19.65	18.49-21.17	16.05-16.44
Expected average forfeiture rate (%)	2-6	1-5	1-5

NOTE 21: - TAXES ON INCOME

a. Tax laws applicable to the Company

Law for the Encouragement of Industry (Taxes), 1969

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

NOTE 21: - TAXES ON INCOME (CONT.)

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

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

Law for the Encouragement of Capital Investments, 1959

Tax benefits prior to Amendment 60

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

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

The benefit period for part of the Company plants has ended by 2017.

NOTE 21: - TAXES ON INCOME (CONT.)

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

Tax benefits under Amendment 60

On April 1, 2005, an amendment to the Investment Law was effected ("Amendment 60"). The amendment revised the criteria for investments qualified to receive tax benefits. An eligible investment program under the amendment will qualify for benefits as a Privileged Enterprise (rather than the previous terminology of Approved Enterprise).

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

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

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

NOTE 21: - TAXES ON INCOME (CONT.)

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

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

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

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

Preferred Enterprise

Tax Benefits under the 2011 Amendment

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

NOTE 21: - TAXES ON INCOME (CONT.)

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

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

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

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

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

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

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

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

The Israeli corporate income tax rate was 23% in 2019 and 2018 and 24% in 2017.

NOTE 21: - TAXES ON INCOME (CONT.)

c. Tax assessments

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

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

As of December 31, 2019, the Company has carry forward losses and other temporary differences in the amount of $ 47,400 thousands. Final tax assessments for the years 2015 onwards could have an impact on the balance of carry forward tax losses for which deferred tax asset was not recognized. During 2019, the Company recorded deferred tax asset at an amount of $ 1,311 thousands representing utilization of $ 20,484 thousands of its carry forward losses in the foreseeable future. The Company did not record deferred tax asset for the remaining portion of its carry forward losses due to estimation that their utilization in the foreseeable future is not probable.

e. Uncertain tax positions

The Company analyzed uncertainty involving income taxes on its financial statements and whether it has any potential impact on the financial statements. As of December 31, 2019 and 2018, the application of IFRIC 23 did not have a material effect on the financial statements.

f. Deferred taxes:

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

	Total U.S Dollars in thousands
Balance at January 1, 2019	$ 2,048
Amount carried to profit and loss	(726)
Amount carried to other comprehensive income	(11)
Balance as of December 31, 2019	$ 1,311

Deferred tax liabilities have not been recognized for the immaterial temporary differences associated with investments in subsidiaries because the disposal of these subsidiaries in the foreseeable future is not probable and because distributions of dividends by these companies are not subject to tax.

NOTE 21: - TAXES ON INCOME (CONT.)

g. Composition:

	Statements of financial position December 31,		Statements of profit or loss Year ended December 31,		
	2019	2018	2019	2018	2017
	U.S Dollars in thousands				
Deferred tax liabilities:					
Financial assets measured at fair value through other comprehensive income	(32)	(12)			
Revaluation of derivatives	(4)				
Deferred tax assets:					
Carryforward tax losses	1,330	2,056	(726)	(1,944)	-
Employee benefits	25	1			
Issuance of sheers					
Revaluation of derivatives		3			
Deferred tax income (expenses)			(726)	(1,944)	
Deferred tax assets, net	$ 1,311	$ 2,048			

The deferred taxes are reflected in the statement of financial position as follows:

	December 31,	
	2019	2018
	NIS in thousands	
Non-current assets	$ 1,311	$ 2,048

h. Taxes on income

	Year ended December 31,		
	2019	2018	2017
	U.S. Dollars in thousands		
Current taxes	$ -	$ -	$ 129
Deferred tax expenses (income)	726	(1,944)	-
Taxes in respect of prior years	4	(11)	140
Taxes on income	$ 730	$ (1,955)	$ 269

NOTE 21: - TAXES ON INCOME (CONT.)

i. Theoretical tax

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

	Year ended December 31, 2019
	U.S. Dollars in thousands
Gain before taxes on income	$ 22,981
Statutory tax rate	23%
Tax calculated using the statutory tax rate	5,286
Increase (decrease) in taxes resulting from permanent differences - the tax effect:	
Adjustment of deferred tax balances following a change in tax rates	(356)
Taxable income with preferred income tax rates by virtue of the Encouragement Law	(3,747)
Tax exempt income, income subject to special tax rates and nondeductible expenses and other	(105)
Increase in unrecognized tax losses in the year	(352)
Prior year taxes	4
Tax on income	$ 730
Effective tax rate	3.2%

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

NOTE 22: - SUPPLEMENTARY INFORMATION TO THE STATEMENTS OF PROFIT AND LOSS

a. Additional information about revenues

	Year Ended December 31,		
	2019	2018	2017
	U.S. Dollars in thousands		
Revenues from major customers each of whom amount to 10% or more, of total revenues			
Customer A[1]	$ 68,138	$ 63,788	$ 60,383
Customer B	16,369	11,779	-
Customer C	14,454	-	-
	$ 98,961	$ 75,567	$ 60,383

(1) For additional information regarding the aggregate amount of the transaction price allocated to the performance obligations that are unsatisfied, refer to note 17a.

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

	Year Ended December 31,		
	2019	2018	2017
	U.S. Dollars in thousands		
U.S.A	$ 84,572	$ 75,331	$ 60,405
Israel	31,959	28,093	26,355
Europe	4,701	3,594	5,348
Latin America	3,792	3,994	5,248
Asia	2,067	3,336	4,979
Others	96	121	490
Total Revenue	$ 127,187	$ 114,469	$ 102,825

c. Cost of goods sold

	Year Ended December 31,		
	2019	2018	2017
	U.S. Dollars in thousands		
Cost of materials	$ 69,766	$ 56,156	$ 41,179
Salary and related expenses	16,941	15,290	13,755
Subcontractors	4,451	3,633	3,995
Depreciation and amortization	2,991	2,859	2,504
Energy	1,551	1,426	1,202
Other manufacturing expenses	712	566	954
	96,412	79,930	63,589
Decrease (increase) in inventories	(18,962)	(6,933)	7,148
Total Cost of goods sold	$ 77,450	$ 72,997	$ 70,737

d. Research and development

	Year Ended December 31,		
	2019	2018	2017
	U.S. Dollars in thousands		
Salary and related expenses	$ 5,897	$ 5,925	$ 6,537
Subcontractors	5,196	2,275	3,392
Materials and allocation of facility costs	966	1,131	1,597
Depreciation and amortization	663	159	120
Others	337	257	327
Total Research and development	$ 13,059	$ 9,747	$ 11,973

NOTE 22: - SUPPLEMENTARY INFORMATION TO THE STATEMENTS OF PROFIT AND LOSS (CONT.)

e. Selling and marketing

	Year Ended December 31,		
	2019	2018	2017
	U.S. Dollars in thousands		
Salary and related expenses	$ 1,467	1,647	1,470
Marketing support	103	121	95
Packing, shipping and delivery	504	477	607
Marketing and advertising	788	424	627
Registration and marketing fees	917	470	1,162
Others	591	491	437
Total Selling and marketing	$ 4,370	$ 3,630	$ 4,398

f. General and administrative

	Year Ended December 31,		
	2019	2018	2017
	U.S. Dollars in thousands		
Salary and related expenses	$ 3,475	$ 3,085	3,138
Employees welfare	1,296	1,151	2,182
Professional fees and public company expense	2,162	2,012	1,549
Depreciation, amortization and impairment	717	686	649
Communication and software services	799	675	554
Others	745	916	201
Total General and administrative	$ 9,194	$ 8,525	$ 8,273

g. Financial expense(income)

	Year Ended December 31,		
	2019	2018	2017
	U.S. Dollars in thousands		
Financial income			
Interest income and gains from marketable securities	$ 1,146	$ 830	$ 500
Financial expense			
Fees and interest paid to financial institutions	293	172	82
Financial income and (expense)			
Derivatives instruments measured at fair value	(512)	504	(511)
Translation differences of financial assets and liabilities	(139)	98	(101)
Bond securities measured at fair value	(5)	(178)	(80)
Total Financial expense(income)	$ 197	$ 1,082	$ (274)

NOTE 23: - INCOME (LOSS) PER SHARE

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

	Year Ended December 31,					
	2019		2018		2017	
	Weighted Number of Shares	Income Attributed to equity holders of the Company	Weighted Number of Shares	Income Attributed to equity holders of the Company	Weighted Number of Shares	Loss Attributed to equity holders of the Company
		U.S. Dollars in thousands		U.S. Dollars in thousands		U.S. Dollars in thousands
For the computation of basic income (loss)	40,320,888	$ 22,251	40,275,374	$ 22,296	37,970,697	$ 6,901
Effect of potential dilutive ordinary shares	260,739	-	170,043	-	74,400	-
For the computation of diluted income (loss)	40,581,627	$ 22,251	40,445,417	$ 22,296	38,045,097	$ 6,901

b. The computation of the diluted income per share for the years ending December 31, 2019, 2018 and 2017 took into account the options and RSs due to their dilutive effect.

NOTE 24: - OPERATING SEGMENTS

a. General

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

Proprietary Products	Development, manufacturing, sales and distribution of plasma-derived protein therapeutics.
Distribution	Distribute imported drug products in Israel, which are manufactured by third parties.

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

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

The segment liabilities do not include loans and financial liabilities as these liabilities are managed on a group basis.

NOTE 24: - OPERATING SEGMENTS (CONT.)

b. Reporting on operating segments

	Proprietary Products	Distribution	Total
	U.S. Dollars in thousands		
Year Ended December 31, 2019			
Revenues	$ 97,696	$ 29,491	$ 127,187
Gross profit	$ 45,271	$ 4,466	$ 49,737
Unallocated corporate expenses			(26,953)
Finance income, net			197
Income before taxes on income			$ 22,981

	Proprietary Products	Distribution	Total
	U.S Dollars in thousands		
Year Ended December 31, 2018			
Revenues	$ 90,784	$ 23,685	$ 114,469
Gross profit	$ 37,988	$ 3,484	$ 41,472
Unallocated corporate expenses			(22,213)
Finance income, net			1,082
Income before taxes on income			$ 20,341

	Proprietary Products	Distribution	Total
	U.S. Dollars in thousand		
Year Ended December 31, 2017			
Revenues	$ 79,559	$ 23,266	$ 102,825
Gross profit	$ 28,224	$ 3,864	$ 32,088
Unallocated corporate expenses			(26,644)
Finance expense, net			(274)
Loss before taxes on income			$ 7,170

NOTE 25: - BALANCES AND TRANSACTIONS WITH RELATED PARTIES

a. Balances with related parties

	December 31, 2019	December 31, 2018
	U.S. Dollars in thousands	
Other accounts payables	$ 151	$ 336
Employee benefit liabilities, net	$ -	$ 80
Trade receivable	$ -	$ 1,135

NOTE 25: - BALANCES AND TRANSACTIONS WITH RELATED PARTIES (CONT.)

b. Transactions with employed/directors that accounts as related parties

	Year Ended December 31,		
	2019	2018	2017
	U.S. Dollars in thousands		
Salary and related expenses to those employed by the Company or on its behalf	$ 311	$ 352	$ 460
Remuneration of directors not employed by the Company or on its behalf	$ 363	$ 366	$ 107
Number of People to whom the Salary and remuneration Refer:			
Related and related parties employed by the Company or on its behalf	2	2	2
Directors not employed by the Company	7	8	2
Total Directors employed and not employed by the Company	9	10	4

c. Transactions with key executive personnel (including non-related parties)

	Year Ended December 31,		
	2019	2018	2017
	U.S. Dollars in thousands		
Short-term benefits	$ 3,157	$ 2,766	$ 2,959
Share-based payment	188	285	310
Other long-term benefits	-	-	6
Total	$ 3,345	$ 3,051	$ 3,275

d. Transactions with related parties

	Year Ended December 31,		
	2019	2018	2017
	U.S. Dollars in thousands		
Revenues	$ 2,566	$ 3,529	$ 3,455
Cost of Goods Sold	$ 13	$ -	$ -
Selling and marketing expenses	$ 257	$ 313	$ 121
General and administrative expenses	$ 447	$ 408	$ 446

NOTE 25: - BALANCES AND TRANSACTIONS WITH RELATED PARTIES (CONT.)

e. Terms of Transactions with Related Parties

Sales to related parties are conducted at market prices. Open account that have yet to be repaid by the end of the year by a related party bear no interest and their settlement will be in cash and certain balances are guaranteed by letter of credit. For the years ended December 31, 2019, 2018 and 2017, the Company recorded no allowance for doubtful accounts for trade receivable from related parties.

1. On May 26, 2011, the Company entered into an amended agreement with Tuteur SACIFIA ("Tuteur"), a company registered in Argentina, currently under the control of the Hahn family. Such amended agreement revises and replaces the distribution agreement signed in 2001 between the Company and Tuteur in connection with the distribution of Glassia in Argentina and Paraguay. The amended agreement was made as an arm's length transaction. On August 19, 2014 the Company entered into a subsequent amendment to the agreement, pursuant to which, the Company granted Tuteur distribution right in Argentina for its KamRho(D) product. In addition the distribution territory and expanded to include Bolivia.

   Pursuant to the distribution agreement, Tuteur serves as the exclusive distributor of Glassia and KamRho(D), in Argentina, Paraguay and Bolivia. In 2016 the Board of Directors approved a marketing contribution funding to Tuteur for reimbursement of costs associated with marketing activities aimed to locating new AATD patients and increasing the overall number of AATD patients treated with Glassia in Argentina. Such funding was paid by the Company in each of 2016 and 2017. In addition, in 2016 and in 2017 the Board of Directors approved extending a price discount for KamRho(D) to Tuteur.

   During 2018, a third amendment to the agreement was executed, which was effective as of July 1, 2018, pursuant to which the Company extended a price discount for Glassia. Pursuant to the third amendment Tuteur was obligated to issue bank guarantees to cover any future outstanding debt due to supply of products by the Company to Tuteur.

2. On July 29, 2015 the Company entered into a distribution agreement with Khairi S.A. ("Khairi"), a company held, inter alia, by Mr. Leon Recanati, the Chairman of the Company's Board of Directors, and Mr. Jonathan Hahn, a director of the Company and his siblings, for the distribution of Glassia and KamRho(D) in Uruguay. This distribution agreement with Khairi is an arm's length transaction. For the years ending December 31, 2019, 2018 and 2017 there were no sales of Glassi and KamRho(D) by the Company to Khairi

3. FIMI Opportunity Fund 6, L.P. and FIMI Israel Opportunity Fund 6, Limited Partnership (the "FIMI Funds") purchased on November 21, 2019 5,240,956 ordinary shares at a price of $6.00, representing 12.99%. On February 10, 2020, the Company closed a private placement with FIMI Opportunity Fund 6, L.P. and FIMI Israel Opportunity Fund 6, Limited Partnership (the "FIMI Funds"), a then 12.99% stockholder of the Company. Pursuant to the private placement the Company issued 4,166,667 ordinary shares at a price of $6.00 per share, for an aggregate gross proceeds of $25,000 thousands. Upon closing of the private placement, the FIMI Funds ownership represents approximately 21% of the Company's outstanding shares. Concurrently, the Company entered into a registration rights agreement with the FIMI Funds, pursuant to which the FIMI Funds are entitled to customary demand registration rights (effective six months following the closing of the transaction) and piggyback registration rights with respect to all shares held by FIMI Funds. Mr. Ishay Davidi, Ms. Lilach Asher Topilsky and Mr. Amiram Boehm, members of our board of directors, are executives of the FIMI Funds.

   The following Israeli entities: Amnir recycling industries Ltd., Grafity office equipment marketing, G-one security solutions, Carmel Frenkel IND, and Oxygen & Argon works Ltd who are controlled by the FIMI Funds, are currently engaged by the Company for the provision of certain services relating to its continuous operations in non-material amounts and in market prices.

NOTE 25: - BALANCES AND TRANSACTIONS WITH RELATED PARTIES (CONT.)

f. CEO employment terms

On December 20, 2018 the Company's shareholders approved an amendment to the employment terms of the Company's CEO. Pursuant to the amendment the CEO monthly gross salary increased to NIS 82,500 (or $22,627), effective as of July, 1 2018. On June 20, 2019 the Company's Board of Directors approved a subsequent amendment to the employment terms of the Company's CEO, pursuant to which, the monthly gross salary will increased to NIS 88,000 (or $25,462), effective as July 1, 2019. The updated employment terms are subject to the approval of the General Meeting of Shareholders which is expected to take place during March 2020.

During 2019 the Company accounted for a bonus accrual to the CEO in the amount of $189 thousands. As for a grant of options and restricted shares to the CEO, refer to Note 20b.

NOTE 26: - EVENTS SUBSEQUENTS TO THE REPORTING PERIOD

a. As for grant of options to the members of the Board of Directors approved by the Board of Directors on January 20, 2020, refer to Note 20d.

b. As for the private placement closed with the FIMI funds on February 10, 2020 refer to note 25e3.

Exhibit 4.25

KAMADA LTD.

COMPENSATION POLICY FOR EXECUTIVE OFFICERS AND DIRECTORS

1. OBJECTIVES OF THE POLICY

This document is designed to determine, describe and detail the policy of Kamada Ltd. (the "**Company**") with respect to the compensation of the Company's office holders, the amount of the compensation, its components and the method for determining compensation.

The Company's compensation policy and its publication are designed to enhance the level of transparency of the Company's activities relating to the compensation of office holders and to improve the ability of the shareholders to express their opinion and influence the Company's compensation policy for officer and directors.

