KAMADA LTD
Form 20-F
April 28, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 20-F

(Mark One)

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

OR

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

For the fiscal year ended December 31, 2014

OR

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

OR

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

Date of event requiring this shell company report: Not applicable

For the transition period from ____ to _____

Commission file number 001-35548

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

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

Israel
(Jurisdiction of incorporation or organization)

7 Sapir St.
Kiryat Weizmann Science Park
P.O Box 4081
Ness Ziona 74140

Israel
(Address of principal executive offices)

David Tsur, Chief Executive Officer
7 Sapir St., Kiryat Weizmann Science Park
P.O Box 4081, Ness Ziona 74140, 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, 2014, the Registrant had 35,988,563 Ordinary Shares outstanding (excluding treasury shares).

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

o Yes x No

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

o Yes x No

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

x Yes o No

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

x Yes o No

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

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

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

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

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

Item 17 o Item 18 o

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

o Yes x No

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

This Annual Report contains forward-looking statements that relate to future events or our future financial performance, which express the current beliefs and expectations of our management. Such statements involve a number of known and unknown risks, uncertainties and other factors that could cause our actual future results, performance or achievements to differ materially from any future results, performance or achievements expressed or implied by such forward-looking statements. Forward-looking statements include all statements that are not historical facts and can be identified by words such as, but not limited to, “believe,” “expect,” “anticipate,” “estimate,” “intend,” “plan,” “targets,” “likely,” “will,” “would,” “could,” and similar expressions or phrases. We have based these forward-looking statements largely on our management’s current expectations and future events and financial trends that we believe may affect our financial condition, results of operation, business strategy and financial needs. Forward-looking statements include, but are not limited to, statements about:

- our expectation that the number of patients treated by Glassia will double in the next four to five years, that our revenues in the Proprietary Products segment to grow by approximately 75% and that we will achieve our midterm revenue goal of $100 million by 2017;
- our belief that our relationships with our strategic partners will continue without disruption;
- our ability to procure adequate quantities of plasma and fraction IV which are acceptable for use in our manufacturing processes from our suppliers;
- our ability to maintain compliance with government regulations and licenses;
- our ability to identify growth opportunities for existing products and our ability to identify and develop new product candidates;
- our belief that the market opportunity for Alpha-1 Antitrypsin (“AAT”) products will grow;
- our belief that the potential world market for AAT products is significantly larger than current consumption indicates;
- our belief that we will be able to continue to meet our customers' demand for AAT;
- the timing of, and our ability to, obtain and/or maintain regulatory approvals for our products and new product candidates, the rate and degree of market acceptance, and the clinical utility of our products;
- the expected timeline of our development program for our product candidates, including statements about clinical trials and regulatory milestone dates;
- our plan to file a Marketing Authorization Application ("MAA") for our inhaled formulation of AAT for treatment of AAT deficiency (“Inhaled AAT for AATD") with the European Medicines Agency (the “EMA”) during the second half of 2015 and our ability to receive marketing authorization and launch Inhaled AAT for AATD in 2017 in Europe;
- our ability to launch KamRAB in the United States;

- our anticipation that we will complete our United States trial of Inhaled AAT for AATD in 2015 and report results in 2016 and our intention to initiate discussions with the FDA in 2015 to identify the regulatory pathway for registration in the United States;

- our anticipation that we will generate higher revenues as we diversify our revenue base by increasing the number of products we offer;

- legislation or regulation in countries where we sell our products that affect product pricing, reimbursement, access or distribution channels;

- the impact of geographic and product mix on our total revenues and gross profit; and

- the impact of our research and development expenses as we continue developing product candidates.

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

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

The audited consolidated financial statements for the years ended December 31, 2014, 2013 and 2012 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 3.889, the exchange rate published by the Bank of Israel as of December 31, 2014.

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, 2014, 2013 and 2012 and the consolidated balance sheets data as of December 31, 2014 and 2013 from our audited consolidated financial statements included elsewhere in this Annual Report. We have derived the summary consolidated statements of operations data for the year ended December 31, 2011 and the summary consolidated balance sheet data as of December 31, 2011 from our audited consolidated financial statements not included in this Annual Report.

