

KAMADA LTD
Form 20-F
February 25, 2016

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, 2015

OR

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

OR

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

Date of event requiring this shell company report: Not applicable

For the transition period from ____ to ____

Commission file number 001-35548

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

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

Israel
(Jurisdiction of incorporation or organization)

7 Sapir St.
Kiryat Weizmann Science Park
P.O Box 4081
Ness Ziona 7414002

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Israel

(Address of principal executive offices)

Amir London, Chief Executive Officer
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P.O Box 4081, Ness Ziona 74140002, Israel
+972 8 9406472

(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

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

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

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

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

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

As of December 31, 2015, the Registrant had 36,418,741 Ordinary Shares outstanding (excluding treasury shares).

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

Yes No

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

Yes No

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

Yes No

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

Yes No

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

Large accelerated filer Accelerated filer Non-accelerated filer

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

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

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

Item 17 Item 18

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

Yes No

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

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

- our expectation that the number of patients treated by Glassia will double in the next three to four years compared to the number of patients in 2014 and that our revenues in the Proprietary Products segment will grow by approximately 75% by 2017 compared to such segment’s revenues for 2015 and that we will achieve our midterm revenue goal of \$100 million by 2017;
- our belief that our relationships with our strategic partners will lead to increased revenues and other benefits in the future and that such relationships, including with Baxalta US Inc., (“Baxalta”), will continue without disruption;
- our ability to procure adequate quantities of plasma and fraction IV which are acceptable for use in our manufacturing processes from our suppliers;
 - our ability to maintain compliance with government regulations and licenses;
- our ability to identify growth opportunities for existing products and our ability to identify and develop new product candidates;
 - our belief that the market opportunity for Alpha-1 Antitrypsin (“AAT”) products will grow;
- the various uses of AAT products to potentially be effective against various diseases, including cystic fibrosis, bronchiectasis, type-1 diabetes and GvHD, as well as its ability to be used in connection with lung transplantations;
- the beneficial characteristics of Inhaled AAT for AATD, which we believe may result in our increased profitability;

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

- legislation or regulation in countries where we sell our products that affect product pricing, reimbursement, access or distribution channels;
- the impact of geographic and product mix on our total revenues and gross profit; and
- the impact of our research and development expenses as we continue developing product candidates.

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

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

The audited consolidated financial statements for the years ended December 31, 2015, 2014 and 2013 in this Annual Report have been prepared in accordance with the international financial reporting standards (“IFRS”) as issued by the international accounting standards board (“IASB”). None of the financial information in this Annual Report has been prepared in accordance with accounting principles generally accepted in the United States (“U.S. GAAP”).

Unless otherwise noted, NIS amounts presented in this Annual Report are translated at the rate of \$1.00 = NIS 3.902, the exchange rate published by the Bank of Israel as of December 31, 2015.

PART I

Item 1. Identity of Directors, Senior Management and Advisers

Not applicable.

Item 2. Offer Statistics and Expected Timetable

Not applicable.

Item 3. Key Information

A. Selected Financial Data

The following table summarizes our consolidated financial data. We have derived the summary consolidated statements of operations data for the years ended December 31, 2015, 2014 and 2013 and the consolidated balance sheets data as of December 31, 2015 and 2014 from our audited consolidated financial statements included elsewhere in this Annual Report. We have derived the summary consolidated statements of operations data for the years ended December 31, 2012 and 2011 and the summary consolidated balance sheet data as of December 31, 2013, and 2012 and 2011 from our audited consolidated financial statements not included in this Annual Report.

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

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

	Year Ended December 31,				
	2015	2014	2013	2012	2011
	(in thousands, except per share data)				
Consolidated Statements of Operations Data:					
Revenues from Proprietary Products	\$42,952	\$44,389	\$50,658	\$46,445	\$35,308
Revenues from Distribution	26,954	26,676	19,965	26,230	24,175
Total revenues	69,906	71,065	70,623	72,675	59,483
Cost of revenues from Proprietary Products	30,468	32,617	27,104	26,911	22,188
Cost of revenues from Distribution	23,640	23,406	17,112	23,071	20,574
Total cost of revenues	54,108	56,023	44,216	49,982	42,762
Gross profit	15,798	15,042	26,407	22,693	16,721
Research and development expenses	16,530	16,030	12,745	11,821	11,729
Selling and marketing expenses	3,652	2,898	2,100	1,853	2,331
General and administrative expenses	7,040				