This document shall apply to the Company's office holders: the chief executive officer, members of the Company's executive management, each person fulfilling such positions even if his title is different, and directors.

This document does not grant any rights whatsoever to an office holder. Each of the Company's office holders shall be entitled to compensation only in accordance with his respective employment contract approved by the compensation committee, the board of directors (and the shareholders, to the extent required).

This document determines (among other things) the maximum values for the various components of compensation. Awarding compensation to an office holder in an amount that is less than the amounts specified in this document shall not be deemed to be a deviation from the provisions of this compensation policy and shall not require the approval of the shareholders that is required by law in the event of deviation from the terms of the compensation policy.

Except with respect to the terms of service and employment of office holders that were approved prior to the date of approval of this compensation policy, any deviation or exception from this compensation policy (excluding, as described above, awarding compensation which is less than the compensation stated in this policy) shall be subject to the approval of the Company's compensation committee, board of directors and the shareholders, to the extent required by law.

This compensation policy shall apply to the terms of service and employment of office holders that are approved following the date of approval of this compensation policy. This compensation policy does not derogate from existing contractual obligations, as of the date of approval of this compensation policy, between the Company and its office holders.

The policy is drafted in the masculine solely for convenience and applies to both men and women, without distinction.

In this policy, the Company's "competent organizations" are the compensation committee and the board of directors, and with respect to the compensation of the Company's chief executive officer, directors and controlling shareholders, also the shareholders, to the extent required by law.

2. GENERAL BACKGROUND

2.1. PURPOSE OF THE COMPENSATION POLICY FOR OFFICE HOLDERS

This compensation policy for office holders is designed to assist in achieving the Company's objectives and work plans with a long-term view, taking into account, among other things, the Company's risks management policy and to ensure that:

2.1.1. The interests of the Company's office holders shall be as close as possible to and aligned with those of the Company and the shareholders;

2.1.2. The Company may recruit and retain senior officers capable of leading the Company to further business success and able to handle future challenges;

2.1.3. Office holders shall have motivation to attain a high level of business achievements without taking unreasonable risks;

2.1.4. Office holders shall be compensated for achieving the Company's strategic targets; and

2.1.5. An appropriate balance shall be established between the various compensation components – fixed vs. variable compensation, quantitative and measurable components vs. discretionary components, short-term vs. long-term components, compensation in cash vs. equity-based compensation and benefits and perquisites.

2.2. PRIMARY BODIES INVOLVED IN DETERMINING THE COMPENSATION POLICY FOR OFFICE HOLDERS

The parties involved in determining the Company's compensation policy are:

- Compensation committee of the board of directors – makes recommendations to the board of directors regarding the approval of the compensation policy for office holders and any extensions and updates to the policy to the extent required; approves the terms of service and employment of office holders; and may determine to exempt a transaction from shareholder approval (in the event that the compensation committee believes that bringing the transaction to the approval of the shareholders could jeopardize an arrangement with a candidate for chief executive officer).

- Board of directors – approves the compensation policy for office holders; periodically reviews the compensation policy and is responsible for updating it as and when necessary.

- Shareholders – approves the compensation policy, to the extent approval is required by law.

2.3. BUSINESS ENVIRONMENT AND ITS IMPACT ON COMPENSATION OF OFFICE HOLDERS

As a Company engaged in the development of biological based drugs (biopharmaceuticals), the Company competes with other companies in the same and related fields to recruit and retain managers and leading professionals. As at the date of writing this document (July 2013), no shortage of highly talented management personnel with expertise in the Company's specific field of business has been experienced; however, since it is a growing area with several companies joining each year, the Company's management personnel could be a target for recruitment by rival companies alongside a shortage which could develop over the following years.

The Company's compensation policy was designed, among other things, to ensure the Company's ability to recruit and retain the highly talented management personnel it requires to continue to develop its business and business success, all in accordance with and subject to the objectives of the compensation policy set forth in Section 2.1, including the promotion of the Company's goals in the long-term.

3. OFFICER'S COMPENSATION IN VIEW OF COMPANY VALUES AND BUSINESS STRATEGY

3.1. COMPENSATION ACCORDING TO THE OFFICER'S CHARACTERISTICS AND EXPERIENCE

Officer compensation shall take into account the officer's education, skills, expertise, professional experience and achievements, as well as the characteristics of the position which he is intended to fulfill and the responsibilities of the position. It is clarified, however, that the foregoing shall not constitute threshold conditions for purposes of fulfilling a specific position in the Company (because at times prior experience in a position and the relevant field are equivalent to or prevail over formal education in the field), and all of the foregoing characteristics shall be taken into account in the examination of the suitability of a candidate for a particular position. Without derogating from the foregoing, an office's compensation shall be determined, for each of the various compensation components, according to the foregoing parameters, the nature of the position and the areas of responsibility, while preserving an appropriate balance between the various compensation components set out in this document.

3.2. RATIO BETWEEN OFFICER COMPENSATION AND COMPENSATION OF OTHER COMPANY EMPLOYEES

The Company aims to compensate its office holders for their contribution to its business success over time, taking into account the extensive responsibility and authority imposed upon them.

Nevertheless, since the Company employs a relatively small number of employees most of whom have unique professional expertise, the Company attaches importance to the creation of appropriate compensation for all of its employees and in preserving reasonable gaps between the overall compensation of officers and the compensation of the other Company employees.

The compensation committee and the board of directors have examined the ratio between the terms of service and employment of officers and the average and median salary of the other Company employees and contractors, and the ratio between the terms of service and employment of officers and the average and median cost of employment of the other Company employees and contractors.

The compensation committee and the board of directors believe that the ratio is appropriate and reasonable taking into account the nature of the Company, its size, value, scale of activity in the various fields, the mixture of manpower and its field of activity and that it does not adversely impact labor relations within the Company.

3.3. RELATIONSHIP BETWEEN THE COMPANY'S BUSINESS RESULTS AND OFFICER COMPENSATION

The Company's policy is that the overall compensation for officers should be considerably influenced by its business results as well as the individual contribution, responsibility and professional expertise of each officer to the achievement of these results. The higher the management position, the influence of the business results and the individual contribution to the achievement of these results on the executive's compensation shall increase. For this purpose, the higher the management position, the weight of the variable compensation that is performance based in relation to the overall compensation shall increase, all as specified in Section 4.2 below.

4. PRIMARY CONCEPTS OF THE COMPENSATION POLICY

4.1. OVERALL COMPENSATION CONCEPT

The Company's compensation committee and board of directors believe that the overall compensation of each employee and in particular of officers should be comprised of a number of different components, such that each element rewards the employee for a different element of his contribution to the Company, thus achieving the objectives of the Company's compensation policy:

- Base salary – designed to partially reward the employee for the time he devotes to the performance of his role and the daily performance of his tasks. The base salary takes into account, on the one part, the employee's skills (such as experience, know-how, expertise accumulated in the field of business, education, professional qualifications etc.) and, on the other part, the requirements of the role and the responsibility and authority it carries.

- Benefits and perquisites – some of which are mandatory according to law (such as pension, severance pay, vacation days, sick leave, recuperation pay, etc.), some of which are common market practice (such as health insurance, insurance for loss of earning capacity, further education funds, which have certain tax benefits for the employee and the Company) and others are designed to compensate the employee for expenses incurred in fulfilling the position (such as a company car, travel expenses, phone, etc.).

- Variable performance based awards (e.g. annual bonus) – designed to reward the officer for his achievements and contribution to attaining the Company's goals during the course of the period for which the variable compensation is paid and to supplement the base salary. The weight of variable performance based compensation in relation to the overall compensation shall increase the higher the officer's management position.

- Equity-based compensation – designed to link long-term shareholder returns and the compensation of officers and employees of the Company. Equity-based compensation creates a correlation between the interests of employees and officers and the interests of the Company's shareholders and assists in creating motivation and in retaining the key personnel in the Company.

4.2. RATIO BETWEEN COMPENSATION COMPONENTS

The ratio required between the components of an officer's compensation package is set forth in the following table:

RANK	BASE SALARY TO VARIABLE COMPENSATION (BOTH PERFORMANCE AND EQUITY BASED)
Chief Executive Officer and Deputy Chief Executive Officer	up to 1:2
Vice President	up to 1:1

5. COMPENSATION COMPONENTS

5.1. BASE SALARY

5.1.1. **Determination of the base salary for officers**

The base salary for an officer shall be determined during the course of the negotiations for his employment in the Company, which shall be conducted by the person who shall directly supervise the officer (for the chief executive officer – the chairman of the board of directors or whoever is appointed on his behalf for such purpose, for a vice president – the Company's chief executive officer or whoever is appointed on his behalf for such purpose). The officer's intended supervisor may determine the base salary based on a range to be determined and approved in advance for such purpose in accordance with the provisions prescribed in this policy.

The salary to be determined, within the foregoing range, shall express the skills of the candidate (including, among other things, his education, professional experience and expertise) and his suitability to the intended position as well as also the acceptable salary conditions in the relevant market and the Company's financial capability at the time of recruitment.

The Company believes that the emphasis of its compensation policy should be on performance based compensation and therefore, the Company's policy is to determine a base salary which is close to the median salary in the relevant market for similar positions, alongside variable performance based compensation and long-term compensation components that will bring the officer's overall compensation to a level which will allow the Company to recruit and retain the highly talented management personnel it requires for continuation of its success.

Because officers hold a management position within the meaning of the Hours of Work and Rest Law, such law shall not apply to officers and they shall not be entitled to compensation for overtime work or work on the day of rest.

5.1.1.1. Market comparison (benchmark)

To determine the salary for the recruitment of a new officer, a comparison shall be made of the acceptable salary in the market for similar positions in companies similar to the Company. For purposes of the foregoing comparative studies, companies meeting the maximum number as possible of the following characteristics shall be selected:

- Companies in the field of bio-tech, pharmaceuticals, medical devices and other related fields;
- Public companies whose shares are traded either on the Tel Aviv Stock Exchange or the NASDAQ Stock Market;
- Companies of a similar size in the following financial dimensions: shareholder equity, balance sheet, sales turnover, operating profit and net profit;
- Companies having substantial international activity.

The comparative study shall address all the components of the compensation package and shall include (to the extent the information is available):

- the acceptable range of base salaries for similar positions (including the split within the range);
- the acceptable range for annual bonuses;
- the acceptable range for equity-based compensation; and
- the benefits and perquisites that are acceptable in the market.

5.1.1.2. Internal comparison – in determining the salary for the recruitment of a new officer, the following considerations shall be taken into account, as well as their potential impact on the Company's labor relations as a whole and within the management team:

- The gap between the proposed salary of the officer and the salary of the other officers in the Company.
- The ratio between the proposed salary of the officer and the salary of the other employees of the Company.
- If there are officers with similar positions in the Company – the gap between the proposed salary of the officer and the salary of the officers with similar positions.

5.1.1.3. To the extent necessary, the Company may employ an officer outside of Israel. In such instance, the salary shall be determined in a process adjusted to the country where such officer is employed. In the event that the salary of officers who are candidates for employment abroad deviate from this policy, the salary shall be brought before the Company's competent organs for approval, prior to the execution of a binding employment contract.

5.1.1.4. Director compensation

The compensation of directors of the Company (including external directors and others) who are not employed in another position in the Company shall be determined pursuant to the Companies Regulations (Rule Regarding the Compensation and Expenses of an External Director), 5760 – 2000 (the "**Compensation Regulations**") and shall not exceed the maximum compensation permitted under the Compensation Regulations, among other things taking into account their definition as financial experts.

Compensation to directors who are employed in another position in the Company shall be determined in accordance with the Company's customary compensation for similar positions, subject to the provisions of this compensation policy.

The Company may award directors equity-based compensation pursuant to the provisions of Section 5.2.2 below, subject to the provisions of the Compensation Regulations.

Directors shall be entitled only to such compensation that has been expressly provided for in this document.

5.1.2. **Periodical review and update of salary**

In order to retain officers, the officers' base salary shall be reviewed annually during the course of the first quarter of each year, taking into consideration the challenges of the given year and the following year, the complexity of the officers' roles, their scope and importance to the Company's performance, all based upon the Company's resources and in comparison to the acceptable salary for similar roles in the relevant market. To the extent necessary, a proposal regarding an increase to all or any of the officers' salaries shall be prepared and brought before the Company's relevant organs for approval.

5.1.2.1. Linkage

The officers' salary shall not be linked to any index apart from the statutory cost of living increase.

5.2. VARIABLE COMPENSATION

Variable compensation components are intended to achieve several objectives:

- To link part of the officers' compensation to the achievement of business goals and targets which, in the long-term, bring maximum value to the Company and create a joint interest between the officers, the Company and its shareholders.

- Increase the officers' motivation to attain the Company's long-term goals.

- Correlating some of the Company's payroll costs with its performance and enhancing its financial and operational flexibility.

5.2.1. Annual bonus

The Company's officers shall be entitled to an annual bonus, based upon the annual bonuses plan which shall be brought before the compensation committee and the board of directors for approval.

5.2.1.1. Principles

Annual bonuses for officers shall be calculated according to the annual bonus plan, to the extent it is approved by the Company's competent organs. The annual bonus plan shall be comprised of the following provisions:

- Payment thresholds based on one or more quantitative financial measure(s) of Company performance during the year for which the bonus is paid (such as revenue, gross profit, EBITDA, operating profit or net profit). The compensation committee shall determine the measure from the list and according to the Company's objectives for the bonus year. In addition, the compensation committee shall determine a substitute measure which may be used as a payment threshold according to the board of directors resolution during the course of the bonus year where, due to circumstances which could not have been anticipated and which are not in the control of the Company's board of directors, the Company would not succeed in meeting the primary threshold(s).

- Determining the target bonus for each officer – a target bonus is the bonus paid when 100% of the targets have been met – in terms of a salary multiplier. A target bonus shall be identical for each officer of a particular rank and shall not exceed, in percentages, the rate set forth in Section 4.2;

- Determining the maximum bonus (in terms of a salary multiplier) which shall be paid to an officer upon attaining considerably higher results than the targets that were determined;

- The measures according to which the bonus shall be calculated for each officer and their relative weights, in accordance with Section 5.2.1.2 below;

- The targets for each measure, for the bonus year.

5.2.1.2. Determining the bonus plan measures and targets

Personal targets and measures shall be determined for each officer, according to which the officer's performance shall be measured. A weight shall be assigned to each measure for determining the annual bonus for each officer, and the bonus paid to the officer shall be determined in accordance with the weighted percentage of meeting the targets, as described below. There shall be three main categories of performance measures for each officer:

- Company measures – economic or strategic measures, which may be measured quantitatively, in relation to the Company's performance (sales turnover, operating profit, percentage of operating profit, EBITDA, net profit, obtaining approval from the authorities in the target markets, etc.). These measures shall be the same for all Company officers and the extent of meeting their targets shall determine 80% of the total bonus for the Company's chief executive officer and 40% of the total bonus for vice presidents.

Personal measures – quantifiable and measurable key performance indicators (KPIs) shall be determined for each officer separately, in accordance with his position. The extent of meeting these measures shall determine a further 40% of the total bonus of a vice president. No personal measures shall be determined for the chief executive officer.

- Managerial appraisal (the Company's chief executive officer or the chairman of the board of directors, as the case may be) – an evaluation of each officer's performance in terms that are not measurable but which have a contribution to the Company's long-term performance. The managerial appraisal shall determine up to 20% of the officer's total bonus. At the beginning of each year, qualitative measures shall be determined on the basis of which the appraisal of each officer shall be made.

The targets in the personal and managerial measures of each officer shall be determined in accordance with the work plan targets for the bonus year.

5.2.1.3. Determination of the bonus budget

The total annual budget for the bonuses of Company's officers shall be determined according to the sum of the maximum bonuses of all officers. After the Company has achieved a net profit for two consecutive years, a maximum total annual bonus budget shall be determined, in terms of a percentage of the Company's operating profit (or the net profit/ gross profit / EBITDA / other measure or any combination thereof, according to the resolution of the Company's compensation committee and board of directors), unless otherwise determined in the Company's annual budget approved by the board of directors (e.g., if the Company has operating losses as a result of an increase in research and development costs, partnerships or M&A). In years where the Company does not meet the minimum percentage of the target determined by the Company, as determined by the compensation committee from time to time, no bonuses shall be paid to officers.

5.2.1.4. Bonus calculation mechanism

The bonus for each officer shall be determined according to the extent that the officer has met the targets determined for him for the bonus year. The weighted percentage of meeting the targets of each officer shall be translated into a bonus percentage according to the "payment line" formula determined in the bonus plan for officers, which shall be multiplied by the target bonus (the personal bonus) of the officer for the purpose of calculating the actual bonus. The maximum target bonus for vice presidents shall be eight times the base monthly salary, for the deputy chief executive officer, nine times the base monthly salary and for the chief executive officer, ten times the base monthly salary.

The "payment line" shall determine:

- The minimum percentage of meeting targets (the lower performance threshold) up to which the officer shall not be paid any bonus whatsoever; the minimum percentage is 70%.
- The percentage of the target bonus which shall be paid in achieving the lower performance threshold;
- A maximum percentage of the target bonus (the bonus ceiling) which shall be paid upon achieving a considerably higher level of performance than the targets; the maximum percentage is 150% of the target bonus.
- The level of performance where the personal bonus ceiling shall be paid.

Calculation of the target bonus percentage for each level of performance between the above-mentioned points shall be made by a linear method.