We have included, in our opinion, all adjustments, consisting only of normal recurring adjustments, that we consider necessary for a fair presentation of the financial information set forth in those 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,			
	2014	2013	2012	2011
	(in thousands, except per share data)			
Consolidated Statements of Operations Data:				
Revenues from Proprietary Products	$44,389	$50,658	$46,445	$35,308
Revenues from Distribution	26,676	19,965	26,230	24,175
Total revenues	71,065	70,623	72,675	59,483
Cost of revenues from Proprietary Products	32,617	27,104	26,911	22,188
Cost of revenues from Distribution	23,406	17,112	23,071	20,574
Total cost of revenues	56,023	44,216	49,982	42,762
Gross profit	15,042	26,407	22,693	16,721
Research and development expenses	16,030	12,745	11,821	11,729
Selling and marketing expenses	2,898	2,100	1,853	2,331
General and administrative expenses	7,593	7,862	4,781	5,126
Operating income (loss)	(11,479)	3,700	4,238	(2,465)
Financial income	1,611	289	578	870
Income (expense) in respect of currency exchange and translation differences and derivatives instruments, net	—	(369)	(100)	937
Income (expense) in respect of revaluation of warrants to fair value	—	—	(576)	540
Financial expense	(3,293)	(3,153)	(3,357)	(3,597)
Income (loss) before taxes on income	(13,161)	467	783	(3,715)
Taxes on income	52	24	523	—
Net income (loss)	$(13,213)	$443	$260	$(3,715)
Income (loss) attributable to equity holders	$(13,213)	$443	$260	$(3,715)
Income (loss) per share attributable to equity holders:				
Basic	$(0.37)	$0.01	$0.01	$(0.13)
Diluted	$(0.37)	$0.01	$0.01	$(0.15)
Weighted-average number of ordinary shares used to compute income (loss) per share attributable to equity holders:				
Basic	35,971,335	32,714,631	28,078,996	27,550,643
Diluted	35,971,335	33,385,651	28,686,636	27,703,331
Consolidated Statements of Cash Flows:				
Cash flows from operating activities	$(9,918)	$(3,854)	$(8,262)	$994
Cash flows from investing activities	(26,819)	(3,903)	(2,432)	(1,136)
Cash flows from financing activities	(7,640)	49,208	2,966	(403)
Consolidated Balance Sheet Data:				
Cash, cash equivalents, restricted cash and short-term investments	$51,896	$74,177	$33,795	$42,686
Trade receivables	17,514	17,882	13,861	7,131
Working capital (1)	66,206	85,108	40,651	44,185
Total assets	119,140	139,379	89,114	85,114
Total liabilities	38,723	49,409	60,721	62,716
Total shareholders' equity	80,417	89,970	28,393	22,398
Other Data:				

Adjusted net income (loss)(2) (3)	$(4,940)	$9,414	$2,103	$(3,377)
Adjusted EBITDA(2)	$(9,462)	$3,156	$8,549	$1,453

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

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

Non-IFRS financial measures have limitations as an analytical tool and should not be considered in isolation from, or as a substitute for, our IFRS results. We expect to continue reporting non-IFRS financial measures, adjusting for the items described below, and we expect to continue to incur expenses similar to 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, plus a one-time management compensation payment associated with the successful U.S. initial public offering, and plus or minus expense or income in respect of revaluation of our warrants to fair value. Our management believes that excluding non-cash charges related to share-based compensation provides useful information to investors because of its non-cash nature, varying available valuation methodologies among companies and the subjectivity of the assumptions and the variety of award types that a company can use under the relevant accounting guidance, which may obscure trends in our core operating performance. Our management believes that excluding the one-time management compensation payment associated with the successful U.S. initial public offering is useful to investors because of the extraordinary, non-recurring nature of the expense. Similarly, our management believes that excluding the non-cash income (expense) in respect of revaluation of our warrants to fair value is useful to investors because the valuation of our warrants is based on a number of subjective assumptions, the amount of the loss or gain is derived from market forces outside management's control, and it enables investors to compare our performance with other companies that have different capital structures. Additionally, the revaluation of the fair value of our warrants is not expected to recur in future periods after the first quarter of 2013, as the warrants were exercised in the first quarter of 2013.

