



# KAMADA

High Quality Pharmaceuticals



## KAMADA INVESTOR PRESENTATION

February 2015

NASDAQ: KMDA



# Forward Looking Statement

This presentation is not intended to provide investment or medical advice. It should be noted that some products under development described herein have not been found safe or effective by any regulatory agency and are not approved for any use outside of clinical trials.

This presentation contains forward-looking statements, which express the current beliefs and expectations of Kamada's management. Such statements involve a number of known and unknown risks and uncertainties that could cause Kamada's future results, performance or achievements to differ significantly from the results, performance or achievements expressed or implied by such forward-looking statements. Important factors that could cause or contribute to such differences include risks relating to Kamada's ability to successfully develop and commercialize its pharmaceutical products, the progress and results of any clinical trials, the introduction of competing products, the impact of any changes in regulation and legislation that could affect the pharmaceutical industry, the difficulty of predicting U.S. Food and Drug Administration, European Medicines Agency and other regulatory authority approvals, the regulatory environment and changes in the health policies and structures of various countries, environmental risks, changes in the worldwide pharmaceutical industry and other factors that are discussed in Kamada's prospectus related to this offering.

This presentation includes certain non-GAAP financial information, which is not intended to be considered in isolation or as a substitute for, or superior to, the financial information prepared and presented in accordance with GAAP. The non-GAAP financial measures may be calculated differently from, and therefore may not be comparable to, similarly titled measures used by other companies. A reconciliation of these non-GAAP financial measures to the comparable GAAP measures is included in an appendix to this presentation. Management uses these non-GAAP financial measures for financial and operational decision-making and as a means to evaluate period-to-period comparisons. Management believes that these non-GAAP financial measures provide meaningful supplemental information regarding Kamada's performance and liquidity.

Forward-looking statements speak only as of the date they are made, and Kamada undertakes no obligation to update any forward-looking statement to reflect the impact of circumstances or events that arise after the date the forward-looking statement was made. You should not place undue reliance on any forward-looking statement and should consider the uncertainties and risks noted above, as well as the risks and uncertainties more fully discussed under the heading "Risk Factors" of Kamada's 2013 Annual Report on Form 20-F filed with the U.S. Securities and Exchange Commission on March 26, 2014.



# Kamada Overview

- 1 Rapidly Growing, Globally Positioned Biopharmaceutical Company Focused on Orphan Diseases and Plasma-Derived Protein Therapeutics
  - Revenue and Profitability with 10 Marketed Products
- 2 Leader in the Development of Alpha-1 Antitrypsin (“AAT”) Products Globally and specific Immunoglobulin
  - Developed and Obtained FDA Approval for the First and Only Liquid, Ready-to-Use Intravenous AAT Product, Glassia® for AAT Deficiency
  - Selling Glassia® in Selected Emerging Markets Globally and Through Baxter Collaboration in the U.S.
  - KamRAB for rabies prophylaxis (U.S. Phase III complete) to be launched in US through collaboration with Kedrion
- 3 Attractive Pipeline for 5 Orphan Indications including
  - Glassia to treat type-1 diabetes (Phase II/III)
  - Glassia to treat Graft-vs-Host Disease (GVHD) (Phase I/II)
  - Novel Inhaled AAT Product for AATD (EU Phase III completed)
    - Pursuing conditional approval in EU
    - Ongoing Phase II in the U.S.; pathway to be discussed with FDA
- 4 Fully Integrated Manufacturing and Distribution