5.2.1.5. The approval process for the actual bonus

At the end of each year, the extent of meeting targets by each of the officers shall be calculated. The percentage of meeting targets of the officer shall be translated into a percentage of the target bonus according to the payment line formula. The actual bonus to be paid shall be calculated by multiplying the target bonus percentage by the target bonus.

The compensation committee and the board of directors shall be entitled to reduce an officer's annual bonus at their discretion taking into account the following factors:

- The amount of the officer's contribution to the Company's business development beyond the specific responsibility;
- The quality and speed of the officer's response to crises and unanticipated events;
- The officer's contribution to the promotion of the Company within his field of expertise or outside such field.
- The officer's overall management, motivating employees and leadership.

The annual bonuses approved by the compensation committee and the board of directors shall be paid to the officers together with the first monthly salary that is paid after the approval of the annual bonuses by the board of directors.

If annual bonuses have been paid to officers on the basis of financial measures which at a later stage transpire to be erroneous and are restated in the financial statements, the officer shall refund the surplus bonuses sums, within one year from the date of the Company's notice with respect thereto, linked to the consumer price index, and if the officer has received less, the Company shall pay the missing bonus amounts together with the next monthly salary. The Company, by written notice to the officer 60 days in advance, may set-off all or part of the surplus bonuses sums from the bonuses owing to the officer in respect of the following years.

5.2.2. Special bonus

The Company's compensation committee and the board of directors shall be authorized to award any of the Company's officers a one-time special bonus of up to a gross amount of NIS 500,000 (in addition to the annual bonus) in recognition of a significant achievement or for completion of an assignment, such as completion of a major transaction or achieving a major milestone with material effect over the Company's business. Such bonus is individual for any of the Chief Executive Officer, Deputy Chief Executive Officer or Vice Presidents and should be approved by the Company's compensation committee and board of directors.

5.2.3. Equity-Based Compensation

The Company's compensation committee and board of directors believe, in accordance with common practices of public companies in the market, that as part of the officers' total compensation package it is appropriate to offer a component of equity-based compensation, the purpose of which is to establish a joint interest between the officers and the Company's shareholders. By virtue of the long-term nature of equity-based compensation plans, they support the Company's ability to retain senior managers in their position for the long term and are in the interest of the Company and its shareholders.

In view of the advantages of equity-based compensation plans, the Company shall offer its officers participation in an equity-based compensation plan according to the provision set forth below:

5.2.3.1. Equity-based compensation plan

Subject to the approval of the Company's competent organs in accordance with law, the Company shall offer officers and directors, participation in an equity-based company plan, which may include options to purchase shares or restricted share awards or a combination of both (herein described collectively as "**Awards**"). The equity-based compensation plan shall be defined and implemented so that it conforms to the requirements of Section 102 of the Income Tax Ordinance in the capital gains track, to the extent possible.

The equity-based compensation plan to be approved shall include the following:

- The maximum number of securities to be granted and the dilution percentage arising from the grants;
- The method of allocating the grant among the various offerees and also a reserve for grants to office holders who may join the Company during the course of the term of the plan;
- The Awards shall vest over a minimum period of four years and not more than 25% of the Awards shall vest in each of such years. The minimum vesting period for the first portion of the grant shall not be less than one year from the date of grant;
- With respect to options, the exercise price of each option shall be equal to the higher of (i) the average closing price of the Company's ordinary shares on the Tel Aviv Stock Exchange during the 30 trading days prior to the date of the option grant plus 5%; and (ii) the closing price of the Company's ordinary shares on the Tel Aviv Stock Exchange on the date of the option grant;
- The expiration date of the options - up to 10 years from the date of grant; and

- Terms upon termination of employment or service (due to dismissal, resignation, death or disability) and change of control. The terms in the event of a change of control shall include, among others: a definition of a change in control resulting in full acceleration of Awards that have not yet vested as of the date of the change of control. Upon leaving the Company, the compensation committee shall be entitled, at its discretion, to approve the acceleration of Awards.

5.2.3.2. Grants

In accordance with the approval of the compensation committee and the board of directors, Awards shall be granted to officers of the Company in accordance with the terms of the approved equity-based compensation plan. To the extent that an approved plan includes several grants, the future grants shall be made in accordance with the provisions of the plan and on such dates as prescribed in the plan.

When a new officer joins the Company during the course of a plan, the joining officer shall be granted an Award out of the reserve determined in the plan.

The Awards granted shall be deposited with a trustee in accordance with the provisions of Section 102 of the Income Tax Ordinance. The trustee shall report to the offerees about the number of Awards it holds on their behalf, their exercise dates in the case of options and any other details they require in connection with the grant.

The considerations for the allocation of the Awards among the various offerees shall include:

- The officer's contribution to the Company's success;

- The officer's ability to influence the Company's future and performance;

- The amount of the other compensation components to which the officer is entitled;
- The scope of the officer's responsibility and tasks.

5.2.3.3. Exercise of Options

Upon vesting of each portion of an officer's options, the vested options held by the trustee may be exercised into Company shares. The trustee shall act pursuant to the officers' instructions and shall perform for them all the acts required for the exercise of the options into shares and/or cash.

5.2.3.4. Maximum Value of Equity-Based Compensation.

The maximum value of equity-based compensation for all officers shall be fifteen monthly base salaries.

5.3. ADDITIONAL BENEFITS AND PERQUISITES

5.3.1. **Pension**

The Company shall allocate payments to a pension fund (or several pension funds) or a pension agent, all in accordance with the officer's selection in writing and pursuant to the applicable statutory provisions. The allocations shall be made out of the officer's base salary only and shall not be comprised of any other compensation components whatsoever. The Company's allocations to pension funds shall be conditional upon the appropriate contribution from the officer's salary to the pension.

The Company shall insure officers for loss of earning capacity as part of their participation in a pension fund or as an additional policy for office holders that have manager insurance. The Company's allocations to insurance for loss of earning capacity shall not exceed 2.5% of the officer's base salary.

Officers who are recruited by the Company after the publication of this policy shall sign the general consent form of the Israeli Minister of Labor pursuant to Section 14 of the Severance Pay Law and the Company shall allocate the officers' severance pay into the pension fund / manager's insurance in accordance with officer's election.

5.3.2. **Further Education Fund**

Each month the Company shall allocate 7.5% of the officer's base salary and shall deduct a further 2.5% of his base salary to a further education fund at the officer's selection. The allocation and deduction from the officer's salary to a further education fund shall be made up to maximum amount permitted under the Income Tax Regulations.

5.3.3. **Vehicle**

The Company shall provide officers with a vehicle for their personal use, in accordance with the Company's practice, and the Company shall pay the cost of maintaining the vehicle. The officer shall pay any tax applicable under any law on the value of the use of the vehicle placed at his disposal by the Company. The Company shall calculate such tax and shall deduct it from the officer's salary.

5.3.4. **Mobile Phone**

The Company shall provide an officer with a mobile phone for his use, the type of which shall be at the Company's discretion, and the payment for the cost of use of the phone and the device shall be paid by the Company. The officer shall pay any tax which is likely to be levied on him due to the use of the mobile telephone at the Company's expense.

5.3.5. **Meals**

The officer shall be entitled to participate in a payment arrangement for meals during working hours as determined in the Company's policy with respect to all of the Company's employees.

5.3.6. **Annual Vacation**

An officer shall be entitled to annual vacation in the number of days determined in the annual vacation tables and in accordance with the Company's policy (or pursuant to the Annual Vacation Law if no such tables have been defined in the Company's policy).

5.3.7. **Sick Leave**

An officer shall be entitled to be absent from work on account of illness pursuant to the provisions of the Sick Pay Law and in accordance with the Company's policy.

5.3.8. **Recuperation Pay**

An officer shall be entitled to recuperation pay pursuant to the Recuperation Pay Law.

6. TERMINATION OF OFFICE CONDITIONS

6.1. ADVANCE NOTICE

An officer shall be entitled to an advance notice period, as determined by the compensation committee or in accordance with the existing agreements and no more than four months. During the course of the advance notice period, the officer shall be required to continue to fulfill his position, unless the chief executive officer decides to release him from this obligation, and he shall be entitled to the continuation of all the terms of office and employment without change with respect to such period.

6.2. RETIREMENT AND TERMINATION AWARDS

As a general rule, no retirement and termination awards shall be determined in the officers' personal employment agreements. The board of directors, at the chief executive officer's recommendation, may approve the offer to an officer who has been employed by the Company for at least three years, a retirement award in an amount not exceeding twice the officer's base monthly salary. When an officer has been employed by the Company for five years or more, the board of directors may approve a retirement or termination award which may not exceed four times the officer's base monthly salary.

6.3. NON-COMPETITION

Officers shall undertake in writing, at the time they enter into an employment agreement with the Company, to refrain from competing with the Company for a period which is not less than the advance notice period plus the retirement or termination award period to which they shall be entitled after their retirement from the Company.

Officers who are employed in the Company at the date of publication of the policy and who have not signed a non-competition agreement shall sign an agreement as above-mentioned as a condition for payment of any retirement or termination award.

7. EXCULPATION, INDEMNITY AND OFFICERS' INSURANCE

Office holders shall be covered by directors' and officers' liability insurance which the Company shall acquire, from time to time (the "**Policy**"), subject to the Israeli Companies Law, 1999 (the "**Companies Law**"), the Israeli Companies Law Regulations (Reliefs Regarding Transaction with Interested Parties), 2000 (the "**Companies Regulations**") and any other applicable law or regulation. Subject to the provisions of the Companies Law, the Companies Regulations and any other applicable law or regulation, the acquisition, extension, renewal or replacement of the Policy may be approved solely by the Company's compensation committee provided that (i) the maximum aggregate limit of liability pursuant to the D&O Insurance (including Side "A" coverage) shall be not more than US$50,0000,000 (fifty million U.S. Dollars) for each D&O Insurance period; (ii) the annual premium for each D&O Insurance (including Side "A" coverage) shall not exceed US$750,000 (seven hundred and fifty thousand U.S. Dollars); (iii) the maximum aggregate deductible payable by the Company shall not exceed US$2,000,000 (two million U.S. Dollars); and (iv) the D&O Insurance is on market terms and shall not have a material impact on the Company's profitability, assets or liabilities.

The Company awards, and shall continue to award, indemnification undertakings to directors and officers, subject to the approvals required in accordance with the provisions of the Companies Law.

Subject to the provisions of the Companies Law, the Company shall be entitled to exculpate in advance an office holder of the Company from liability, in whole or in part, for damages resulting from a breach of a duty of care towards the Company, subject to the approvals required in accordance with the Companies Law; provided, however, that the Company may not exempt an office holder for an action or transaction in which a controlling shareholder (as such term is defined in the Companies Law) or any other office holder (including an office holder who is not the office holder the Company has undertaken to exempt) has a personal interest (as such term is defined in the Companies Law).

8. MAINTENANCE OF THE COMPENSATION POLICY

8.1. The Company's Vice President, Human Resources shall be responsible for maintaining the compensation policy updated.

8.2. Updates to the compensation policy shall be approved by the compensation committee, the board of directors and the shareholders pursuant to the requirements of the Companies Law.

* * *

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED.
[*****] indicates the redacted confidential portions of this exhibit.

SIXTH AMENDMENT
TO THE
EXCLUSIVE MANUFACTURING, SUPPLY AND DISTRIBUTION AGREEMENT

This SIXTH Amendment to the Exclusive Manufacturing, Supply and Distribution Agreement dated August 23rd, 2010 as amended on September 6th, 2012, May 14th, 2013, February 15th, 2014, August 25th, 2015, and September 30th, 2016, by and between Baxalta US Inc., a member of the Takeda group of companies, having a place of business at 1200 Lakeside Dr., Bannockburn, IL 60015, USA (hereinafter "Baxalta") and **Kamada Ltd**., having a place of business at 2 Holzman Street, Weizmann Science Park, Rehovot 7670402, Israel (hereinafter "Kamada") (the "Agreement") is entered into as of this 30th day of August, 2019 (the "Effective Date"). Baxalta and Kamada shall collectively be referred to as the "Parties".

RECITALS

WHEREAS, the Parties desire to enter into a sixth amendment to the Agreement in order to amend the Minimum Purchase Levels and the Production Capacity for the years 2019 through 2021 as may be set under the Agreement and its prior amendments, as well as other provisions, as elaborated hereunder (hereinafter the "Sixth Amendment").

WHEREAS, Baxalta is interested to secure a Minimum Purchase Levels for the years 2019 through 2021, which exceed the quantities indicated in the Agreement (including its Amendments).

WHEREAS, the Parties desire to amend the Minimum Purchase Levels and Production Capacity for years 2019 through 2021.

NOW THEREFORE, it is hereby agreed as follows:

1. Section 4.5 of the Agreement shall be replaced with the following paragraph:

   4.5 2021 Supply and Post-2021 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 2022 and beyond. For the avoidance of doubt, and except as otherwise stated in the Agreement, Kamada does not guarantee the availability of any Products beyond 2021, and Production Capacity beyond 2021 will be negotiated separately. In addition, Baxalta shall notify Kamada no later than [*****], of Baxalta's requirements of additional Product in the 2021 Minimum Period in excess of the [*****] 50 ml vial Minimum Purchase Level for 2021.

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, 2021 (the ***"Minimums Term"***), Baxalta shall be obligated to purchase minimum volumes (the ***"Minimum Purchase Levels"***) of the Product as follows:

Minimum Period (Calendar Year)	**Minimum Purchase Levels (50 mL vials)**
2010	[*****]
2011	[*****]
2012	[*****]
2013	[*****]
2014	[*****]
2015	[*****]
2016	[*****]
2017	[*****]
2018	[*****]
2019	[*****]
2020	[*****]
2021	[*****]

3. Section 4.2(g) Failure to Supply is hereby amended to add paragraph (iv) as follows:

(iv) Without derogating from Baxalta's obligation to place purchase orders for the Minimum Purchase Levels during a Minimum Period, Kamada shall have the right to deviate from supplying the Production Capacity for the year [*****] by up to plus/minus [*****] vials (in each case, a positive or negative Deviation). In the case that Kamada supplies a positive Deviation for [*****], Baxalta shall purchase the Deviation, and both Baxalta's Minimum Purchase Level for [*****] and Kamada's Production Capacity for [*****] shall be reduced by the number of vials of such positive Deviation. In the case that Kamada supplies a negative Deviation for [*****], Baxalta shall have the option to a) cancel the purchase order for the number of vials of the negative Deviation, wherein such cancelled purchase order will still count towards Baxalta's Minimum Purchase Level for [*****]; or b) increase both Baxalta's Minumum Purchase Level for [*****] and Kamada's Production Capacity for [*****] to add the number of vials of the negative Deviation. Such option for a negative Deviation shall be exercised by Baxalta by written notice to Kamada by [*****].

4. 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/year
2010	[*****]
2011	[*****]
2012	[*****]
2013	[*****]
2014	[*****]
2015	[*****]
2016	[*****]
2017	[*****]
2018	[*****]
2019	[*****]
2020	[*****]
2021	[*****]

5. Section 5.1(d) of the Agreement shall be replaced with the following:

(d) Annual and Market Price Adjustments.

(i) The Transfer Price for 2019 shall be $[*****]. Thereafter, on each January 1 during the Minimums Term, or as soon thereafter as practicable, the then-current Transfer Prices (taking into account any prior year adjustments and Market Price adjustments) shall be increased by the lesser of: (A) [*****] ([*****]%) and (B) the percentage increase, if any, in the Producer Price Index total final demand, without any deductions, over the previous 12 months ending December as published in the December PPI Detailed Report by the U.S. Bureau of Labor Statistics for the prior year.

(ii) With respect to the year [*****], the Transfer Price shall be the [*****] Transfer Price plus the PPI increase allowed in Section 5.1(d) (i), above, plus [*****] dollars ($[*****]) per vial. Kamada shall provide a discount of [*****] dollars ($[*****]) per vial off the then current Transfer Price (at which point the Transfer Price shall be the [*****] Transfer Price plus the PPI increase allowed in Section 5.1(d) (i), above), for the incremental Product purchased by Baxalta from Kamada during [*****] in excess of [*****] 50 mL vials. Such discounts shall be reflected on both the purchase order and invoice for such Product purchased during [*****] in excess of [*****] 50 mL vials.

(iii) The Transfer Price specified in this Section 5.1(d) applies only to Products which are indicated for the treatment of Alpha-1 antitrypsin deficiency (AATD).

6. Section 8.1(b)(iii) shall be replaced with the following:

(iii) Until the First Commercial Sale (as defined in the License Agreement), and in connection with the conduct of the Clinical Studies, Kamada shall supply Baxalta with up to an aggregate amount, together with the Product supplied under Section 7.3(b), of [*****] [*****] mL vials of Product during the Term of this Agreement to be utilized solely in the conduct of such Clinical Studies at a discounted price (such vials being "Clinical Product"). These [*****] vials of Clinical Product provided under this Section 8.l(b)(iii) shall be at a price of US$ [*****] per vial. As of August 15, 2019, Kamada has supplied [*****] vials of Clinical Product, with [*****] vials of Clinical Product remaining. Such Clinical Product prices shall be reflected on both the purchase order and invoice for such Clinical Product. Prior to [*****], the Clinical Product shall count towards Kamada's Production Capacity for the year in which the Clinical Product is supplied, but not towards the Minimum Purchase Level for the Minimum Period in which the Clinical Product is supplied. Starting [*****], the Clinical Product shall count towards Kamada's Production Capacity for the year in which the Clinical Product is supplied, and towards the Minimum Purchase Level for the Minimum Period in which the Clinical Product is supplied

7. All provisions of the Agreement and its prior amendments which are not expressly amended by the terms of this Sixth Amendment shall remain in effect and without change. In the event of any conflict or inconsistency between the terms and conditions of this Sixth Amendment and the terms and conditions of the Agreement and its prior amendments, the terms and conditions of this Sixth Amendment shall govern and control the rights and obligations of the Parties.