(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, plus or minus income or expense in respect of revaluation of our warrants to fair value, and plus one-time management compensation payment. Management believes that adjusted EBITDA provides useful information to investors for the same reasons discussed above for adjusted net income (loss).

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

	Year Ended December 31,			
	2014	2013	2012	2011
	(in thousands)			
Net income (loss)	$(13,213)	$443	$260	$(3,715)
Non-cash share-based compensation expenses	3,751	1,327	1,267	878
One-time management compensation payment	-	1,386	—	—
Expense (income) in respect of revaluation of warrants to fair value	—	—	576	(540)
Adjusted net income (loss)	$(9,462)	$3,156	$2,103	$(3,377)

	Year Ended December 31,			
	2014	2013	2012	2011

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

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

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

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

We rely heavily upon the sales of our AAT intravenous product, Glassia. Revenue from our intravenous AAT deficiency ("AATD") products comprised approximately 42%, 49% and 47% of our total revenues for the years ended December 31, 2014, 2013 and 2012, respectively. If Glassia were to lose significant sales, or was substantially or completely displaced in the market, we would lose a significant and material source of our total revenues. Similarly, if Glassia were to become the subject of litigation and/or an adverse governmental ruling requiring us to cease the manufacturing or sales of Glassia, our business would be adversely affected.

We have a partnership arrangement with Baxter International Inc., pursuant to which Baxter is the sole distributor of Glassia in the United States, Canada, Australia and New Zealand. Revenue derived from our partnership with Baxter, which consists of sales of Glassia and milestone revenue, accounted for approximately 36%, 40% and 42% of our total revenues in the years ended December 31, 2014, 2013 and 2012, respectively. Additionally, we depend upon Baxter for the supply of fraction IV plasma for our production of Glassia to be sold in the United States. If our relationship with Baxter were to deteriorate, or if Baxter's sales of Glassia were to decline, our business would be adversely affected. See "In our Proprietary Products segment, we currently rely on one of our strategic partners that accounts for a significant portion of our total sales and our distribution plan for our principal product candidate relies on another strategic partner, and any disruption to our relationships with these distributors would have an adverse effect on our results of operations and profitability."

We rely heavily upon sales from the United States, which comprised approximately 37%, 41% and 43% of our total revenues for the years ended December 31, 2014, 2013 and 2012, respectively. If our U.S. sales were significantly impacted by either material changes to government or private payor reimbursement, by other regulatory developments, by competition or other factors, then our business would be adversely affected.

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 and/or new indications for our products and product candidates. In particular, obtaining marketing approval of our Inhaled AAT for AATD from the European Medicines Agency (the "EMA") is critical to our business plan. Failure to obtain regulatory approval of the Inhaled AAT for AATD product or of any of our other product candidates or additional indications would materially adversely impact our business prospects.

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

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

Before obtaining regulatory approval for the sale of our product candidates, including Inhaled AAT for AATD, or for the marketing of existing products for new indications, we must conduct, at our own expense, extensive preclinical tests to demonstrate the safety of our product candidates in animals and clinical trials to demonstrate the safety and efficacy of our product candidates in humans. We cannot predict how long the approval processes of the United States Food and Drug Administration ("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 drug approval process, and positive results in preclinical testing or early phases of clinical studies offer no assurance of success in later phases of the approval process. The approval process varies from country to country and the requirements governing the conduct of clinical trials, product manufacturing, product licensing, pricing and reimbursement vary greatly from country to country.