## Notes

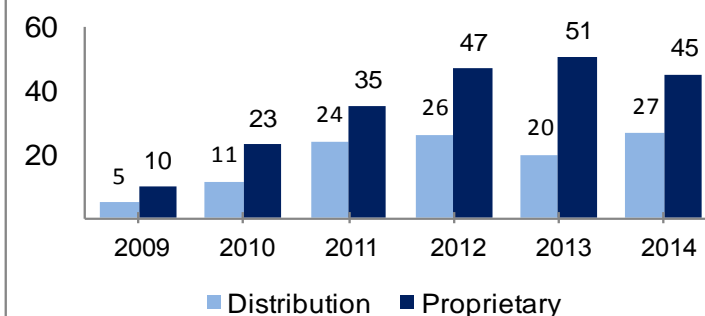
1. As of December 31, 2014

2. Market data as of Feb 16, 2015

## Key Statistics

- Founded in 1990 and based in Weizmann Science Park, Israel
- Employees: ~300 <sup>(1)</sup>
- Listed on NASDAQ since 2013 & TASE since 2005 (KMDA)
- Current market capitalization: ~\$152MM <sup>(2)</sup>
- Cash, cash equivalents and ST investments: \$52MM<sup>(1)</sup>
- Total Debt: \$8MM <sup>(1)</sup>

## Historical Revenue



## Historical Adjusted EBITDA <sup>(3)</sup>





# Integrated, Efficient, Scalable Platform Technology

## Proprietary, Innovative and Patented Technology Platform

- Patent protected: Chromatography-based purification process
- Enables high purity extraction
- Ready-to-use, liquid and stable specialty protein therapeutics (AAT, Albumin, Transferrin and many others)
- Enables production of almost any human plasma-derived specific immunoglobulins



## Fully-Invested Manufacturing Facility & Marketed Products

- FDA approved since 2010
- cGMP compliant
- Multiple countries' certifications (US, Brazil, Israel, Mexico, Russia)
- State-of-the-art clean room environment
- Located in Beit Kama, Israel



## Benefits

- Enables manufacturing of plasma-derived protein therapeutics with differentiated product profiles
- Efficient production process with higher yield than manufacturing methods employed by competitors
- High safety profile and proven track record
- Infrastructure in place to meet future pipeline product demand
- Expandable product platform to additional territories and indications