[Signature page to follow]

IN WITNESS WHEREOF, the Parties have caused this Sixth Amendment to be executed by their duly authorized representatives.

BAXALTA US INC.

By: _____
Name:
Title:
Date: _____

KAMADA LTD.

By: /s/ Amir London
Name: Amir London
Title: Chief Executive Officer
Date:

By: /s/ Chaime Orlev
Name: Chaime Orlev
Title: Chief Financial Officer
Date:

Exhibit 4.31

CONFIDENTIAL

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED.
[*****] indicates the redacted confidential portions of this exhibit.

CLINICAL STUDY SUPPLY AGREEMENT

between

KAMADA LTD.

and

PARI PHARMA GMBH

CLINICAL STUDY SUPPLY AGREEMENT

This Clinical Study Supply Agreement (the "CSSA") is made effective as of May 8th, 2019 (the "CSSA Effective Date") by and between KAMADA Ltd., an Israeli company, with a principal place of business at 2 Holzman St., Science Park, P.O. Box 4081, Rehovot, 7670402, Israel ("KAMADA") and PARI Pharma GmbH, with its registered office at Mooosstrasse 3, 82319 Starnberg, Germany ("PARI"). In this CSSA, either PARI or KAMADA is referred to as a "Party," and collectively as the "Parties."

RECITALS

WHEREAS, PARI and KAMADA are parties to a certain License Agreement dated November 16, 2006 (the "License Agreement").

WHEREAS, PARI has developed and produced an eFlow Technology controller incorporating certain technologies to track, transfer, display and store information about patients adherence to inhaled medication by using data from their eFlow Technology Nebulizer Systems made available to the patients and the clinical development team for storing and transmitting nebulizer adherence data (the "eTrack Controller Kit" as defined in more detail in Schedule 1, Position No. 1) and the PARItrack Web Portal (as further described in Section 2.5 below) to track, display, store and report patients' adherence to inhaled medication by using the transferred nebulization data from the eTrack Controller, which together allow access to and evaluation of the nebulization data (which is available only to KAMADA and the clinical research and development team, but not provided to the patient, subject to personal data protection law as described in more detail in Schedule 2) (the eTrack Controller Kits and the PARItrack Web Portal are collectively referred to as "eTrack"); and

WHEREAS, KAMADA desires to use the eTrack under the License Agreement for the purpose of conducting its human factor studies and Phase III clinical trial relating to its Drug Product, in accordance with the License Agreement (the "Evaluation Studies"), as set forth under Article 6 "The Device and its Supply" thereof; and

WHERAS, PARI, being the owner of the entire right (including intellectual property rights), title and interest in eTrack, is willing to provide KAMADA with the eTrack Controller Kits (comprising certain accessories as described in Schedule 1 hereto) and Nebulizer Handsets and to provide access to the PARItrack Web Portal for the sole purpose of conducting the clinical Evaluation Studies in accordance with the provisions of the License Agreement; and

WHEREAS, the Parties wish to incorporate and supplement the supply and use of the eTrack and Nebulizer Handsets thereunder into the License Agreement for the purpose of the performance of the Evaluation Studies; and

WHEREAS, terms not defined in this CSSA shall have the meaning as set forth in the License Agreement.

NOW, THEREFORE, in consideration of the mutual covenants, terms and conditions hereinafter set forth, and intending to be legally bound hereby, the Parties agree as follows:

1. SUPPLY AND USE OF MATERIAL

1.1 Provision of Material

PARI will provide eTrack Controller Kits with monitoring and data transmission functionality used to operate and control Nebulizer Handsets as part of the Device and as specified in Schedule 1 of this CSSA to KAMADA to conduct the clinical Evaluation Studies under Section 6 of the License Agreement. Prices and service fees of eTrack are set forth in Schedule 1 of this CSSA. Following completion of the clinical Evaluation Studies, KAMADA shall ensure that the eTrack Controller Kits are fully returned to PARI and shall retrieve the eTrack Controller Kits at KAMADA's expense and the eTrack Controller Kits will be stored by KAMADA or a third party on behalf of KAMADA until fully returned to PARI.

1.2 Restriction of Use

The Parties agree for the purpose of this CSSA that the term "Device" as used in Section 1.8 of the License Agreement shall include the eTrack Controller Kit and to the extent applicable the PARItrack Web Portal. In addition to the provisions set forth in the License Agreement, KAMADA agrees to be bound by the following restrictions of use.

Use of eTrack Controller Kits. KAMADA agrees to comply with all Applicable Laws and Standards applicable to the clinical Evaluation Studies and eTrack. As used herein, "Applicable Laws and Standards" means (a) all laws, ordinances, rules, directives and regulations applicable to eTrack, the clinical Evaluation Studies or this CSSA, including without limitation applicable local laws and regulations in each relevant country in which the clinical trials are conducted or personal data of study participants is processed, (b) applicable regulations and guidelines of the U.S. Food and Drug Administration ("FDA") and other regulatory authorities and applicable guidelines of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use ("ICH"); (c) as applicable to the particular activities performed under this CSSA, Good Manufacturing Practices, Good Laboratory Practices and Good Clinical Practices promulgated by the FDA and other regulatory authorities or the ICH; (d) any applicable data protection laws and regulations applicable to the clinical Evaluation Studies and the processing of personal data, including without limitation HIPAA; and (e) all applicable industry and trade standards.

Use of the Documentation: Subject to the terms under the Applicable Laws and Standards, PARI shall provide KAMADA with an appropriate description of eTrack for use in specific regulatory filings or other documentation (e.g. Patient Information and Consent Form (as defined below), etc.) required by regulatory authorities for clinical trial applications related to the clinical Evaluation Studies. KAMADA shall not use any description of eTrack or language on eTrack (e.g., the labelling, including the name) other than that provided by PARI in any such regulatory documentation without first obtaining PARI's written approval of the changes to that description. Any section in a regulatory filing mentioning eTrack must be approved by PARI in writing prior to any submission to such regulatory authority.

Restricted Access to the eTrack Controller Kits. KAMADA shall only distribute or release the eTrack Controller Kits to any patients taking part in the clinical Evaluation Studies who have signed the Patient Information and Consent Form (as defined below) (the "Probands").

KAMADA, its Affiliates and Permitted Sublicensees shall retain control of the Device and shall not distribute or release the Device to any person or entity other than KAMADA's, its Affiliates' and Permitted Sublicensees' or the clinical trial site's employees, consultants or contractors ("KAMADA Representatives") and individuals who will be participating in the clinical trials who have a need to access the Device in connection with use of the Device for the clinical trials and who have been advised of KAMADA's obligations with respect to such Device. KAMADA shall not allow its Affiliates, its Sublicensees or KAMADA Representatives to keep or disburse the Device to any other person or other location, unless KAMADA first obtains PARI's written permission, such permission shall not unreasonably withheld or delayed. KAMADA shall be liable for the use of the Device by its Affiliates, its Permitted Sublicensees or KAMADA Representatives in violation of this Section 1.2(d).

The Device is to be used in accordance with the terms and conditions of this Agreement only by KAMADA, its Affiliates, its Permitted Sublicensees or KAMADA Representatives or patients participating in the clinical trials under KAMADA's control, at the clinical trial sites listed in the applicable purchase order for such Devices accepted by PARI.

KAMADA, its Affiliates and Sublicensees shall conduct the clinical trials pursuant to a written protocol (the "Study Protocol"). KAMADA shall provide a synopsis of the Study Protocol to PARI prior to the commencement of the applicable clinical trials. Following the completion of the clinical Evaluation Studies, KAMADA shall use commercially reasonable efforts to ensure that the Material (as described in Schedule 1, but excluding Pos. 2 of Schedule 1) is fully returned to PARI and shall retrieve the Material at KAMADA's expense and the Material shall be stored by KAMADA or a third party on behalf of KAMADA until fully returned to PARI.

KAMADA shall not, and shall cause its Affiliates and Sublicensees not to, subject to analysis or have subjected to analysis the Devices or components constituting Devices received from PARI for the purpose of reverse engineering or in a manner that would reveal material composition or internal design or operation of such sample or component or its method of manufacture. KAMADA shall be responsible for any breaches of this Section 1.2 by any of its Affiliates or Sublicensees.

1.3 Patient Information and consent Form

In addition to any other information material or declarations of consent that may be required to conduct the clinical Evaluation Studies, KAMADA shall not include any patients into the clinical Evaluation Studies who will use eTrack who did not validly and unequivocally sign a Patient Information and Consent Form approved by the applicable Ethics Committees (the "Patient Information and Consent Form") containing substantially all of the content of Schedule 2 of this CSSA. The content of Schedule 2 may be modified if required by the regulatory authority of the country in which the clinical Evaluation Studies will be conducted and KAMADA shall be entitled to add provisions and third party entities as processors to Schedule 2, provided that any change in Section 1 of Schedule 2 requires PARI's prior written approval before implementation.

2. DATA COLLECTION AND TRANSMISSION

2.1 Any data captured by the investigational eTrack Controller Kit is transmitted encrypted (in a format determined by PARI but at all times in compliance with Applicable Laws and Standards) via telecommunication services to be provided by a third party (the "Telecommunication Services") to a computer server hosted by or on behalf of PARI (the "PARI Server"). The Parties agree that, except as provided otherwise under Schedule 3 to this CSSA, as between the Parties, KAMADA shall act as the data controller and therefore is responsible for compliance with all data controller's obligations under the Applicable Laws and Standards. PARI operates the PARItrack Web Portal on the PARI Server, shall use commercially reasonable efforts to ensure the correctness of the data displayed in the PARItrack Web Portal and shall act as KAMADA's contract data processor (and therefore, if applicable, as a business associate under HIPAA) and, subject to any applicable law, shall have no responsibility towards Probands or other third parties other than KAMADA. KAMADA confirms to PARI that, as between the Parties, only KAMADA and no third party will have ownership of the Probands' personal data collected during the clinical Evaluation Studies. In case of access to such personal data by third parties, KAMADA will implement the legally required contractual provisions with such third parties and, if necessary, with the Probands, and PARI shall implement the legally required contractual provisions with any third party acting as PARI's data processor, including a data processing agreement as required in Schedule 3. To comply with applicable data protection laws, if applicable, the Parties will enter into the data processing agreement attached to this CSSA as Schedule 3 or any other written instrument containing all of the content of Schedule 3 (the "Data Processing Agreement"). In the event that applicable data protection laws require a change to the data protection provisions of this CSSA (including Schedule 3), the Parties shall amend the Data Processing Agreement accordingly.

2.2 PARI makes no representation regarding availability, timeline or functionality of the Telecommunication Services, but shall be responsible for the collection of the data by the eTrack Controller Kits and its processing on the PARI Central Servers in accordance with all Applicable Laws, Standards and the Data Processing Agreement. The Parties acknowledge that a delay or cancelation of the third party Telecommunication Services or their implementation with eTrack may lead to potentially severe restriction of the functionalities of eTrack.

2.3 KAMADA ACKNOWLEDGES THAT THE TELECOMMUNICATION SERVICES ARE MADE AVAILABLE ONLY WITHIN THE OPERATING RANGE OF THE NETWORK. SERVICE MAY BE TEMPORARILY REFUSED, INTERRUPTED, OR LIMITED BECAUSE OF AMONG OTHER THINGS: (i) FACILITIES LIMITATIONS; (ii) TRANSMISSION LIMITATIONS CAUSED BY ATMOSPHERIC, TERRAIN, OTHER NATURAL OR ARTIFICIAL CONDITIONS ADVERSELY AFFECTING TRANSMISSION, AND OTHER CAUSES REASONABLY OUTSIDE OF PARI'S OR ITS SUBCONTRACTORS' CONTROL; OR (iii) EQUIPMENT MODIFICATIONS, UPGRADES, RELOCATIONS, REPAIRS, AND OTHER SIMILAR ACTIVITIES NECESSARY FOR THE PROPER OR IMPROVED OPERATION OF THE TELECOMMUNICATION SERVICES. CONNECTIONS MAY BE "DROPPED" (I.E., INVOLUNTARILY DISCONNECTED) FOR A VARIETY OF REASONS, INCLUDING, WITHOUT LIMITATION, ATMOSPHERIC CONDITIONS, TOPOGRAPHY, WEAK BATTERIES, SYSTEM OVERCAPACITY, MOVEMENT OUTSIDE A SERVICE AREA OR GAPS IN COVERAGE WITHIN A SERVICE AREA.

2.4 Without derogating from the foregoing, PARI undertakes, for no consideration, to make commercially reasonable efforts to fix, within reasonable time and in compliance with the Data Processing Agreement, any defect or bug discovered in the data transmission, or its implementation with eTrack which is reported by KAMADA to PARI, as follows: PARI will (i) identify the source of the bug or defects as stated above, (ii) determine appropriate Solutions to repair such bug or defects, and (iii) initiate without undue delay repairs, including, if commercially reasonable, by giving patches or other temporary repairs of the services to allow for continuous use thereof.

2.5 EXCLUDING CASES OF PARI'S GROSS NEGLIGENCE, WILFUL MISCONDUCT, NEITHER PARI NOR PARI'S SUBCONTRACTORS NOR THE UNDERLYING CARRIER SHALL INCUR ANY LIABILITY FOR ITS INABILITY TO PROVIDE ADEQUATE SERVICES HEREUNDER IF SUCH INABILITY IS DUE TO THE LIMITATIONS SET FORTH IN SECTION 2.3 ABOVE OR TO CAUSES BEYOND THE REASONABLE CONTROL OF PARI, ITS SUBCONTRACTORS OR THE UNDERLYING CARRIER. EXCLUDING CASES OF BREACH OF THE DATA PROCESSING AGREEMENT, PARI SHALL NOT BE RESPONSIBLE FOR ANY ACT OR OMISSION RELATED TO EQUIPMENT OR SYSTEMS USED IN CONNECTION WITH THE TELECOMMUNICATION SERVICES OR OTHER DATA PROCESSING ACTIVITIES OTHER THAN eTrack.

2.6 PRIVACY: THE NETWORK USED TO PROVIDE THE TELE-COMMUNICATION SERVICES HAS MANY COMPLEX ELEMENTS AND IS NOT GUARANTEED AGAINST EAVESDROPPERS OR INTERCEPTORS. EXCLUDING CASES OF PARI'S GROSS NEGLIGENCE, WILFUL MISCONDUCT OR BREACH OF THE DATA PROCESSING AGREEMENT, AND EXCEPT AS OTHERWISE PROVIDED BY THE DATA PROCESSING AGREEMENT, KAMADA AGREES THAT NEITHER PARI NOR ITS SUBCONTRACTORS NOR AN UNDERLYING CARRIER SHALL BE LIABLE TO KAMADA FOR ANY LACK OF PRIVACY OR SECURITY.

2.7 The Parties agree that any rights in and to the software backend solution for managing the functionality of data transfer from eTrack, processing and accessing the collected data and any related features (collectively the "PARItrack Web Portal") and eTrack Controller Kit, including without limitation copyrights, know-how and other intellectual property rights, shall at all times remain the sole and exclusive property of PARI. Any inventions, improvements or discoveries that are based upon, or derived from the eTrack, but not from any data collected using the Probands, shall be promptly disclosed to and are and shall be the sole and absolute property of PARI. PARI declares and covenants that it retains all right, title to and interest to the PARItrack Web Portal and eTrack Controller Kit, including all intellectual property ownership rights related thereto, or that it is an authorized licensee of the PARItrack Web Portal and eTrack Controller Kit for the duration of this CSSA. KAMADA shall be granted a license to use PARI's eTrack Controller Kit for the sole purpose of conducting the clinical Evaluation Studies in accordance with the provisions of the License Agreement. The eTrack Controller Kit shall be considered part of the Device as defined in Section 1.8 of the License Agreement.

2.8 In accordance with Section 15.3 of the License Agreement, Kamada shall solely own the data collected and captured by PARI's eTrack during the Evaluation Studies, including without limitation any know-how and intellectual property rights conceived in the course of such Evaluation Studies relating to the Drug Product, and shall be exclusively entitled to incorporate such data and results in its drug master file and to disclose them to any regulatory authority, worldwide, without paying any additional consideration to PARI. In addition, Kamada shall be solely entitled to make any commercial use in such data, subject to the terms under the Applicable Laws and the Data Processing Agreement.

2.9 Subject to the terms under the Applicable Laws and the Data Processing Agreement, PARI may use the data captured by the investigational eTrack Controller Kit together with other technical data (including the serial numbers of the aerosol heads used with such investigational eTrack Controller Kit) solely for PARI's internal business purposes to monitor and analyze the Device performance.

3. MISCELLANEOUS

3.1 Term and Termination

This CSSA shall commence as of the CSSA Effective Date and expire concurrently with the expiration or termination of the License Agreement unless otherwise agreed to in writing by the Parties. Either Party may terminate this CSSA (i) upon ninety (90) days' written notice, or (ii) upon written notice to the other Party in the event a material breach of this CSSA by such other Party (including an infringement of third party's IP rights by PARI's PARItrack Web Portal or eTrack Controller Kit) is incurable or remains uncured sixty (60) days after notice of such breach was received by such other Party. Notwithstanding the termination of this CSSA, the provisions of Sections 2.3, 2.4, 2.8, 2.9, 3.1, and 3.2 shall survive the termination of this CSSA.