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

- regulators may not authorize us to commence or conduct a clinical trial within a country or at a prospective trial site;

- the regulatory requirements for product approval may not be explicit, may evolve over time and may diverge among jurisdictions;

- delays may occur in obtaining our clinical materials;

- our preclinical tests or clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical testing or clinical trials or to abandon strategic projects;

    - the number of patients required for our clinical trials may be larger than we anticipate, enrollment in our clinical trials may be slower or more difficult than we anticipate or participants may withdraw from our clinical trials at higher rates than we anticipate, any of which would result in significant delays in our clinical testing process;

- delays may occur in reaching agreement on acceptable clinical trial agreement terms with prospective sites or obtaining institutional review board approval;

- our strategic partners may not achieve their clinical development goals and/or comply with their relevant regulatory requirements;

- our third-party contractors, such as a contract research organization, may fail to comply with regulatory requirements or meet their contractual obligations to us;

- we may be forced to suspend or terminate our clinical trials if the participants are being exposed to unacceptable health risks or if any participant experiences an unexpected serious adverse event;

- regulators or institutional review boards may require that we hold, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements;

    - undetected or concealed fraudulent activity by a clinical researcher, if discovered, could preclude the submission of clinical data prepared by that researcher, lead to the suspension or substantive scientific review of one or more of our marketing applications by regulatory agencies, and result in the recall of any approved product distributed pursuant to data determined to be fraudulent;

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

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

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

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

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

- decide to halt the clinical trial or other testing;

- be unable to obtain regulatory and marketing approval;

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

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- be unable to obtain reimbursement for our products in all or some countries;
- obtain approval for indications that are not as broad as we intended;
- 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; or
- be delayed in, or prevented from, the receipt of clinical milestone payments from our strategic partners.

Our product development costs will also increase if we experience delays in testing or approvals. We do not know whether any preclinical tests or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, if at all. Significant preclinical or clinical trial delays also could lead to a shorter patent protection period during which we may have the exclusive right to commercialize our product candidates or could allow our competitors to bring products to market before we do, impairing our ability to commercialize our products or product candidates. For example, in the past, we have experienced delays in the commencement of clinical trials, such as a delay in patient enrollment for our clinical trials in Europe for Inhaled AAT for AATD and a delay in receiving approval for the commencement of Phase II trials in the United States for Inhaled AAT for AATD until further preclinical testing results were submitted.

Even if preclinical trials are successful, we still may be unable to commercialize a product because of difficulties in obtaining regulatory approval for its engineering process or problems in scaling that process to commercial production.

Pre-clinical studies, including studies of our product candidates in animal models of disease, may not accurately predict the result of human clinical trials of those product candidates. In particular, new indications for our AAT products that are entering into Phase I and II clinical trials may be found not to be safe and/or efficacious when studied further in Phase III trials. To satisfy FDA or foreign 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 have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier clinical trials.

We cannot provide assurance that any products we may seek to develop or are currently developing, such as Inhaled AAT for AATD, will ever be successfully commercialized, and to the extent they are not successfully commercialized, such products could be a significant expense with no reward.

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.

Many of our products and product candidates, including Inhaled AAT for AATD, have been granted the designation of an orphan drug. 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. While the marketing exclusivity of an orphan drug would prevent other sponsors from obtaining approval of the same drug compound for the same indication unless the subsequent sponsors could demonstrate clinical superiority or a market shortage occurs, it 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. We may not be the first product licensed for the treatment of a particular rare disease. In such a situation, with limited exception, we would not be able to take advantage of market exclusivity and instead the other sponsor would receive such

exclusivity. 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 the market exclusivity. The FDA or the EMA may also, in the future, revisit any orphan drug designation it has conferred upon a drug and retains the ability to withdraw the 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 will remain in effect.

The commercial success of any 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.

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;
- the ability to offer our product candidates for sale at competitive prices;
- relative convenience and ease of administration;
- 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 have been approved for commercial sale, we may be unable to recover the large investment we have made and plan to make in research and development efforts and our growth strategy will be adversely affected.

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

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

Additionally, 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 the contaminant through our manufacturing process or failure to maintain a high level of sterility within our manufacturing facilities.