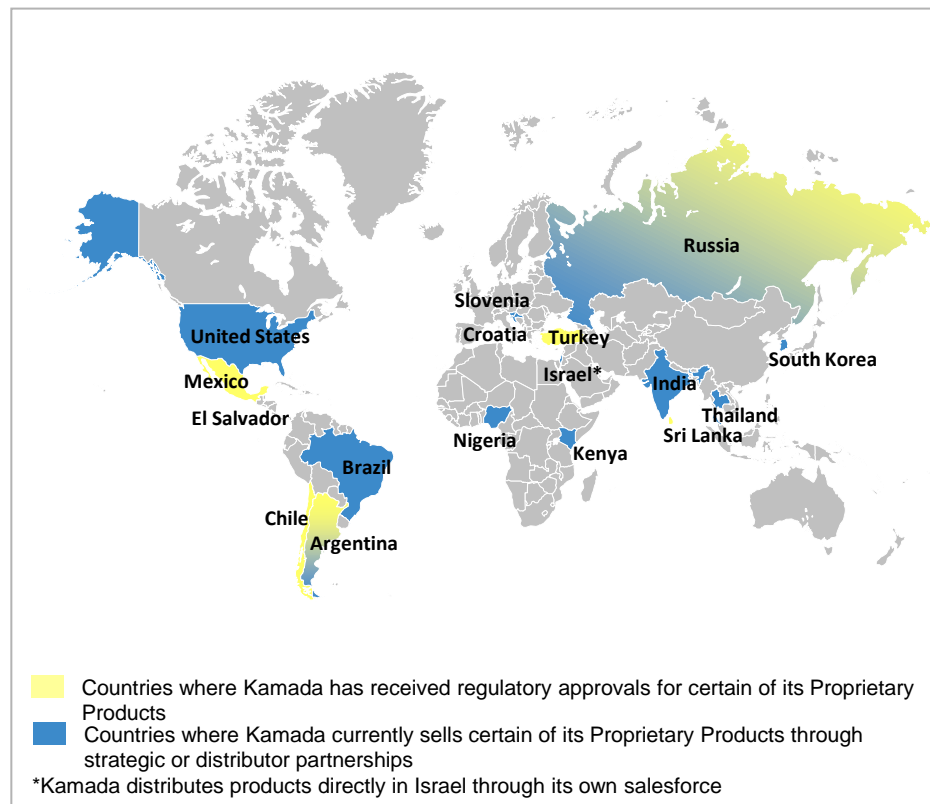


# Diversified Product Portfolio with Extended Global Reach

## Diverse Portfolio of Predominantly Plasma-Derived Protein Therapeutics

<b>Proprietary Products Segment</b>  2013 Revenue: \$51MM	Respiratory	Glassia®	Alpha-1 Antitrypsin (human)
	Immunoglobulin	KamRAB™ KamRho (D) IM KamRho (D) IV Snake Antiserum	Anti-rabies immunoglobulin (human) Rho(D) immunoglobulin (human) Rho(D) immunoglobulin (human) Anti-snake venom
	Other Products	Heparin Lock Flush Kamacaine 0.5% Human Transferrin	Heparin sodium Bupivacaine HCl Transferrin (Diagnostic grade)
<b>Distribution Segment</b>  2013 Revenue: \$20MM	Respiratory	Bramitob Foster	Tobramycin Beclomethasone+Formoterol
	Immunoglobulins	IVIG 5% Varitect Hepatect CP Megalotect Zutectra	Gamma globulins (IgG) (human) Varicella zoster immunoglobulin (human) Hepatitis B immunoglobulin (human) CMV immunoglobulin (human) Hepatitis B Immunoglobulins S.C
	Critical Care	Heparin sodium injection Albumin	Heparin sodium Human serum Albumin
	Other	Factor VIII Factor IX	Coagulation Factor VIII (human) Coagulation Factor IX (human)

## Global Presence with Exposure to Emerging Markets



## Growing Proprietary Products Segment Through Glassia®



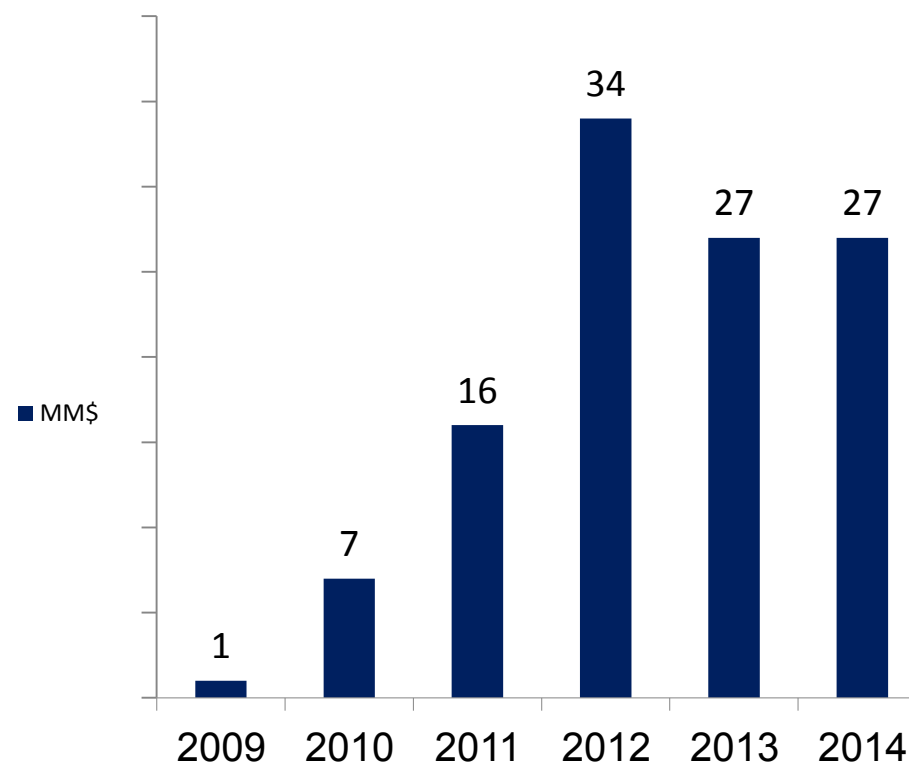
# Glassia® Is A Differentiated Product

## Key Product Advantages

- Glassia® is the first and only liquid, ready-to-use, IV plasma-derived AAT product
- No reconstitution required, reducing risk of contamination and infection and reducing treatment time
- Potentially reduced risk for adverse event and/or allergic reaction due to the absence of preservatives and stabilizing agent(s)
- Glassia® is sold in the U.S. by Baxter, a leading plasma therapeutics company (in the U.S.)
- Significantly faster infusion rate was recently approved by the U.S.-FDA