3.2 Disclaimer of Warranties and Limitation of Liability; Indemnification

EXCLUDING CASES OF FRAUD AND INTENTIONAL MISLEADING, eTrack AND CONFIDENTIAL INFORMATION IS PROVIDED "AS IS" AND PARI MAKES NO REPRESENTATION OR WARRANTY, EITHER EXPRESSED OR IMPLIED, CONCERNING eTrack OR THE CONFIDENTIAL INFORMATION CONTAINED THEREIN OR ANY TELECOMMUNICATION SERVICES. PARI DISCLAIMS ALL EXPRESS AND IMPLIED WARRANTIES RELATED TO eTrack INCLUDING WITHOUT LIMITATION FOR MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE; CONFIDENTIAL INFORMATION AND THE TELECOMMUNICATION SERVICES, INCLUDING BUT NOT LIMITED TO THE IMPLIED WARRANTY OF MERCHANTABILITY AND THE IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE.

Notwithstanding the generality of the foregoing paragraph, if eTrack Controller Kits or Nebulizer Handsets or Hubs supplied by PARI to KAMADA hereunder should not correspond with the Device Specifications (as defined in the License Agreement or amended in accordance with Appendix D of the License Agreement) or KAMADA becomes aware of defective Devices at the time of delivery, PARI shall at its own discretion rectify that defect, provide a replacement product, or provide a credit note to offset any future payment or, in case no later payment is due, repay the purchase price for the affected product. KAMADA's claims for defects of the Device are subject to notification of PARI of any visibly detectable defects and quantity variances within sixty (60) days after receipt of the relevant delivery. In case of defects of the Device, which were not visibly detectable at receipt by customary inspection of such Device made in due care by a suitable qualified person, PARI shall be notified by KAMADA immediately, but not later than ten (10) Business Days from such recognition of the defect. KAMADA's claims for defects shall expire in any case eighteen (18) months after delivery of an eTrack Controller Kit to KAMADA. KAMADA shall provide defect Devices to PARI for PARI's inspection and evaluation of the claimed defect. In the event eTrack data collection, transmission and processing services described or amended in the License Agreement do not comply with this CSSA or the Applicable Laws and Standards, PARI shall use commercially reasonable efforts to amend its services and to repeat such services in compliance with this CSSA.

IN NO EVENT SHALL PARI BE LIABLE TO KAMADA FOR ANY SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL DAMAGES OR DAMAGES FOR LOST PROFITS ARISING FROM THE USE OF eTrack OR CONFIDENTIAL INFORMATION, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY. This shall not apply either insofar as liability is mandatory, e.g. under the German Product Liability Act, in cases of intent or gross negligence or of injury of life, limb or health, as well as of breach of essential contractual obligations. However, claims for damages in case of breach of essential contractual obligations shall be limited to foreseeable damage typical for the contract insofar as there is no gross negligence and no liability for injury of life, limb or health.

Section 18 (Indemnification) of the License Agreement shall apply to this CSSA *mutatis mutandis*.

3.3 Counterparts

This CSSA may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

3.4 Severability

If any portion of this CSSA is determined invalid by any court, the rest shall remain in force and shall be construed as if not containing the invalid provision. The Parties undertake to replace the invalid provision or parts thereof by a new provision which will approximate as closely as possible the economic result intended by the Parties.

3.5 Applicable Provisions

This CSSA shall supplement the License Agreement. The Parties agree that the applicable provisions of the License Agreement shall apply to this CSSA mutatis mutandis, including without limitation Article 25. “Governing Law; Arbitration”, Article 20. “Relationship between the Parties”, Article 22. “Force Majeure”, Article 23. “Confidentiality” and Article 26. “Notices”.

[Signature Page follows]

IN WITNESS WHEREOF, the Parties have entered into the CSSA Agreement as of the CSSA Effective Date:

SIGNATURES

SIGNED for and on behalf of **KAMADA Ltd.**		SIGNED for and on behalf of **PARI Pharma GmbH**	
/s/ Amir London			
Amir London CEO	Date	*****	Date
/s/ Chaime Orlev			
Chaime Orlev CFO	Date		

Schedule 1
Prices and Service Fees

Following table contains prices and service fees for eTrack.

Pos	Description	Price
1	eTrack Controller Kit (comprising of the following components): · One (1) eTrack Controller · One (1) carrying bag · One (1) Nebulizer Handset connection cord · One (1) AC power supply · All outer packaging · Instructions for Use · Batteries · One (1) easycare cleaning aid (the “Easycare”), if required	[*****]
2	One (1) hub for access to Telecommunication Services (the “Hub”)	[*****]
3	Nebulizer Handset (including required aerosol heads)	To be determined

[Table continues on following page]

[Continuing table from preceding page - Schedule 1]

Pos	Description	Price	
4	One time set-up fee per trial (including the first training of study personnel)	[*****]	
5	Monthly fee for the PARItrack Web Portal	Up to [*****] patients per trial	[*****]
		Between [*****] and [*****] patients per trial	[*****]
		[*****] patients and more per trial	[*****]
6	Data transmission fee per month and active Hub	[*****]	
7	1st level support / training (excluding the first training of study personnel)	[*****]	
8	Travel expenses	[*****]	

Schedule 2

PATIENT INFORMATION AND CONSENT FORM

We hereby inform you as follows:

1. INVESTIGATIONAL EFLOW TECHNOLOGY NEBULIZER SYSTEM WITH ETRACK CONTROLLER

(a) Ownership

The investigational eFlow Technology nebulizer system handed out to you is provided only for the purpose to conduct the [Partner_Study_Title_No] and as long such Study is conducted. Ownership to such nebulizer system will not be transferred to you and you are obligated to return the nebulizer system after the conclusion of the Study or anytime upon request.

(b) Use of the investigational eFlow Technology nebulizer system

The nebulizer system is intended to be used by you exclusively for the purpose to conduct the Study.

You are not allowed to:

- use the nebulizer system or any component thereof (including the hub) for any purpose other than the inhalation therapy within the Study as advised by the investigator;
- give the nebulizer system to any other person or entity (other than persons helping you with your inhalation therapy);
- destroy, modify, analyze, reverse engineer, the nebulizer system or any components thereof, including any accessories and the hub, or modify, analyze, reverse compile or translate any software contained therein;

2. INFORMATION AND CONSENT TO THE PROCESSING OF PERSONAL DATA WITH ETRACK

You are thinking of taking part in the clinical study [Partner_Study_Title_No]. This study will be conducted by using an eTrack Controller which will collect and transfer certain data about your use of the device. We hereby inform you as follows with respect to the processing of your personal data:

(a) What data will be processed and what is the purpose of the processing?

The eTrack Controller, once connected to the internet via the wireless hub, will collect and transfer the serial number of the inhalation device and certain data about the use of the device such as the time of starting the nebulization and the time nebulization ends. Additional technical data of your inhalation device may be processed as well. Other data like your name, address, birthdate, etc. will not be transmitted but an allocation of the processed data to your person will take place at the receiving study centers via the serial number of your eTrack Controller. This is why we consider the pseudonymized data processed as your personal data.

Your personal and sensitive data will be collected and processed for the following purposes:

Provision of telemedicine services, in particular delivery of data showing the adherence to inhaled medication in the course of the clinical study [Partner_Study_Title_No].

(b) Modalities of processing

Your data will be processed by means of electronic devices and will be transmitted through IT networks with a high level of security. In particular, all preventative measures set forth in data protection legislation, including measures for segregation and encryption of data, will be adopted. Your data will be encrypted directly after creation within the eTrack Controller and transmitted only in encrypted form and without connection to your name (i.e. pseudonymous). Third parties involved in data transmission, other than the receiving healthcare professionals at the study centers as well as the principal investigator of the study, will not have the means to de-pseudonym your data.

(c) Scope of communication of data

Your data will be processed through IT instruments that will allow health operators to access patients' information and monitor their treatment. Access to your health data may only occur through the points of access authorized to access such data by authorized health operators.

Your data will be transmitted, by means of an IT network, to a central collection system. In order to make your data accessible to authorized health operators, your data may be processed by third parties entrusted with technical, logistic, IT, storage and transmission services. If collected within the European Union, your data will not be transferred outside the European Union. However, your data may be accessible in pseudonymized and encrypted form only for purposes of 24/7 technical support provided by service personnel in other territories by contractors of the data processor who are bound by confidentiality obligations and EU Commission standard contractual clauses outside of the European Union, including but not limited to the United States of America, whose legislation may not ensure the same level of protection of personal data as the one ensured in the European Union.

(d) Data controller and data processor

For the purposes of the provision of telemedicine services, KAMADA Ltd., the sponsor of the [Partner_Study_Title_No] study, shall act as data controller and PARI Pharma GmbH, Moosstrasse 3, 82319 Starnberg, Germany, shall act as data processor. PARI may internally use pseudonymized data for the sole purpose of monitoring and analyzing the technical performance of your nebulizer system.

(e) Categories of persons in charge of the processing

Healthcare operators and administrative personnel subject to professional secrecy obligations may process the data, each within their respective competences. The data controller and the data processor indicated in this information document may also entrust their respective personnel, collaborators, contractors and other third parties that may perform on their behalf and under their supervision supporting services for the processing of the data. Recipient of your personal data are the healthcare professionals conducting the [Partner_Study_Title_No] study at the [Partner_Study_Center].

(f) Sub-processor

Your data will be also processed by sub-processors engaged by PARI. KAMADA and PARI ensure that any processing of your data by such sub-processors will be subject to data processing agreements ensuring your rights under applicable data protection laws. Should you wish to obtain more information on such sub-processors, please contact KAMADA using the contact details below.

(g) Duration of processing

Your data will be processed for as long as your handheld nebulizer device is connected to the internet via the 2net Hub.

(h) Exercise of rights

You are entitled, inter alia, to the following rights:

Request the following information: origin of the data; purposes and modalities of processing; logic applied to the processing; identifying information of the data controller and data processors; persons or categories of persons to whom the data may be communicated or that may access the data as data processors or persons in charge of the processing;

Request the update, correction or integration of your data;

Request the cancellation, anonymization or block of your data without prejudice to the obligations to keep the data provided by law.

You may exercise the above mentioned rights by submitting a request to:

KAMADA Ltd.

[Partner_Address]

[Partner_Phone]

[Partner_Email]

(i) Optional/mandatory nature of the consent and consequences of denial

Your consent is optional. You are free to refuse your consent or revoke your consent at any time without stating any reason. However, failure to provide your consent for the purposes of the provision of telemedicine services will prevent the processing of your data for the purposes of providing such services to you. In this case, your participation in the [Partner_Study_Title_No] study will not be possible.

By signing this document you consent to the processing of your personal data for the purposes and in the way as described above.

I hereby confirm that I understand and agree to the information contained herein above.

Place and Date: _____

_____ _____

Full Name (block letters) Signature

Schedule 3

DATA PROCESSING AGREEMENT

The Data Processing Agreement set forth in this Schedule 3 hereby is incorporated into and made part of the CSSA. This Schedule 3 shall apply when KAMADA is acting as a data controller (particularly in the meaning of Article 4 No.7 of EU Regulation 2016/679) ("Controller"), and PARI is acting as a data processor for KAMADA (particularly in the meaning of Article 4 No.8 of EU Regulation 2016/679) ("Processor").

1. DEFINITIONS

1.1 Unless otherwise specified in this Schedule 3, all capitalized terms used in this Schedule 3 not otherwise defined in this Schedule 3 or otherwise in the CSSA have the meanings established for purposes of EU Regulation 2016/679. Capitalized terms used in this Schedule 3 that are not otherwise defined in this Schedule 3 and that are defined in the CSSA shall have the respective meanings assigned to them in the CSSA.

1.2 "GDPR" shall mean EU Regulation 2016/679 of the European Parliament and of the Council of 27th April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data ("General Data Protection Regulation"), as well as any EU or national statute implementing or replacing it.

1.3 "Applicable Laws" shall mean (a) European Union or Member State laws with respect to any Controller Personal Data in respect of which the Controller is subject to EU Data Protection Laws; and (b) any other applicable law with respect to any Controller Personal Data in respect of which the Controller is subject to any other Data Protection Laws

1.4 "Data Protection Laws" shall mean EU Data Protection Laws and, to the extent applicable, the data protection or privacy laws of any other country;

1.5 "EU Data Protection Laws" shall mean EU Directive 95/46/EC, as transposed into domestic legislation of each Member State and as amended, replaced or superseded from time to time, including by the GDPR and laws implementing or supplementing the GDPR;

1.6 "Breach" shall mean the acquisition, access, use or disclosure of PD in a manner not permitted by the GDPR or national data protection laws or this Schedule 3, as well as a 'personal data breach' in the meaning of EU Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications).

1.7 “Compliance Date” shall mean, in each case, the date by which compliance is required under the referenced provision of GDPR or its implementing regulations, as applicable; provided that, in any case for which that date occurs prior to the CSSA Effective Date, the Compliance Date shall mean that CSSA Effective Date.

1.8 “Data Subject” shall mean a data subject as defined in Article 4 No.1 of the GDPR.

1.9 “Personal Data” or “PD” shall have the meaning as provided for in Article 4 No.1 of the GDPR.

1.10 “Electronic Protected Health Information” (“ePHI”) shall mean PHI as defined in Section 1.11 that is transmitted or maintained in electronic media.

1.11 “PHI” shall mean Personal Data concerning health, as defined in Article 4 No.15 of the GDPR, and is limited to the data concerning health received from, or received or created on behalf of, KAMADA by PARI pursuant to performance of the Services.

1.12 “Security Rules” shall mean the EU or national security regulations, whether or not included in the GDPR, with respect PHI.

1.13 “Services” shall mean, to the extent and only to the extent they involve the processing of PD, the services provided by PARI to or on behalf of KAMADA under the CSSA.

2. SCOPE, ROLES OF THE PARTIES, OWNERSHIP OF PD

2.1 This Schedule 3 applies to all PD that PARI collects, processes and uses in the course of providing the Services under the CSSA and in accordance with KAMADA's instructions.

Kind of PD concerned:	Serial number of the device; Serial number of aerosol heads used in the device; Date, time and duration of nebulization and easycare backwash with such device; patient ID that is collected under the PARItrack portal; patient's study start/end; and therapy monitoring start/end.
Data Subjects concerned:	Probands participating in KAMADA's clinical studies which comply with the Development Agreement.
Purpose of collection, processing and use of PD:	Provision of telemedicine services, in particular delivery of data showing probands' adherence to inhaled medication.

2.2 Without prejudice to processing of PD that is carried out in accordance with this Data Processing Agreement, in the event that PARI infringes the Applicable Laws and this Data Processing Agreement by processing the PD for another reason than to provide the Service, the Processor will be regarded as the controller in respect of that processing. It should be noted that PARI, under the aforementioned circumstances, will be fully liable as the controller for such processing under the Applicable Laws including in relation to any sanctions under the said provisions.

3. RESPONSIBILITIES OF PARI

With regard to its collection, processing and use of data that is PD, PARI agrees to:

3.1 collect, process and use PD only as necessary to provide the Services, including monitoring and analysing the performance of the nebulizer systems, and in accordance with the instructions given by KAMADA in text format or oral instructions that are then confirmed in text format from time to time, and in compliance with each applicable requirement of the GDPR or as otherwise required by Applicable Law. PARI shall immediately inform KAMADA in writing if, in PARI's opinion, an instruction infringes Data Protection Laws, and provide an explanation of the reasons for this opinion in writing. PARI shall pursue appropriate investigations, if PARI doubts the lawfulness of an instruction.

3.2 inform KAMADA in writing, in case PARI is required to process PD under mandatory laws, before processing unless that law prohibits such information on important grounds of public interests, in which case PARI shall immediately inform KAMADA without undue delay once PARI is permitted to inform KAMADA.

3.3 taking into account the nature of the processing, implement and use appropriate administrative, organizational, physical and technical safeguards, and at all times as may be required by Applicable Laws, to (i) prevent use or disclosure of PD other than as permitted or required by this Schedule 3; (ii) appropriately protect the confidentiality, integrity, and availability of the PD that PARI creates, receives, maintains, or transmits on behalf of KAMADA; (iii) assist KAMADA when data subjects make use of their rights under Chapter III of the GDPR and (iv) as of the Compliance Date, comply with the Security Rules which shall ensure a level of security appropriate to the risk in accordance with GDPR Art. 32. Exhibit 1 to this Schedule 3 contains a description of safeguards implemented by PARI.

3.4 without unreasonable delay, report to KAMADA (i) any use or disclosure of PD not provided for by this Schedule 3 of which it becomes aware; or (ii) any accidental or unlawful destruction or accidental loss, alteration, unauthorized disclosure or access, and against all other unlawful forms of processing.

3.5 in the event of a Breach or in the event PARI has a reason to believe that a Breach occurred , without any delay, and in any event no later than two (2) working days after discovery, PARI shall provide KAMADA with written notification that includes a description of the Breach, the relevant data accessed, disclosed or used pursuant to such Breach, a list of Data Subjects and other information as required by, and in accordance with, the data breach notification requirements set forth in the GDPR and EU Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications). In case not all information is already available after two (2) working days, PARI shall inform KAMADA of data breach and provide further information without undue delay once it is reasonably available in order to enable KAMADA to comply with applicable breach notification requirements under Applicable Laws.