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

While we expect to write off small amounts of work-in-process inventories in the ordinary course of business because of the complex nature of plasma and plasma derivatives, our processes and our plasma-derived protein therapeutics, unanticipated events may lead to write-offs and other costs materially in excess of our expectations. We had in the past situations that have caused us to write off the value of our product. For example, in 2014 we have had to discard a material amount of inventory that did not pass our inspections due to deviations in the production process that had created a higher risk of contamination or that had short shelf life. Such write-offs and other costs could cause material fluctuations in 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 adversely affect sales and operating results.

Our ability to continue manufacturing and distributing our plasma-derived protein therapeutics depends on our continued adherence to cGMP regulations.

The manufacturing processes for our products are governed by detailed written procedures and regulations that set forth current Good Manufacturing Practice standards (“cGMP”) requirements for blood products, including plasma and plasma derivative products. Failure by our quality operations unit to adhere to established procedures or regulations, or to meet a specification set forth in cGMP requirements, could require that a product or material be rejected and destroyed. There are relatively few opportunities for us to rework, reprocess or salvage nonconforming materials or products. Our manufacturing process and facilities are not currently approved by the EMA, and we will need to obtain such approval prior to beginning manufacture of products (including Inhaled AAT for AATD) to be marketed and sold in Europe. Any failure in cGMP inspection will affect marketing in other territories, including the U.S. and Israel.

Our adherence to cGMP regulations and the effectiveness of our quality control systems are periodically assessed through inspections of our manufacturing facility in Beit Kama, Israel by the FDA and regulatory authorities of other countries. Such inspections could result in deficiency citations, which would require us to take action to correct those deficiencies to the satisfaction of the applicable regulatory authorities. If serious deficiencies are noted or if we are unable to prevent recurrences, we may have to recall products or suspend operations until appropriate measures can be

implemented. The FDA could also stop import of product into the United States if there are potential deficiencies. We are required to report certain deviations from procedures to the FDA. Even if we determine that the deviations were not material, the FDA could require us to take certain measures to address the deviations. Since cGMP reflects ever-evolving standards, we regularly need to update our manufacturing processes and procedures to comply with cGMP. These changes may cause us to incur additional costs and may adversely impact our profitability. For example, more sensitive testing assays (if and when they become available) may be required or existing procedures or processes may require revalidation, all of which may be costly and time-consuming and could delay or prevent the manufacturing of a product or launch of a new product.

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

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

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

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

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

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

Any new product must undergo lengthy and rigorous testing and other extensive, costly and time-consuming procedures mandated by the FDA and similar authorities in other jurisdictions, including the EMA and the regulatory authorities in Israel. Our facilities must be approved and licensed prior to production and remain subject to inspection from time to time thereafter. Failure to comply with the requirements of the FDA or similar authorities in other jurisdictions, including a failed inspection a failure in our reporting system for adverse effects of our products experienced by the users of our products, or any other non-compliance could result in warning letters, product recalls or seizures, monetary sanctions, injunctions to halt the manufacture and distribution of products, civil or criminal sanctions, import or export restrictions, refusal of a regulatory authority to grant approvals or licenses, restrictions on operations or withdrawal of existing approvals and licenses. In addition, we rely to a large extent on Baxter 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 Baxter to properly advise us regarding, or properly perform tasks related to, regulatory compliance requirements could adversely affect us. If our relationship with Baxter 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 adversely affect our sales, reputation, and results of operations. Similarly, we rely on other third–party vendors, for example, in the production, handling, and distributions of Glassia. If any of these companies incur enforcement action from regulatory authorities due to noncompliance, this could negatively affect product sales, our reputation, and results of operations.

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

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

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

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

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

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

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

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

We are also dependent on a number of suppliers who supply specialty ancillary products used in the production process, such as specific gels and filters. Each of these specialty ancillary products is provided by a single, exclusive supplier. If these suppliers were unable to provide us with these specialty ancillary products, if our relationships with these suppliers deteriorate, or these suppliers' operations are negatively affected by regulatory enforcement due to noncompliance, the manufacture and distribution of our products would be materially adversely affected, which would adversely affect our sales and results of operations.