## AATD (IV) Product Sales W/O Milestone Revenues

**Sold in 7 countries, with majority of sales in the US**





# Growth of Glassia® Driven by Strategic Partnership

## Strategic Partnership with Baxter

- Sales to Baxter commenced in September 2010
- Agreements: distribution, technology license and fraction IV supply
- Product: AAT IV (Glassia®), including future AAT IV
- Territories: US, Canada, Australia and New Zealand
- Milestone and upfront revenues: \$45MM (\$34.5MM received)
- Agreement recently extended:
  - Baxter to distribute Glassia® produced by Kamada through 2017
  - Minimum revenues of \$191MM through 2017 (\$121MM already recognized through 12/31/2014)
- Royalties from sales of Glassia® produced by Baxter expected from 2018



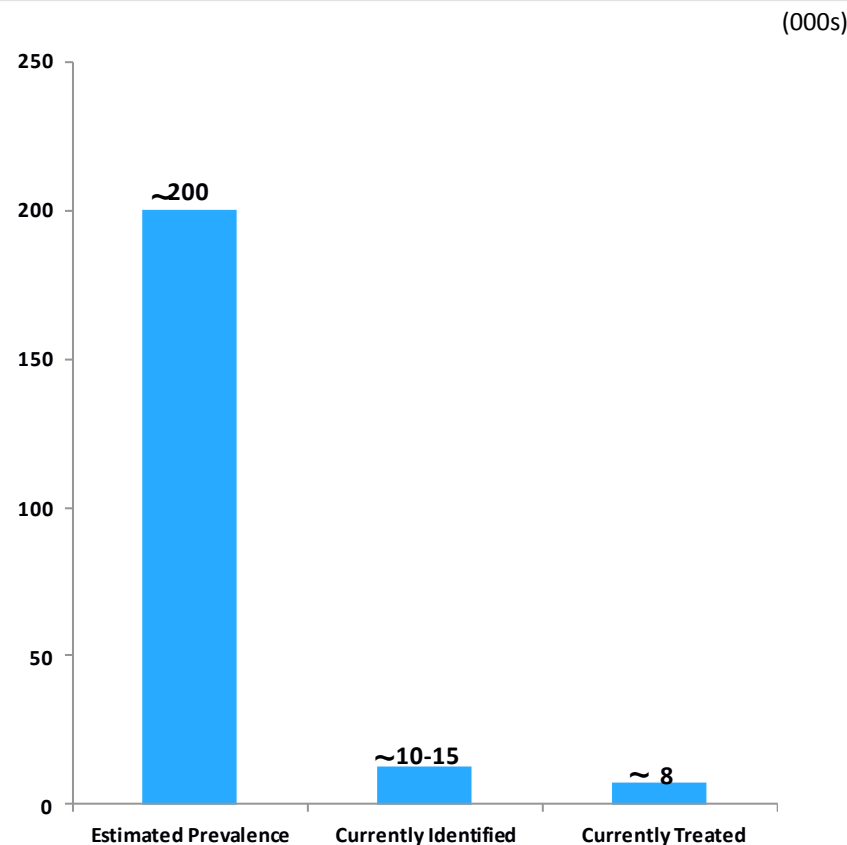


# Significant Opportunity to Expand the AATD Market

## Sustainable Market with Strong Growth Potential

- Patients suffering from AAT Deficiency (“AATD”) remain under-identified and under-treated
  - Only ~6% of cases treated in the US and ~2% in EU
- Simple blood test for diagnosis expected to impact demand
- Greater AAT use in Europe and other geographies could further accelerate market growth
- Chronic therapy creates sustainable product opportunity
- Average annual cost of treatment estimated at ~\$80-\$100K per patient