3.6 use its best efforts to immediately remedy any security incident and Breach that occurred on PARI information systems and prevent any further consequences at its own expense in accordance with Applicable Laws, regulations and standards.

3.7 assist KAMADA by providing necessary information, insofar as this is possible, for the fulfilment of KAMADA's obligations to respond to requests to exercise Data Subject rights under the Data Protection Laws. PARI shall promptly notify KAMADA if it receives a request from a Data Subject under any data protection law in respect of Controller Personal Data, and shall document, and within five (5) working days after receiving a written request from KAMADA, make available to KAMADA, information necessary for KAMADA to comply with an information request of Data Subject and upon written notice of KAMADA implement any Data Subject's request concerning the correction, deletion or blocking of data, in accordance with GDPR.

3.8 ensure that it does not respond to any Data Subject's request, except on the documented instructions of KAMADA or as required by Applicable Laws to which PARI is subject, in which case PARI shall to the extent permitted by Applicable Laws inform KAMADA of that legal requirement before PARI responds to the request.

3.9 notwithstanding Section 3.7, in the event that PARI in connection with the Services uses or maintains an electronic health record of PHI of or about a Data Subject, then PARI shall only if and as directed by KAMADA, make an accounting of disclosures of PHI directly to such Data Subject within five (5) working days, in accordance with the requirements for accounting for disclosures made through an electronic health record, as of its Compliance Date.

3.10 provide access, within five (5) working days after receiving a written request from KAMADA, to PHI in a set of data concerning health relating to a Data Subject, to KAMADA, sufficient to allow KAMADA to comply with the requirements of the GDPR.

3.11 notwithstanding Section 3.7, in the event that PARI in connection with the Services uses or maintains an electronic health record of PHI of or about a Data Subject, then PARI shall provide an electronic copy of the PHI within two (2) working days, to KAMADA, sufficient to allow KAMADA to comply with GDPR requirements as of its Compliance Date, all in accordance with the GDPR as of its Compliance Date.

3.12 to the extent that the PHI in PARI's possession constitutes data concerning health relating to a Data Subject, PARI shall make available, within five (5) working days after a written request by KAMADA, PHI for amendment and incorporate any amendments to the PHI as directed by KAMADA, all in accordance with the GDPR.

3.13 assist KAMADA with respect to, where applicable, data protection impact assessment in the meaning of Art. 35 and 36 of the GDPR, by providing such information and cooperation as KAMADA may require, for the purpose of assisting it in carrying out a data protection impact assessment and periodic reviews to assess if the processing of PD is performed in compliance with the data protection impact assessment and by assisting KAMADA with prior consultations with any competent data privacy authorities, and in case of a Breach.

3.14 not make or cause to be made any communication about a product or service that is prohibited by the GDPR or applicable law as of its Compliance Date.

3.15 not make or cause to be made any written fundraising communication that is prohibited by applicable law as of its Compliance Date.

3.16 shall appoint a data protection officer that has sufficient mandate and responsibilities to fulfil his or her tasks set forth in Art. 38 and 39 GDPR and that monitors compliance of the data processing for the purpose of this Data Processing Agreement and the GDPR on a permanent and continuous basis.

4. RESPONSIBILITIES OF KAMADA

In addition to any other obligations set forth in the CSSA, including in this Schedule 3, KAMADA:

4.1 shall be responsible for using administrative, physical and technical safeguards at all times to maintain and ensure the confidentiality, privacy and security of PHI transmitted by KAMADA to PARI pursuant to the CSSA, including this Schedule 3, in accordance with the standards and requirements of HIPAA (if applicable) and the GDPR, until such PHI is received by PARI.

4.2 shall ensure that there is a legal ground for processing the PD covered by this Data Processing Agreement.

4.3 shall be responsible for implementation of procedures for Data Subjects' rights to access to personal data concerning health as required under Article 15 GDPR and shall function as point of contact for Data Subjects seeking to exercise these rights.

4.4 shall appoint a data protection officer that has sufficient mandate and responsibilities to fulfil his or her tasks set forth in Art. 38 and 39 GDPR, to function as single point of contact with regard to the processing of Personal Data contemplated under this Data Processing Agreement and that monitors compliance of Processor and Controller for the purpose of this Data Processing Agreement and the GDPR on a permanent and continuous basis.

5. SUB PROCESSING

5.1 PARI shall provide KAMADA with a full list of sub-processors, including the name and jurisdiction of each sub-processor and the type of the processing to be undertaken by such sub-processors, before starting any processing operations concerning PD under the Agreement. PARI shall inform KAMADA of any intended changes concerning the addition or replacement of any sub-processors with KAMADA being permitted to object to such a change upon reasonable grounds only, by sending a notice to PARI, before the PD is made accessible to the sub-processor. If KAMADA notifies PARI in writing of any objections (on reasonable grounds) to the proposed appointment:

5.1.1 PARI shall work with KAMADA in good faith to make available a commercially reasonable change in the provision of the Services which avoids the use of that proposed sub-processor; and

5.1.2 where such a change cannot be made within 30 days from PARI's receipt of KAMADA's notice, notwithstanding anything in the CSSA, KAMADA may by written notice to PARI with immediate effect terminate the CSSA to the extent that it relates to the Services which require the use of the proposed sub-processors.

5.2 Before any new sub-processor first processes Controller Personal Data, PARI shall ensure that such sub-processor is capable of providing the level of protection for Controller Personal Data required by the CSSA and this Data Processing Agreement; PARI shall ensure that each sub-processor enters into a data processing agreement as required under Applicable Law.

5.3 PARI shall remain responsible for all obligations performed and any omission to perform or comply with the provisions under this Data Processing Agreement by subcontractors to the same extent as if such obligations were performed or omitted by PARI. PARI shall also remain the KAMADA's sole point of contact.

5.4 PARI shall ensure that only such employees which must have access to the PD in order to meet PARI's obligations under this Data Processing Agreement, shall have access to the PD processed on behalf of KAMADA, and that such employees have received appropriate training and instructions regarding processing of PD and are subject to a confidentiality undertaking that provides that he/she must keep all PD secret and may not use it for other purposes not required for the performance of the tasks he/she may be assigned to in performing the Services.

6. AUDIT RIGHTS

6.1 PARI shall regularly monitor and control compliance of the collection, processing and use of PD with the CSSA and KAMADA's instructions. Prior to beginning of the data processing under this Data Processing Agreement it shall confirm in writing that it has implemented the technical and organizational measures as set forth in Section 3.3 above. PARI then shall perform a yearly audit of such technical and organizational measures and make available to KAMADA a copy of the audit report in order to enable KAMADA to monitor compliance with agreed terms upon KAMADA's written request. In addition, once a year PARI shall make available to KAMADA on request all other information necessary to demonstrate compliance with this Data Processing Agreement.

6.2 If KAMADA reasonably determines that the yearly audit report is not sufficient to comply with its duty, as a Controller, to monitor its Processor (e.g. because there was a data breach or because a competent data protection authority requests it) KAMADA may instruct an auditing company to perform an external audit of PARI at its own cost, except where the audit reveals non-negligible non-compliance with this Data Processing Agreement or the Applicable Laws, in which case PARI shall bear all costs of such audit. Within such audit PARI shall make available to KAMADA on request all information necessary to demonstrate compliance with this Data Processing Agreement. It is being understood, that the audit report may contain parts which have to be kept confidential in which case it shall suffice that auditors declare that this issue was complied with, unless a competent data protection authority requests more detailed information. PARI shall also allow audits from data protection authorities competent for KAMADA.

7. PERMITTED USES AND DISCLOSURES OF PHI

Unless otherwise limited in this Schedule 3, in addition to any other uses or disclosures permitted or required by this Schedule 3, PARI may:

7.1 make any and all uses and disclosures of PHI, solely when necessary to provide the Services to KAMADA in accordance with the CSSA.

7.2 subject to the terms of Section 5 above, use and disclose to subcontractors and agents the PHI in its possession for its proper management and administration or to carry out the legal responsibilities of PARI under the CSSA, provided that any third party to which PARI discloses PHI for those purposes provides written assurances in advance that: (i) the information will be held confidentially and used or further disclosed only as required for performance of the Services; (ii) the information will be used only for the purpose for which it was disclosed to the third party; and (iii) the third party promptly will notify PARI of any instances of which it becomes aware in which the confidentiality of the information has been breached; (iv) subcontractor or agent is subject to audit obligations to ensure that full audit according to Section 6 can be performed;

7.3 use the PHI and other data for the sole purpose of monitoring and analyzing the technical performance of the nebulizer system, but in no event for any other business activity or purpose of PARI.

8. TERMINATION AND COOPERATION

8.1 Termination. This Schedule 3 terminates automatically, if the CSSA terminates. In addition, if either party knows of a pattern of activity or practice of the other party that constitutes a material breach or violation of this Schedule 3 then the non-breaching party shall provide written notice of the breach or violation to the other party that specifies the nature of the breach or violation. The breaching party shall cure the breach or end the violation on or before thirty (30) days after receipt of the written notice. In the absence of a cure reasonably satisfactory to the non-breaching party within the specified timeframe, or in the event the breach is reasonably incapable of cure, then the non-breaching party may, if feasible, terminate the CSSA, including this Schedule 3.

8.2 Effect of Termination or Expiration. Within sixty (60) days after the expiration or termination for any reason of the CSSA or this Schedule 3, PARI shall upon KAMADA's choice return or destroy all PHI, if feasible to do so, including all PHI in possession of PARI's agents or subcontractors. In the event that PARI determines that return or destruction of the PHI is not feasible, PARI shall notify KAMADA in writing and may retain the PHI subject to this Section 8.2 if permitted by GDPR. Under any circumstances, PARI shall extend any and all protections, limitations and restrictions contained in this Schedule 3 to PARI's use or disclosure of any PHI retained after the expiration or termination of the CSSA or this Schedule 3, and shall limit any further uses or disclosures solely to the purposes that make return or destruction of the PHI infeasible.

9. INDEMNIFICATION

9.1 PARI will indemnify, hold harmless and defend KAMADA and its Affiliates and their respective officers, employees and agents from and against any and all third party, claims and related expenses (including reasonable attorney fees) resulting from, or arising out of any negligent non-compliance of the responsibilities of PARI as described in this Data Processing Agreement.

9.2 PARI acknowledges and agrees that any unauthorized access to, use or disclosure of PD would cause immediate and irreparable harm for which money damages would not constitute an adequate remedy and that in the event of any unauthorized use or disclosure of PD, KAMADA shall be entitled to immediate injunctive relief.

10. MISCELLANEOUS

10.1 Contradictory Terms; Construction of Terms. Any other provision of the CSSA that is directly contradictory to one or more terms of this Schedule 3 ("Contradictory Term") shall be superseded by the terms of this Schedule 3 to the extent and only to the extent of the contradiction, only for the purpose of KAMADA's and PARI's compliance with the GDPR, and only to the extent reasonably impossible to comply with both the Contradictory Term and the terms of this Schedule 3. The terms of this Schedule 3 to the extent they are unclear shall be construed to allow for compliance by KAMADA and PARI with the GDPR.

10.2 Survival. Sections 8.2, 10.1, and this 10.2 shall survive the expiration or termination for any reason of the CSSA or of this Schedule 3.

10.3 Assignation of rights or obligations. PARI shall not assign its rights or obligations under this Data Processing Agreement without the prior written consent of KAMADA. KAMADA shall be entitled to assign its rights and obligations under this Data Processing Agreement, specifically for the purpose of conducting clinical studies using third party contractors and processors, other than PARI.

10.4 Notices. All notices to a party under this Data Processing Agreement shall be in writing and sent to its address as set forth at the beginning of this CSSA, or to such other address as such party has provided the other in writing for such purpose. Notices may be sent by post, courier, fax or email. Notices shall be deemed to have been duly given (i) on the day of delivery when delivered in person or by courier, (ii) three (3) business days after the day when the notice was sent when sent by post, and (iii) on the day when the receiver has manually confirmed that it is received when sent per fax or email.

IN WITNESS WHEREOF, the Parties have entered into the CSSA as of the CSSA Effective Date; Schedule 3 will be made an integral part of it:

SIGNED for and on behalf of **KAMADA Ltd.**		SIGNED for and on behalf of **PARI Pharma GmbH**	
/s/ Amir London			
Amir London CEO	Date	*****	Date
/s/ Chaime Orlev			
Chaime Orlev CFO	Date		

Exhibit 1 to Schedule 3

Description of Technical and Organizational Safeguards

This Exhibit 1 forms an integral part of Schedule 3 (Data Processing Agreement)

1. **Physical access control**

Are there any regulations governing access to the building, to the computer centre and to the premises comprising the IT infrastructure?

Explanations / comments:

The physical approach to a data processing system ("**DPS**") must be controlled. Unauthorised persons must be prevented from gaining access to and operating the DPS in any way.

Examples: - access control system, badge reader

- magnetic card, chip card

- keys, key allocation

- door lock mechanism (electrical door opener, etc.)

- company security, gatekeeper

- monitoring facility, alarm system, video/closed-circuit TV

Measures implemented on Data Processor's premises:

PARI IT infrastructure components are located in two separated data centres at Moosstraße 3, 82319 Starnberg. Access to these data centres is controlled by E-Token/smartcard and allowed only to defined persons.

SAP infrastructure as well as digital infrastructure are hosted by QSC AG in Hamburg (contract information available if requested). QSC is audited by PARI QM department.

2. Computer access control

Are there any regulations governing the use of DP systems?

Explanations / comments:

Any unauthorised use of DPS must be prevented, no matter whether or not such use is effected by means of data transmission equipment (e.g. via the internet).

Examples: - password procedures (including special characters, minimum length, regular change of password)

- automatic blocking (e.g. password or pausing)

- setting up one user master record per user

- encryption of data volumes

Measures implemented on Data Processor's premises:

Use of Laptops/desktops is secured by E-Token/smartcard and Password; every application needs user and Password authentication.

3. Data access control

Are there any regulations governing the allocation of user rights, their modification and withdrawal?

Explanations / comments:

It must be ensured that the authorised persons have access only to those data they are authorised to access. A set of rules for the allocation and withdrawal of authorisations must be organised and implemented to protect personal data, at all stages of their collection, processing and use and after their storage, in such a way that they cannot be read, copied, altered or removed by unauthorised persons.

Examples: - differentiated authorisations (profiles, roles, transactions, objects), data encryption

Measures implemented on Data Processor's premises:

There must be a written request for system access and authorisation (documented by Sharepoint workflow) made by GPO's (Global process owner) or line manager; they define which role IT adds to a specific person.

All Laptop Harddrives are encrypted by Bitlocker.

The eFlow data are encrypted (transformation: Rijndael/ECB/NoPadding; Algorithm: AES).

4. Disclosure control

Is the transfer or transmission of data controlled? Is the dispatch of data volumes (including paper) controlled? Are there any regulations governing the transmission of sensitive or personal data (passwords, encryption, etc.)? Are there any process-independent plausibility and security checks in place upon data input by the Data Processor? Are the results checked for correctness by the Controller?

Explanations / comments:

During transport or electronic transmission, personal data must be protected in such a way that they cannot be read, copied, altered or removed by unauthorised persons (encryption may be an option). Besides the verifiability and traceability of data transmission it must be ensured that unauthorised persons are prevented from accessing the data during their transmission. Since this cannot be guaranteed by technical means at this point, it must be ensured that any modification or deletion of data can be recognised.

Examples: - encryption / tunnelling connection (VPN = Virtual Private Network)

- electronic signature

- logging

- transport protection

Measures implemented on Data Processor's premises:

If somebody wants to have access to our infrastructure from outside our network, again a specific written request is needed (documented by Sharepoint workflow) and if allowed implemented by VPN tunnel.

In SAP we have implemented the Standard SAP Audit Trail as well as an extended Audit Trail.

5. Input control

Are the collection, modification and deletion of personal data logged?

Explanations / comments:

It must be ensured (by logging) that it is possible after the fact to check and ascertain whether personal data have been entered, altered or removed, and if so, when and by whom.

Examples: - logging systems and report evaluation systems

Measures implemented on Data Processor's premises:

See point 4 Audit Trail and extended Audit Trail

6. Job control

Is it ensured that the data to be processed by the Data Processor are processed exclusively according to the Controller's instructions? Are these instructions implemented by the Data Processor without delay? Are there any checks in place to prevent the data from being copied, altered or transmitted to unauthorised third parties?

Explanations / comments:

It must be verified and ensured that personal data processed on behalf of others are processed strictly in compliance with the Controller's instructions.

Examples: - obligation of staff involved in data processing to maintain data secrecy

- code of conduct for data processing by the Data Processor

- procedures for revealing any error instructions

- checking compliance with instructions

- granting the Controller monitoring rights as per data privacy agreement

Measures implemented on Data Processor's premises:

The use of IT Systems is described in a standard operating procedure of PARI.

PARI IT is audited by internal QM department as well as external audits by cancom/acentrix (detailed audit documentation available if requested).

7. Availability control

Does the Data Processor has a backup scheme in place and is it checked at regular intervals? Are there any disaster response exercises in place? Is the place of storage and processing clearly identified? Has the storage period for the data sets and possibly for the software been defined?

Explanations / comments:

The availability of personal data must be ensured. Appropriate measures are to be taken to protect DPS (hardware and software) against accidental destruction (disaster case).

Examples: - backup procedures

- mirror disks, e.g. RAID procedure

- uninterruptible power supply (UPS)

- separate storage

- antivirus protection, firewall

- contingency plan

Measures implemented on Data Processor's premises and are described in several standard operation procedures at PARI.