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

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

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

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

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

In our Proprietary Products segment, we currently rely on one of our strategic partners that accounts for a significant portion of our total sales and our distribution plan for our principal product candidate relies on another strategic partner, and any disruption to our relationships with these distributors would have an adverse effect on our results of operations and profitability.

Pursuant to our partnership arrangement with Baxter, Baxter is the sole distributor of Glassia in the United States, Canada, Australia and New Zealand. Sales to Baxter accounted for approximately 36%, 40% and 42% of our total revenues in the years ended December 31, 2014, 2013 and 2012, respectively. We also depend upon Baxter for the supply of fraction IV plasma for our production of Glassia to be sold in the United States. See "—We would become supply-constrained and our financial performance would suffer if we were unable to obtain adequate quantities of source plasma or plasma derivatives or specialty ancillary products approved by the FDA, the EMA or the regulatory authorities in Israel, or if our suppliers were to fail to modify their operations to meet regulatory requirements."

Currently, revenue derived from our relationship with Baxter consists of sales of Glassia, which we incur cost of revenues to produce, and milestone revenue. After 2017, Baxter has no obligation to purchase a minimum amount of Glassia; however, Baxter's failure to purchase a specified minimum amount of Glassia over a period of 24 consecutive months beginning in 2017 until the expiration of the agreement provides us with the right to terminate the agreement. Additionally, Baxter is expected to begin producing Glassia itself in 2018 at the earliest, at which point it will pay us royalties. While we would generate higher margins from royalties, as we would not incur cost of revenues, we will receive lower revenues per unit sold. We plan to replace that revenue by producing other AAT products, including for sales in Europe, and increases in the volume of units sold. If we could not obtain approval and make such sales in Europe or were unable to increase sales of our products, our revenues would be impacted and our operating results would be impacted as we would continue to incur the fixed costs relating to our manufacturing facility.

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

If our relationship with Baxter were to deteriorate, our sales through this channel and our supply of fraction IV could be adversely affected. If we fail to maintain our relationship with Baxter or Chiesi, we could face significant costs in finding a replacement distributor for the markets Baxter and Chiesi serve for Glassia and Inhaled AAT for AATD, respectively, and a replacement supplier of fraction IV for Glassia. Delays in establishing a relationship with a new distributor and supplier could lead to a decrease in our sales and a deterioration in our market share compared to one or more of our competitors. Any of the foregoing developments could have an adverse effect upon our sales, margins and profitability.

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

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

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

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

Sales of products supplied by Bioproducts Laboratories Ltd. and Biotest A.G., which are sold in our Distribution segment, together represented approximately 36%, 26% and 35% of our total revenues for the years ended December 31, 2014, 2013 and 2012, respectively. While we have distribution agreements with each of these suppliers, these agreements do not obligate these suppliers to provide us with minimum amounts of our Distribution segment products. Purchases of our Distribution segment products from our suppliers are typically on a purchase order basis. We work closely with our suppliers to develop annual forecasts, but these forecasts are not obligations or commitments. However, if we fail to submit purchase orders that meet our annual forecasts, we could lose exclusivity or the agreement could be terminated. These suppliers may experience capacity constraints that result in their being unable to supply us with products in a timely manner, in adequate quantities and/or at a reasonable cost. Contributing factors to supplier capacity constraints include, among other things, industry or customer demands in excess of machine capacity, labor shortages and changes in raw material flows. These suppliers may also choose not to supply us with products at their discretion or raise prices to a level that would render our products noncompetitive. Any significant interruption in the supply of these products could result in us being unable to meet the demands of our customers, which would have a material adverse effect on our business, financial condition and results of operations.

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

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

In order to obtain FDA, EMA and other regulatory approval for product candidates and new indications for existing products, we are required to enhance the facilities in which and processes by which we manufacture existing products, to develop new product delivery mechanisms for existing products and to develop innovative product additions and conduct clinical trials. We face a number of obstacles that we will need to overcome in order to achieve these goals,

including but not limited to the successful development of an experimental product 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 our products or processes and successfully marketing an approved product or new product with our new process. To finance these various activities, we may need to incur future debt or issue additional equity, and we may not be able to structure our debt obligations on favorable economic terms. A failure to fund these activities may harm our growth strategy, competitive position, quality compliance and financial condition.