## North America and Europe AATD Patient Counts



Source Alpha 1 Foundation, MRB and Company estimates

Source MRB and Company estimates

# KamRab




KEDRION  
B I O P H A R M A

## Human Rabies Immune Globulin

- Kamada's human rabies immune globulin is a post-exposure prophylaxis (PEP) for rabies that is marketed in 7 countries
- Strategic agreement with Kedrion S.p.A for the clinical development and marketing of KamRAB in the U.S.
  - U.S. Phase II/III clinical trial completed, with data by mid 2015
  - Expect to file Biological License Application with the FDA in 2015
  - U.S. launch expected by 2016
- In the U.S., there are ~40,000 post-exposure prophylaxis treatments administered each year, representing an ~\$100 million market opportunity
  - Currently only one significant provider of anti-rabies immunoglobulin in U.S.
- WHO estimates ~10 million people worldwide require medical treatment against rabies each year after being bitten by an animal suspected of rabies infection
  - Product sold in ROW for years



# High Value Pipeline Focused on Orphan Indications

	Product	Indication	Phase I	Phase II	Phase III	Market	Partners
1	Intravenous AAT	AAT Deficiency	FDA Approved (2010)				US: <b>Baxter</b>
2	D1-AAT (IV)	Type 1 Diabetes*	Completed	Ph II/III In Process			US: <b>Baxter</b>
3	G1-AAT (IV)	GVHD*	Ph I/II In Process				US: <b>Baxter</b>
4	Inhaled AAT	AAT Deficiency*	EU: Completed				EU:  <b>Chiesi</b>
				US: Ph II In Process			
5	B1-AAT (IH)	Bronchiectasis*	Completed				
6	C1-AAT (IH)	Cystic Fibrosis (CF)*	Completed				
				US: IND Approved			
7	KamRAB (IM)	Prophylaxis of Rabies	Completed	Phase III Completed (LPO)			US: <b>KEDRION</b> BIOPHARMA

\* Orphan drug designation



# Inhaled AAT for AATD Completed Pivotal Phase II/III Trials in Europe and Initiated Phase II in the US

	Phase II / III EU	Phase II US
<b>Description</b>	<ul style="list-style-type: none"> <li>• Randomized; Over 160 AATD subjects, majority are treatment naïve</li> <li>• Double blind, placebo controlled, randomized</li> <li>• Multi center international study: Western EU (UK, IR, SC, SW, NL, DK, GR) and Canada</li> <li>• 80% power to detect a difference between the two groups at 1 year</li> <li>• Powered for 20% difference between the two groups</li> <li>• Power is based on number of events collected during the study</li> </ul>	<ul style="list-style-type: none"> <li>• Randomized; Sample size of ~ 36-40 subjects</li> <li>• Double blind, placebo controlled, randomized</li> </ul>
<b>Route &amp; Dosage Form</b>	<ul style="list-style-type: none"> <li>• Inhalation of human AAT, 160mg total, twice daily ~10-15 minutes; eFlow® device</li> </ul>	<ul style="list-style-type: none"> <li>• Inhalation of human AAT; two dosage groups (80mg and 160mg daily); eFlow® device</li> </ul>
<b>Clinical Endpoints</b>	<ul style="list-style-type: none"> <li>• Exacerbation events (Primary: time to first moderate/severe, Secondary (among others): rate, severity of first event; Lung Function)</li> </ul>	<ul style="list-style-type: none"> <li>• Primary: Concentration of AAT in ELF</li> <li>• Secondary: safety and tolerability, Concentration AAT in serum, ELF inflammatory analytes</li> </ul>
<b>Duration</b>	<ul style="list-style-type: none"> <li>• 50 wk treatment in DB period; daily treatment</li> <li>• 50 wk open label extension ; daily treatment</li> <li>• Study completed</li> </ul>	<ul style="list-style-type: none"> <li>• 12 weeks double blind +</li> <li>• 12 weeks open label extension</li> <li>• Study initiated in 1Q2014</li> </ul>