Data are hosted by QSC AG; Information regarding backup procedure etc are available if requested.

8. Separation control

Has the separation control requirement been fulfilled to ensure the separate processing of data collected for different purposes (separation rule)? Are the systems multi-client capable?

Explanations / comments:

It must be ensured that personal data collected for different purposes can be processed separately. Logical rather than physical separation is required.

Examples: - "internal client capability" / earmarking

- functional separation (production, testing)

Measures implemented on Data Processor's premises:

Data access is based on different roles so that the users only see the data they need for work.

Relevant system landscape is separated into Development system, Quality system and Production system.

Exhibit 4.32

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED.
[*****] indicates the redacted confidential portions of this exhibit.

BINDING TERM SHEET
[*****]®

December 6, 2019

RECITALS	This Binding Term Sheet ("**Term Sheet**") summarizes the main terms and conditions under [*****], of [*****] ("**COMPANY**") and Kamada Ltd. of 2 Holzman St. Science Park, P.O. Box 4801, Rehovot, 7670402, Israel ("**SUPPLIER**") will enter into a long-term agreement for the supply of the Product (as defined below) and for the grant of exclusive distribution rights to SUPPLIER in certain territories and ancillary agreements. (Each of COMPANY and SUPPLIER is referred to hereunder as a "**Party**" and together the "**Parties**".) By signing this Term Sheet, the Parties agree to be legally bound by the provisions set forth below, and each Party shall be legally bound to proceed to negotiate in good faith and then execute the following agreements incorporating the terms set forth herein: i. a Contract Manufacturing and Supply Agreement (the "**Supply Agreement**"); ii. a Plasma Supply Agreement (the "**Plasma Agreement**"); iii. a Quality Agreement (the "**Quality Agreement**"); iv. a Technology Transfer Agreement (the "**Technology Transfer Agreement**"); and v. an Exclusive Distribution Agreement (the "**Exclusive Distribution Agreement**") (Each of the agreements listed in (i) through (v) above, collectively, the "**Definitive Agreements**" and individually, a "**Definitive Agreement**"). The Plasma Agreement, the Quality Agreement and the Technology Transfer Agreement will each include a three-way executed annex that will include a detailed list of COMPANY, SUPPLIER and [*****] (as defined below) roles and responsibilities with respect to the scope of each of those agreements. The Parties shall make all commercial reasonable best efforts to execute the Technology Transfer Agreement within [*****] ([*****]) days following the execution of this Term Sheet. The Parties shall make all commercial reasonable best efforts to execute the other Definitive Agreements not later than [*****]. The execution of the Definitive Agreements is subject to obtaining the approval of the Parties' respective senior management and Board of Directors.
PRODUCT	The pharmaceutical product, [*****]®[*****] (the "**Product**").
TERRITORY	Worldwide (other than the Exclusive Distribution Territories (as defined below) (the "**Territory**"). The "**Exclusive Distribution Territories**" shall mean the territories in respect of which COMPANY shall grant SUPPLIER exclusive distribution rights under the Exclusive Distribution Agreement as follows: (a) Israel; (b) the areas or territories administered or controlled by Palestinian Authorities which shall be deemed to include the West Bank and Gaza (the "Palestinian Territories"); and (c) any other country/ies or territory/ies mutually agreed upon by the Parties. SUPPLIER will be solely responsible for obtaining, and the costs associated with, all necessary product registrations and Regulatory Approvals in the Exclusive Distribution Territories.
SUBCONTRACTOR	Following the written approval of COMPANY, SUPPLIER may engage subcontractors to perform specific services and/or obligations under any of the Definitive Agreements (each a "**Subcontractor**"). Unless specifically agreed under any Definitive Agreement(s), the SUPPLIER will remain primarily liable to COMPANY for the performance of its Subcontractors performance and obligations under the Definitive Agreements. Without derogating from the foregoing, it is hereby agreed between the Parties that for the purposes of this Term Sheet and the Definitive Agreements, [*****] ("[*****]") shall be considered to be a Subcontractor of the SUPPLIER for the purpose of the performance of certain Plasma's fractionation services and related services.

Supplier Registration and Regulatory Approval	The SUPPLIER, as manufacturer of the Product (including, the manufacturing facilities of SUPPLIER and its Subcontractor, [*****]), has or will obtain and maintain any and all manufacturing and GMP approvals for its manufacturing facilities as may be required by [*****] (the "**[*****]**"), [*****], or other regulatory authorities in the Territory (such required registrations/licenses, the "**Supplier Registration**"). As used herein, the term "**Regulatory Approval**" shall mean the manufacturing and GMP approvals required in order to manufacture or sell the Product, obtained by [*****] and [*****] under current licenses in the Territory, including, but not limited to, the Supplier Registration. In the event that COMPANY wishes to register the Product in other territories which will require additional regulatory oversight other than the [*****] or [*****] (other than territories that will be covered under the Exclusive Distribution Agreement), then the Parties shall negotiate and endeavor to reach an agreement, in good faith, with respect the additional activities that may be required, timelines and costs associated with such additional registration. For purposes of clarity, SUPPLIER shall be responsible for the costs to obtain Regulatory Approval by the applicable regulatory agency or authority in each of the Exclusive Distribution Territories.
Term	The Supply Agreement shall provide for an initial term of twelve (12) years, commencing on the date of the grant of Regulatory Approval by either the [*****] or [*****] (the "**Supply Agreement Effective Date**"), which is projected to be by [*****], the expiration date to be [*****], (such period, the "**Initial Term**"); provided however, that the Parties may mutually agree to extend the term of the Supply Agreement for consecutive [*****] ([*****]) year renewal terms (each a "**Renewal Term**" and together with the Initial Term, the "**Supply Agreement Term**"), by mutual agreement at least [*****] ([*****]) months prior to the end of the Initial Term or the then current Renewal Term. Each of the Plasma Agreement and the Quality Agreement shall have a commencement date as of the date of its execution and shall remain in effect until the later of: (i) the termination of the Technology Transfer Agreement; or (ii) the termination of the Supply Agreement. The Technology Transfer Agreement shall have a commencement date as of the date of its execution and shall remain in effect until Regulatory Approval by both the [*****] and [*****] has been obtained by the COMPANY, or until COMPANY chooses not to pursue such approval, unless earlier terminated as set forth in this Term Sheet and/or in accordance with the terms of the Technology Transfer Agreement.
Supply Agreement	The Supply Agreement will set forth in detail the respective responsibilities and obligations of the Parties (including any regulatory responsibilities and requirements) with respect to the manufacture and supply by SUPPLIER to COMPANY of commercial batches of the Product (as shall be more fully described in the Supply Agreement, and all references in this Term Sheet to "batches" shall refer to commercial batches of the Product, unless otherwise expressly provided herein), including, but not limited to, the following: i. [*****] (the "**Source Plasma**") – COMPANY shall be responsible for the timely supply of all quantities of the Source Plasma required for the manufacturing of the Product. The specific terms of the Source Plasma supply, including the specifications therefor and other requirements (including current good manufacturing practices and other applicable laws, regulations and standards) to be complied with by COMPANY, will be set forth in the Plasma Agreement. ii. Raw Materials – SUPPLIER will be responsible for sourcing and qualifying all raw materials (other than the Source Plasma) necessary for production of the Product. iii. Raw Materials Storage – SUPPLIER will be obligated to store all raw materials and Source Plasma as required by COMPANY's specifications (as shall be set forth in the Quality Agreement), SUPPLIER's standard operating practices and applicable regulatory standards. iv. [*****]Testing of Product – The COMPANY will be responsible for the performance of the [*****] testing of the Product at its own cost.

v. Rolling Forecast – The COMPANY shall be required to provide a [*****] ([*****]-month rolling forecast for the Product ("Rolling Forecast") on a monthly basis, with the first [*****] ([*****]) months of each Rolling Forecast being binding (the "Binding Forecast"), and the COMPANY shall issue purchase orders for the quantities of the Product in the Binding Forecast. The first Rolling Forecast shall be submitted to SUPPLIER one (1) year prior to the expected Supply Agreement Effective Date, but shall not be binding on either Party until the Supply Agreement Effective Date. The first Binding Forecast shall be effective as of the Supply Agreement Effective Date. The COMPANY shall provide SUPPLIER with purchase orders for the naked filled vials of the Product not less than [*****] ([*****]) months prior to the required delivery date, and for final packed vials not less than [*****] ([*****]) months prior to the required delivery date.

In addition, upon termination of the Supply Agreement, other than as a result of COMPANY's uncured material breach, or as a result of SUPPLIER's inability to supply the Product due to force majeure (as shall be defined in the Supply Agreement), COMPANY shall have the right, but not the obligation, to order up to [*****] ([*****]) additional batches of the Product in accordance with the then applicable Rolling Forecast, subject to the timely supply by COMPANY of the required quantities of Source Plasma.

vi. Minimum Commitment – During the Supply Agreement Term, COMPANY will be obligated to acquire and SUPPLIER will be obligated to supply a minimum of [*****] ([*****]) [*****] of the Product per year for each of the first five full calendar years of the Initial Term, and [*****] ([*****]) batches of the Product per year for the remaining [*****] years of the Initial Term ("**Minimum Annual Commitment).** In the event that COMPANY fails to order the Minimum Annual Commitment in a given year, then the COMPANY will be obligated to pay SUPPLIER an amount equal to [*****]% of the Supply Price per each of the batches not ordered under the Minimum Annual Commitment.

vii. Batch Size – The current batch size is [*****] of Source Plasma.

viii. Supply Price – The price payable by COMPANY to the SUPPLIER per batch of the Product supplied shall be as follows (the "**Supply Price**"):

a. $[*****][*****]per batch; and
b. $[*****][*****]per batch for the incremental batches supplied in a given year in excess of the 1st 12 batches.

Delivery of the Product will be made [*****] (Incoterms 2010) [*****][*****][*****]in [*****].

The Supply Price does not include costs associated with Source Plasma (covered under the Plasma Agreement), [*****] and batch release services as may be required to release the Product, except in [*****].

COMPANY will be responsible for Product Qualified Person batch release in [*****] and all costs associated with it. In the event that COMPANY wishes SUPPLIER to provide with the Product Qualified Person batch release in [*****], then COMPANY shall reimburse SUPPLIER for all of its costs and expenses associated with such additional service.

Payment shall be made by COMPANY in full within [*****] ([*****]) days from the date of SUPPLIER's invoice.

ix. Supply Price Adjustment – As of [*****], and at the beginning of every calendar year thereafter, the Supply Price will be increased on an annual basis by the lower of: (a) [*****]; or (b) [*****]%.

In addition, in case of substantial change in the cost to SUPPLIER to manufacture and supply the Products under the Supply Agreement due to statutory or regulatory changes or a change in the specifications of the Product, or due to other changes, such as significant increase in cost of raw material or cost of activities subcontracted, SUPPLIER will provide such documentation for such increases as COMPANY may reasonably request and the Parties agree to negotiate and endeavor to reach agreement in good faith regarding adjustment (increase) to the Supply Price.

x. Production failure –The COMPANY will become obligated to pay the Supply Price for a Product batch upon initiation of the first step of the production process by SUPPLIER (i.e. thawing of plasma), even in case the production or manufacture of such batch is not completed either at the direction of the COMPANY or as a result of the termination of the Supply Agreement following a default by COMPANY; provided, however, that if a batch of Product shall fail to meet the specifications for the Product, and an independent mutually agreed laboratory shall determine that the batch failure was through the fault of SUPPLIER, then the SUPPLIER will replace the failed batch at SUPPLIER's cost, following the supply by the COMPANY of Source Plasma required for such replacement batch.

In the event that the total number of failed batches in a given calendar year exceed [*****] ([*****]), then SUPPLIER will reimburse COMPANY for the value of the Source Plasma, included in each of the failed batches over the first [*****] ([*****]) failed batches. SUPPLIER's responsibility to reimburse COMPANY for the costs of the Source Plasma will be capped at [*****]% of Supplier's annual sales from supply Product to the COMPANY.

xi. Yields – Current estimated batch yields based in [*****] process – [*****]vials.

The Parties will negotiate in good faith the mechanism of determination pricing modifications (increase or decrease) in relation to batch yields. Such negotiations will be initiated following the manufacturing and supply of the first [*****] ([*****]) batches (excluding [*****] ("[*****]") batches) by SUPPLIER, and will be based on actual data resulting from the manufacturing of those batches.

xii. Art Work – The COMPANY shall be required to provide SUPPLIER with the artwork and labeling specifications for the Product at its own cost and in coordination with SUPPLIER preferred vendors.

xiii. Back-Up Supplier –COMPANY shall be entitled to qualify an alternative supplier of the Product ("**Back-Up Supplier**") solely for the purpose of supplying Product to COMPANY in the event that SUPPLIER is unable to supply the Product in the circumstances and subject to the conditions set forth below. SUPPLIER agrees to reasonably cooperate with COMPANY, at COMPANY's expense, to transfer to such Back-Up Supplier or reasonably assist with the replication by such Back-Up Supplier of [*****] manufacturing technology, know-how and trade secrets that have been transferred to SUPPLIER pursuant to the Technology Transfer Agreement and are used by SUPPLIER in the manufacture of the Product, for the limited purposes set forth in this subsection, provided that reasonable and customary written undertakings from such Back-Up Supplier are in place to protect SUPPLIER's, the COMPANY's, and any third-party's confidential and proprietary information and to ensure compliance by such Back-Up Supplier with any obligations of SUPPLIER under any license with respect to any manufacturing technology, know-how and trade secrets transferred.

In the event that SUPPLIER is unable to supply the Product during a consecutive period of [*****] ([*****]) months after the scheduled delivery date of the Product (except due to the failure of COMPANY to supply Source Plasma or any other fault of the COMPANY), the COMPANY may utilize the services of such Back-Up Supplier until such time as the SUPPLIER resumes production and delivery of the Product, and the quantities of Product supplied by such Back-Up Supplier shall be deemed to have been supplied by SUPPLIER for the purposes of the Minimum Annual Commitment.

The cost payable to SUPPLIER for such technology transfer will be specified in a separate work order.

xiv. Joint Steering Committee – the COMPANY, SUPPLIER and [*****] will form a joint steering committee including representatives of each entity which will oversee all activities during the Term of the Supply Agreement ("JCT"). The JCT will meet as needed but not less than on a quarterly basis.

	xv. Termination – In the event of Termination of the Supply Agreement by COMPANY during the Initial Term, other than as a result of SUPPLIER's material and uncured breach of its obligations under the Supply Agreement, then in addition to all other remedies agreed upon, and subject to SUPPLIER and/or [*****] provides such documentation to support the actual CAPEX Investment (as such term is defined under the Technology Transfer Agreement) made through such termination, the COMPANY will be obligated to compensate SUPPLIER and/or [*****] for [*****]% of the CAPEX Investment (as such term is defined under the Technology Transfer Agreement) up to an amount of [*****] on a Pro-Rata basis. For clarification, the [*****] represents the [*****]% portion of the CAPEX Investment. An example is below for clarification: In the event the Supply Agreement is terminated at the end of its fourth year than COMPANY will be required to pay the that portion that represents the balance of the Initial Term; [*****] of the [*****]years: [*****] × [*****] = [*****] xvi. The Supply Agreement shall contain representations, warranties, covenants, indemnification obligations, insurance commitments, limitation of liability and other provisions that are customary for manufacture and supply agreements.
PLASMA AGREEMENT	The Plasma Agreement will set forth in detail the respective responsibilities and obligations of the Parties (including any regulatory responsibilities and requirements) with respect to the supply by COMPANY to SUPPLIER of Source Plasma, including, but not limited to, the following: i. The Source Plasma – COMPANY shall be responsible for the timely supply of all quantities of the Source Plasma required for the manufacturing of the Product, whether under the Supply Agreement, the Technology Transfer Agreement and/or the Exclusive Distribution Agreement (as applicable). COMPANY shall bear all costs associated with the procurement and delivery of the required quantities of the Source Plasma indicated in the binding purchase order and will make such quantities available in the location designed by SUPPLIER, at least [*****] months in advance of each scheduled Product delivery date. COMPANY shall deliver the Source Plasma and any COMPANY-supplied components (to be specified in the Plasma Agreement) to the location designated by SUPPLIER [*****] (Incoterms 2010), In the event that SUPPLIER and/or [*****] support is required with respect to shipment and/or delivery of the Source Plasma, then SUPPLIER and/or [*****] will be entitled for reimbursement of its costs associated with such activities. ii. Excess Plasma – COMPANY agrees to allow SUPPLIER and its Subcontractor to utilize excess fractionated plasma (of the supplied Source Plasma), free of charge, to further process into products and potentially resell. Save for any liability for defective or any other non-conforming Source Plasma supplied by COMPANY, COMPANY will not be responsible for any liability, or regulatory and reporting requirements in connection with products that are produced from such excess plasma. COMPANY will provide SUPPLIER or its Subcontractor with information related to the Source Plasma supplied by the COMPANY to the extent required for submission to any regulatory authorities, or under applicable laws, regulations or rules, and/or otherwise required for the exercise of SUPPLIER's rights and/or fulfillment of any of its obligations under the Definitive Agreements. SUPPLIER will fairly compensate COMPANY for the information related to the Source Plasma and time to support such activities above a minimal level which will be defined in the Plasma Agreement. iii. The Plasma Agreement shall contain representations, warranties, covenants, indemnification obligations, insurance commitments, and limitation of liability provisions and other provisions that are customary for agreements of this kind. iv. COMPANY responsibility with respect to [*****] or any other third party Source Plasma supplier cooperation – COMPANY shall use commercially reasonable best efforts to obtain the support of [*****] or any other third party Source Plasma supplier as may be needed to ensure: (a) Adequate supply of Source Plasma to ensure Source Plasma availability at [*****] at least [*****] weeks in advance of the relevant scheduled manufacturing start date. (ii) Supplies of the Source Plasma in a refrigerated container and provides the associated electronic shipment notice detailing all relevant Source Plasma unit information (Electronic Bleeding List), and (iii) Responsibility for the initiation of the look-back handling.