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

Our Proprietary Products segment operates in a highly competitive market.

We compete with well-established drug companies, including two to four large competitors for each of our products in the Proprietary Products segment. These large competitors include CSL Behring Ltd., Baxter, Cangene Corporation and Grifols S.A., which acquired a previous competitor, Talecris Biotherapeutics, Inc., in 2011. We compete against these companies for, among other things, licenses, expertise, clinical trial patients and investigators, consultants and third-party strategic partners. We also compete with these companies for market share for certain products in the Proprietary Products segment. Our large competitors have advantages in the market because of their size, financial resources, markets and the duration of their activities and experience in the relevant market, especially in the United States and countries of the European Union. As a result, they may be able to devote more funds to research and development and new production technologies, as well as to the promotion of their products and business. These competitors may also be able to sustain for longer periods a deliberate substantial reduction in the price of their products or services. Some of them also have an additional advantage regarding the availability of raw materials, as they manufacture plasma and its products, and own companies that collect or produce raw materials such as plasma. Other than our AAT products, our products generally do not benefit from patent protection and compete against similar products produced by other providers.

Additionally, the development by a competitor of a similar or superior product or increased pricing competition may result in a reduction in our net sales or a decrease in our profit margins.

For example, we believe that there are two main competitors in the AAT market: Grifols and CSL. We estimate that Grifols’s AAT by infusion product for the treatment of AATD, Prolastin A1PI, accounts for more than 70% of sales in the worldwide market for the treatment of AATD, and is the only product that is allowed to be sold in both Europe and the United States. Due to its limited availability, CSL’s product is mainly sold in the United States. Apart from its sales through Talecris, Grifols is also a local producer of the product in the Spanish market and operates in Brazil. There is another, smaller local producer in the French market, LFB S.A.

Similarly, if a new AAT formulation with a significantly improved rate of administration is adopted (including, for example, aerosol inhalation or one that can demonstrate statistically significant efficacy), the market share of our current AAT product, Glassia, could be negatively impacted. While we are in the process of developing Inhaled AAT for AATD, our competitors may also be attempting to develop similar products or products which could be substitutions for AAT products, such as gene therapy. For example, Grifols has completed a limited clinical trial for the development of an inhaled formulation of AAT for the indication of cystic fibrosis. While we believe that these products are in the early stages of development, they may eventually be successfully developed and launched. Furthermore, even if we are able to commercialize Inhaled AAT for AATD prior to the development of comparable

products by our competitors, sales of Inhaled AAT for AATD could adversely impact our revenue and growth of sales of Glassia, our current AATD product.

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

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

We primarily sell our Distribution segment products through offers to participate in public tenders, which occur on an annual basis. The public tender process involves health maintenance organizations and hospitals soliciting bids from several potential suppliers, including us, and selecting the winning bid based on several attributes, primarily 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.

In 2010 through 2012, we benefitted from the temporary suspension of two of our competitors from selling their IVIG products in Israel. This suspension has been lifted and both competitors are now able to distribute plasma-derived protein therapeutics in the Israeli market. As these competing IVIG products returned to the market at the end of 2012, we experienced increased competition for our Distribution segment products. For example, we participated in 2013 in a public tender in Israel with these competitors. During this public tender process, some of our customers in prior years chose to purchase their supply requirements from our competitors. As a result of these competitors returning to the market, revenues from our Distribution segment decreased in 2013 and may further decrease in the future. Our existing and new competitors may also have significantly greater financial resources than us, which they could use to promote their products and business. Greater financial resources would also enable our competitors to substantially reduce the price of their products or services. If our competitors are able to offer prices lower than us, our ability to win tender bids during the annual tender process will be materially affected, and could reduce our total revenues or decrease our profit margins.

Certain of our products have historically been, and may in the future be, subject to supply-driven price fluctuations.

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.

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

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

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