# Inhaled AAT Phase II/III trial Results

## Summary of the Results

- Primary and secondary endpoints didn't demonstrate statistical significant difference
- First AAT deficiency treatment to show impact on lung function
- Concordance of the data in lung function (statistically significant collected for safety data) and signals in reduction in exacerbation severity in favor of AAT suggests possible therapeutic benefit of AAT
- Study supports understanding the mechanism of action of the disease and the treatment - lung inflammation
- The company is advancing its discussions with the European Medicines Agency with the intent to submit for conditional approval on the basis of:
  - Orphan drug and unmet need
  - Statistically significant data for lung function
  - Co-rapporteurs advised they would consider the entire study data once submitted, including post hoc
  - Precedents of similar cases for drugs of orphan diseases



## Inhaled AAT Phase II/III trial Results (cont.)

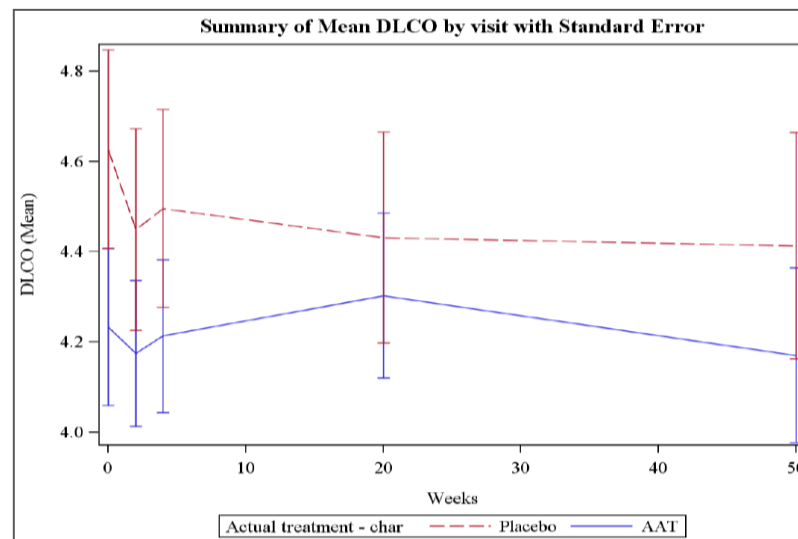
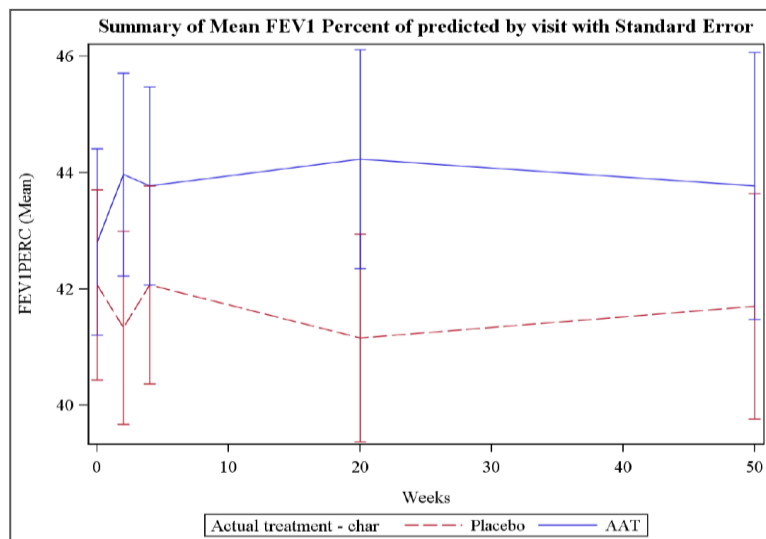
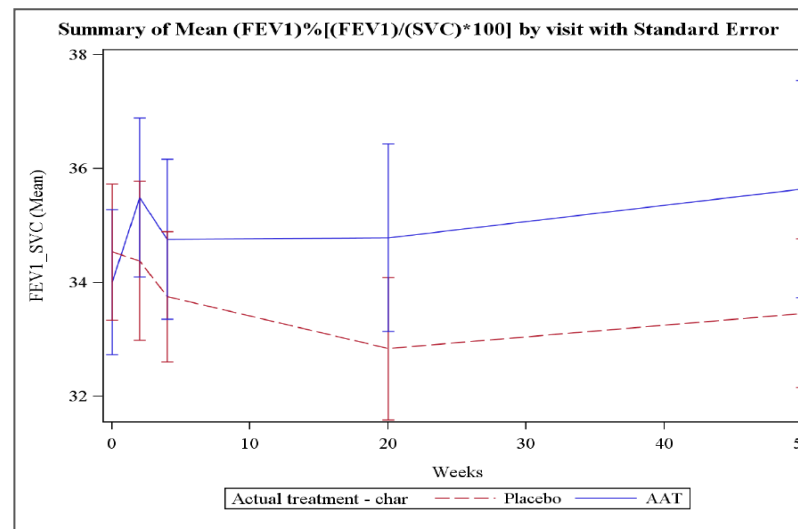