	v. Complaints – the Plasma Agreement will include a reference to a complaints mechanism as will be further defined under the Quality Agreement. vi. Three Way Annex – The Plasma Agreement shell include a three-way executed annex that will include a detailed list of COMPANY, SUPPLIER and [*****] roles and responsibilities with respect to the Supply and handling of the Source Plasma. vii. The Plasma Agreement shall contain representations, warranties, covenants, indemnification obligations, insurance commitments, limitation of liability and other provisions that are customary for supply agreements.
Technology Transfer Agreement	The Technology Transfer Agreement will set forth in detail the respective responsibilities and obligations of the Parties (including any regulatory responsibilities and requirements) with respect to technology transfer and other services with respect to the Product, Product manufacturing qualification and Regulatory Approval by the [*****] and/or [*****], including, but not limited to, the following: i. Transition/qualification of Product manufacturing – SUPPLIER shall use commercially reasonable best efforts to work with COMPANY and [*****] in order to transition and qualify the Product manufacturing from [*****] to SUPPLIER and its Subcontractor, [*****], with a target date for obtaining Regulatory Approval by the [*****] and [*****]. COMPANY shall use commercially reasonable best efforts to obtain the support of [*****] as may be reasonably needed to facilitate the technology transfer process and meet defined timelines. ii. Regulatory Approval – The Parties acknowledge that the COMPANY requires that the Regulatory Approval by both the [*****] and [*****] be obtained by [*****]. The Parties will finalize a detailed timeline for all required activities, which would be included as an annex to the Technology Transfer Agreement. Each of the SUPPLIER and COMPANY shall make commercially reasonable best efforts to meet the timelines as will be set forth in the Technology Transfer Agreement for obtaining such Regulatory Approval. In the event of (a) a delay in the technology transfer activities or timelines due to COMPANY responsibility or otherwise due to [*****] inability to cooperate; and/or (b) COMPANY does not obtain the Regulatory Approval by the [*****] or [*****] (or by both of them) by [*****]; and/or (c) based on discussions with the [*****] and/or [*****], such Regulatory Approval is not expected to be obtained by [*****], through no fault of SUPPLIER, then, since the technology transfer costs and activities referred to herein are based on assumptions made with respect to such timelines and the required activities; the Parties shall negotiate and endeavor to reach agreement, in good faith, with respect the additional activities that will be required (i.e. clinical trials, process changes etc.), adjusted timelines and actual and reasonable costs which shall be supported by appropriate documentation. iii. Technology Transfer Services – The technology transfer services shall be described in the Technology Transfer Agreement (the "**Technology Transfer Services**"), and will include all labor associated with development, engineering, qualification, manufacturing and supply of up to [*****] batches of Product, methods transfer, project management and other necessary services. The Technology Transfer Services do not currently include the following: a. [*****]; and b. [*****] c. Any Post-Approval commitments required by the [*****], [*****], or the applicable regulatory agency or authority in any other country or territory The addition of these activities, if required, will be done under a separate work order.

iv. [*****] of Product – The COMPANY will be responsible for the performance of the [*****] of the Product at its own cost.

v. [*****] Support – The COMPANY is responsible for any costs or payment to be made to [*****]for its support and/or services related to this project and/or for the grant of its approval or license with respect to the transfer to SUPPLIER of [*****]Product manufacturing technology, know-how and trade secrets (including analytical methods). [In addition, COMPANY is responsible to ensure that [*****]shall provide SUPPLIER analytical services beyond [*****] as a back-up, in case there is a delay in the technology transfer of the analytical methods and/or their validation. Such analytical services may comprise full product release services, or alternatively, outsourcing of certain of the testing.

vi. Cost of Services – The COMPANY shall pay SUPPLIER a total amount of $[*****] for the provision of the Technology Transfer Services in accordance with the following payment schedule:

a. During [*****]–[*****]equal quarterly payments of $[*****]each, payable on the 1st day of every calendar quarter;
b. During [*****]–[*****]equal quarterly payments of $[*****]each, payable on the 1st day of every calendar quarter;
c. During [*****]–[*****]equal quarterly payment of $[*****]each, payable on the 1st day of every calendar quarter;
d. Upon [*****]– a one-time payment of $[*****]payable within [*****] days of obtaining such approval; and
e. Upon [*****]– a one-time payment of $[*****]payable within [*****]days of obtaining such approval.

All travel, equipment purchase and installation costs, audit costs (associated with regulatory agency pre-approval inspections), internal hours and consultants required by SUPPLIER or Subcontractor and materials, excluding plasma, are also covered by the quarterly technology transfer payment set forth above.

vii. CAPEX Investment – COMPNAY acknowledge that in addition to the agreed upon technology transfer costs specified above, [*****] requires to make certain immediate CAPEX investments in order to be able to support the technology transfer and future planned manufacturing.

viii. Termination - COMPANY retains the right to terminate the Technology Transfer Agreement by written notice to SUPPLIER if the technology transfer contemplated therein is not feasible for any reason to be set forth in such notice, which may include, without limitation, technical challenges, regulatory agency requirements for significant changes and/or clinical studies or any other reason that may make commercialization of the Product impractical. COMPANY will be required to pay a final quarterly payment for the quarter in which the decision was notified to SUPPLIER. In the event that the Parties fail to execute the Supply Agreement in the date set forth above under the Recitals, other than as a result of SUPPLIER's material and uncured breach of its obligations under this Term Sheet or the Technology Transfer Agreement, and as a result thereof, the Technology Transfer Agreement is terminated, then COMPANY will pay SUPPLIER pursuant to subsection (v) above (pro-rata) for all Technology Transfer Services performed until the effective date of termination of the Technology Transfer Agreement.

In addition to the above, in any event of termination of the Technology Transfer Agreement, and subject to SUPPLIER and/or [*****] provides such documentation to support the actual CAPEX Investment made through such termination, then the COMPANY will be obligated to compensate SUPPLIER and/or [*****] for [*****]% of the CAPEX Investment (as such term is defined under the Technology Transfer Agreement) up to the amount of €[*****] ([*****]). For clarification, the €[*****]represents the [*****]% portion of the CAPEX Investment.

In the event that the COMPANY terminates the Technology Transfer Agreement, the Supply Agreement will terminate automatically and become null and void.

	viii. Three Way Annex – The Technology Transfer Agreement shall include a three-way executed annex specifies a detailed list of COMPANY, SUPPLIER and [*****] roles and responsibilities with respect to the technology transfer activities. ix. Joint Steering Committee – the COMPANY, SUPPLIER and [*****] will form a joint steering committee including representatives of each entity which will oversee all activities related to the Technology Transfer Agreement and the three-way executed annex during the term of the Technology Transfer Agreement. The Joint Steering Committee will meet as needed but not less than on quarterly basis. x. The Technology Transfer Agreement shall contain representations, warranties, covenants, indemnification obligations, insurance commitments, limitation of liability and other provisions that are customary for manufacture and supply agreements.
Exclusive Distribution Agreement	The Exclusive Distribution Agreement will set forth in detail the respective responsibilities and obligations of the Parties (including any regulatory responsibilities and requirements) with respect to the grant by COMPANY to SUPPLIER of exclusive marketing and distribution rights with respect to the Product in the Exclusive Distribution Territories, including, but not limited to, the following: i. Exclusive Marketing & Distribution Rights - COMPANY shall grant to the SUPPLIER the exclusive rights to market and distribute the Product in Israel and the Palestinian Territories during the period of the Supply Agreement. Following obtaining of Regulatory Approval by the [*****] or [*****], the Parties shall discuss and endeavor to reach agreement, in good faith, regarding the possibility of a grant of additional exclusive marketing and distribution rights to SUPPLIER in other territories in the Territory, it being understood that COMPANY may, at its sole option decline to expand such exclusive distribution and marketing rights. ii. Regulatory approval in such territories - SUPPLIER will be solely responsible for the costs of manufacturing the Product for Israel and Palestinian Territories and if applicable, for other Exclusive Distribution Territories, (it being agreed that the costs of the Source Plasma shall be covered under the Plasma Agreement) and will incur full responsibility for the regulatory and operating requirements for the Product in Israel and the Palestinian Territories and if applicable in other Exclusive Distribution Territories. COMPANY shall co-operate with and assist SUPPLIER as required by SUPPLIER, but at SUPPLIER's cost, in order to obtain Regulatory Approval by the applicable regulatory agency or authority in each of the Exclusive Distribution Territories, including, without limitation, by permitting access to and/or use of information in the COMPANY's Product dossier and drug master file (including the right to cross-reference any Product regulatory approvals and/or registrations). SUPPLIER shall be required to build its forecasts for Product into the COMPANY's overall demand plan for the Product by cooperating with COMPANY in the creation of the forecasts. COMPANY shall not be responsible for the remainder of any batch if SUPPLIER orders Product outside of COMPANY's demand plan. SUPPLIER shall market the Product under the name [*****]® in the Exclusive Distribution Territories. The Exclusive Distribution Agreement shall include a license section to allow for SUPPLIER's limited use of the tradename [*****]® in the Exclusive Distribution Territories. iii. Consideration - SUPPLIER agrees to pay COMPANY a [*****]% royalty on net sales (to be defined in the Exclusive Distribution Agreement) of the Product in Israel and the Palestinian Territories, and if applicable, in other Exclusive Distribution Territories, payable quarterly for the duration of the Exclusive Distribution Agreement. iv. The Exclusive Distribution Agreement shall contain representations, warranties, covenants, indemnification obligations, insurance commitments, and limitation of liability provisions and other provisions that are customary for exclusive distribution agreements.

	v. COMPANY will supply the Product for distribution by SUPPLIER under the Exclusive Distribution Agreement. SUPPLIER agrees to purchase such quantities of unlabeled finished goods from the COMPANY with a [*****]% markup on the COMPANY's actual acquisition costs plus shipping expenses and shipping insurance costs. Actual acquisition costs will include the actual cost of the plasma plus the actual cost of the of batch production and any additional costs associated with the batch (potency testing and release) divided by the total number of vials produced in that actual batch. An example is below for clarification: [*****] vi. The Exclusive Distribution Agreement shall contain representations, warranties, covenants, indemnification obligations, insurance commitments, limitation of liability and other provisions that are customary for manufacture and supply agreements.
EXCLUSIVITY	COMPANY shall exclusively purchase all of its requirements of the Product for sale in the Territory from SUPPLIER except as shall be permitted under the Supply Agreement with respect to purchases of Product from a Back-Up Supplier. SUPPLIER shall manufacture the Product exclusively for COMPANY and shall not manufacture or develop for sale, for SUPPLIER or any third party, any [*****]product. This section shall be subject to applicable antitrust laws.
CONFIDENTIALITY	The terms of the Mutual Confidentiality Agreement entered into between [*****] (of [*****]) and SUPPLIER effective as of [*****] (the "CDA"), are incorporated herein by reference, and will apply to any and all discussions and Confidential Information (as defined in the CDA) exchanged by the Parties under this Term Sheet and/or any Definitive Agreements as contemplated herein, in any form, whether oral, written, electronic or otherwise. In addition, the "Purpose" as defined in the CDA shall be deemed to include discussions between the Parties with respect to the terms of this Term Sheet and the Definitive Agreements and with respect to the transactions contemplated herein. Without derogating from the foregoing, neither Party shall disclose or discuss the terms of this Term Sheet with any persons other than its representatives who have a "need to know" and who are bound by similar confidentiality and non-use obligations, without the prior written approval of the other Party. The confidentiality and non-use obligations of the Parties herein shall continue for the period/s set forth in the CDA. The COMPANY acknowledges that SUPPLIER is a public company whose shares are publicly traded on the Tel-Aviv Stock Exchange and the NASDAQ. Accordingly: (a) SUPPLIER's confidential information, as well as this Term Sheet may be considered as "inside information" pursuant to Israeli and US securities laws and regulations and the COMPANY undertakes not to use any confidential information in violation of the applicable securities laws; and (b) SUPPLIER may be required to make certain disclosures and publications under applicable laws, which may include this Term Sheet and/or the Parties' discussions, such disclosure not to be deemed a breach of this Term Sheet, the Definitive Agreements and related agreements. This provision shall survive the termination or expiration of this Term Sheet for any reason.
PUBLIC ANNOUNCEMENT	Notwithstanding the foregoing, if an announcement concerning this Term Sheet, and the Definitive Agreements is required by applicable law or any listing agreement with a national securities exchange or quotation system, the Party required to make such announcement may do so, provided that such Party shall provide notice to and a copy of such announcement as promptly as practicable in advance of such announcement and, to the extent practicable, take the views and comments of the other Party in respect of such announcement into account prior to making such announcement. Following the execution of this Term Sheet, COMPANY shall inform SUPPLIER of its decision regarding the identification of its name under the public announcement.
EXPENSES	Each Party shall bear its own expenses, including fees and expenses of legal, regulatory and financial advisors, in connection with the negotiation and execution of this Term Sheet, the Definitive Agreements and any ancillary agreements.

Termination	If the Definitive Agreements are not executed by the Parties within the timelines specified above, notwithstanding their reasonable commercial best efforts, then such period shall be extended automatically for an additional [*****] ([*****]) day period, during which period the Parties shall continue to make reasonable commercial best efforts to finalize and execute the Definitive Agreements. Upon the earlier of the expiration of such additional [*****] ([*****]) day period or the execution of the Definitive Agreements, this Term Sheet shall terminate automatically and will be null and voided, except any terms hereof that are expressly provided herein or intended by the Parties to survive the termination hereof. In the event of such termination, COMPANY will be required to reimburse SUPPLIER for any costs incurred by Supplier with respect to initial Technology Transfer activities performed during such period. In no event, such costs will be in excess of the amount defined above as the payment due on account of Technology Transfer Services for the year [*****], on a pro-rata basis.
Governing law and jurisdiction; miscellaneous	This Term Sheet shall be governed by and construed in accordance with the laws of [*****], without regard to the conflicts of law principles thereof and the competent state or federal courts located in [*****] shall have exclusive jurisdiction with respect to any disputes or actions arising from this Term Sheet. This Term Sheet may be executed in one or more counterparts, and by Parties in separate counterparts, each of which when so executed shall be deemed an original, but all of which together shall constitute one and the same instrument. This Term Sheet, to the extent signed and delivered by electronic means, shall be treated in all manner and respects as an original agreement or instrument and shall be considered to have the same binding legal effect as if it were the original signed version thereof delivered in person. Any amendments or modifications to this Term Sheet must be in writing and signed by duly authorized representatives of both of the Parties.
Assignment	Neither Party shall assign or otherwise transfer this Term Sheet or any of its rights and obligations hereunder without the prior written consent of the other Party, which shall not be withheld or delayed unreasonably. Notwithstanding the foregoing, either Party shall not be restricted in any way from assigning this Term Sheet or any of the Definitive Agreements to any affiliate, or in connection with any sale or transfer of all or substantially all of the assets to which the Supply Agreement relates, or in connection with any change of control.

[Signature Page Follows]

Executed by the Parties:

COMPANY

By: _____
Name: [*****]
Its: [*****]
Date: _____

SUPPLIER

By: /s/ Amir London
Name: Amir London
Its: CEO
Date: _____

By: /s/ Amir London
Name: Chaime Orlev
Its: CFO
Date: _____

Exhibit 8.1

SIGNIFICANT SUBSIDIARIES

Our significant subsidiaries are set forth below, all of which are either 100% owned by us or controlled by us.

Legal Name	Jurisdiction
Kamada Biopharma Limited	England and Wales
Kamada Inc.	Delaware
Kamada Ireland Limited	Ireland
Kamada Assets (2001) 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 26, 2020

/s/ Amir London

Amir London
Chief Executive Officer

Exhibit 12.2

I, Chaime Orlev, certify that:

1. I have reviewed this annual report on Form 20-F of Kamada Ltd.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: February 26, 2020

/s/ Chaime Orlev

Chaime Orlev
Chief Financial Officer

Exhibit 13.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Kamada Ltd. (the "Company") on Form 20-F for the period ended December 31, 2019 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 26, 2020

/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, 2019 as filed with the Securities and Exchange Commission (the "Report"), I, Chaime Orlev, Chief Financial Officer of the Company, hereby certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) the Report fully complies with the requirements of section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 26, 2020

/s/ Chaime Orlev
Chaime Orlev
Chief Financial Officer

Exhibit 15.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statement on Form S-8 (File Nos 333-192720, 333-207933, 333-215983, 333-222891 and 333-233267) and in Registration Statement on Form F-3 (File No. 333-214816) of Kamada Ltd. (the "Company") of our reports dated February 26, 2020, with respect to the Company's consolidated financial statements and the effectiveness of internal control over financial reporting of the Company included in this Annual Report on Form 20-F for the year ended December 31, 2019.

KOST FORER GABBAY & KASIERER

A member of Ernst & Young Global

Tel Aviv, Israel
February 26, 2020