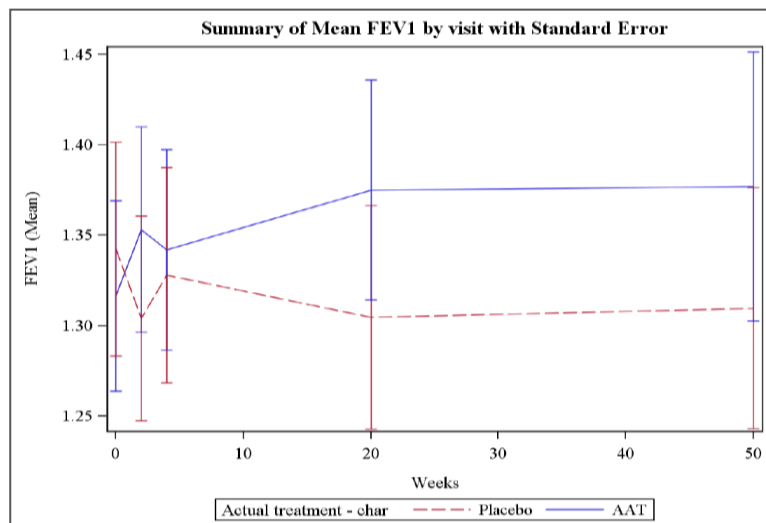
Parameter	ITT
<b><u>Lung function:</u></b> FEV <sub>1</sub> % of SVC Change from baseline till end of treatment	+0.34% AAT vs -1.17% PL <b>P Value= 0.033</b>
<b><u>Lung function:</u></b> FEV <sub>1</sub> % predicted Change from baseline till end of treatment	-0.509 AAT vs -1.37 PL P Value= NS
<b><u>Lung function:</u></b> FEV <sub>1</sub> (liters) Change from baseline till end of treatment	-25ml AAT vs -52ml PL P Value= NS
DLCO [mMol/min/Kpa]	-0.168 % AAT vs -0.28% PL P Value= NS

**Dr Jan Stolk , Principal Investigator of the Inhaled AAT Phase II/III study,  
Department of Pulmonology Leiden University Medical Center, Leiden, The Netherlands:**

*“This study is the first study ever that suggests inhaled AAT’s ability to potentially reduce lung inflammation as expressed by its preservation of lung function and the trends shown in the reduction in intensity of exacerbation events. I am encouraged by these results and hope that the regulatory authorities will acknowledge the progress in clinical research demonstrated in this trial.”*



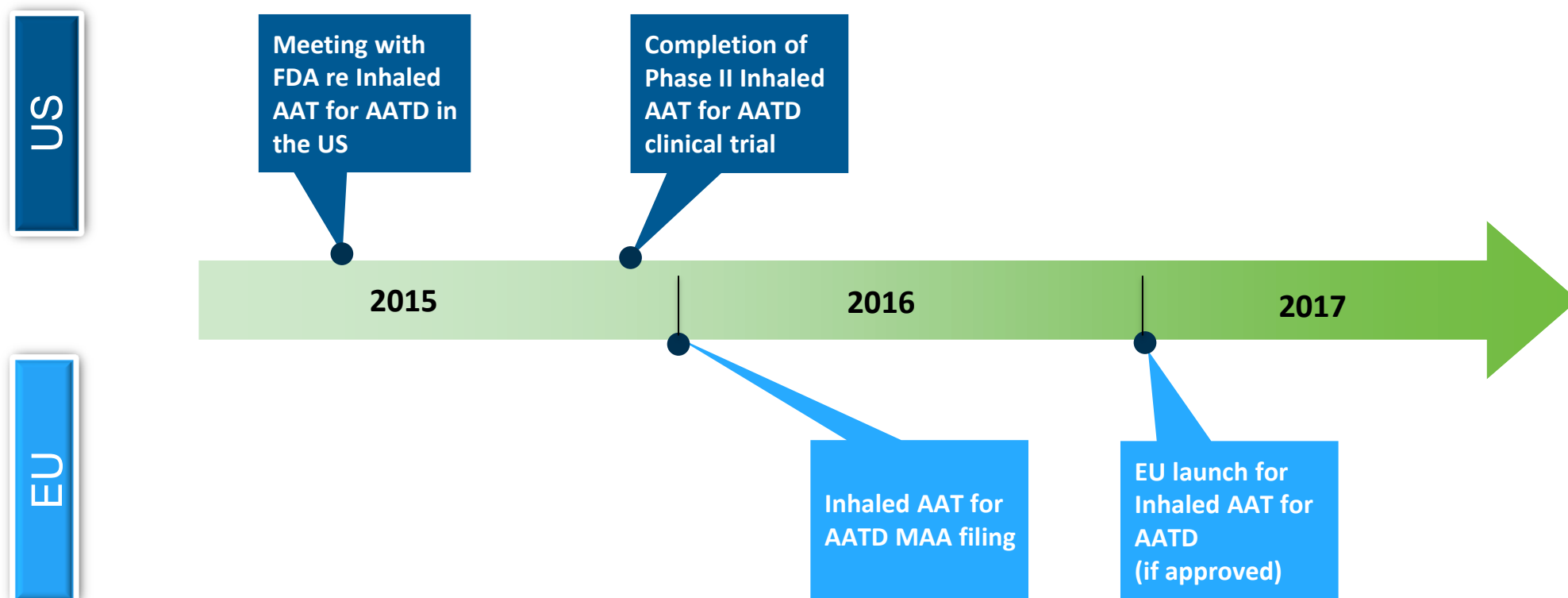
# Inhaled AAT Phase II/III trial Results: Lung Function Graphs





# Expected to Launch 2016/17 in the EU

## *Indicative Development Timeline:*





# AAT (IV) is a Promising Potential Treatment For Newly Diagnosed Type-1 Diabetes Patients

## Type-1 Diabetes

occurs when the immune system attacks and destroys beta cells in the pancreas

- More than 10 million suffer from T1D globally
- 100,000 new patients diagnosed annually
- In the US alone: 3 million patients, with 30,000 new patients diagnosed annually

## Studies have shown that AAT protects beta cell islets

- Delays the onset of autoimmune diabetes
- Reduces the incidence of diabetes
- Inhibits insulinitis and beta-cell apoptosis
- Decreases beta-cell inflammation

## Preservation of beta cells correlates with reduced risk of long term complications

- DCCT\* indicated that patients with C-peptide on MMTT  $\geq 0.2$  pmol/mL were less likely to complicate of retinopathy and hypoglycemia (Greenbaum et al 2012)
- Higher / sustained levels of C-peptide correlate with reduced incidences of the microvascular complications (Steffes et al 2013)

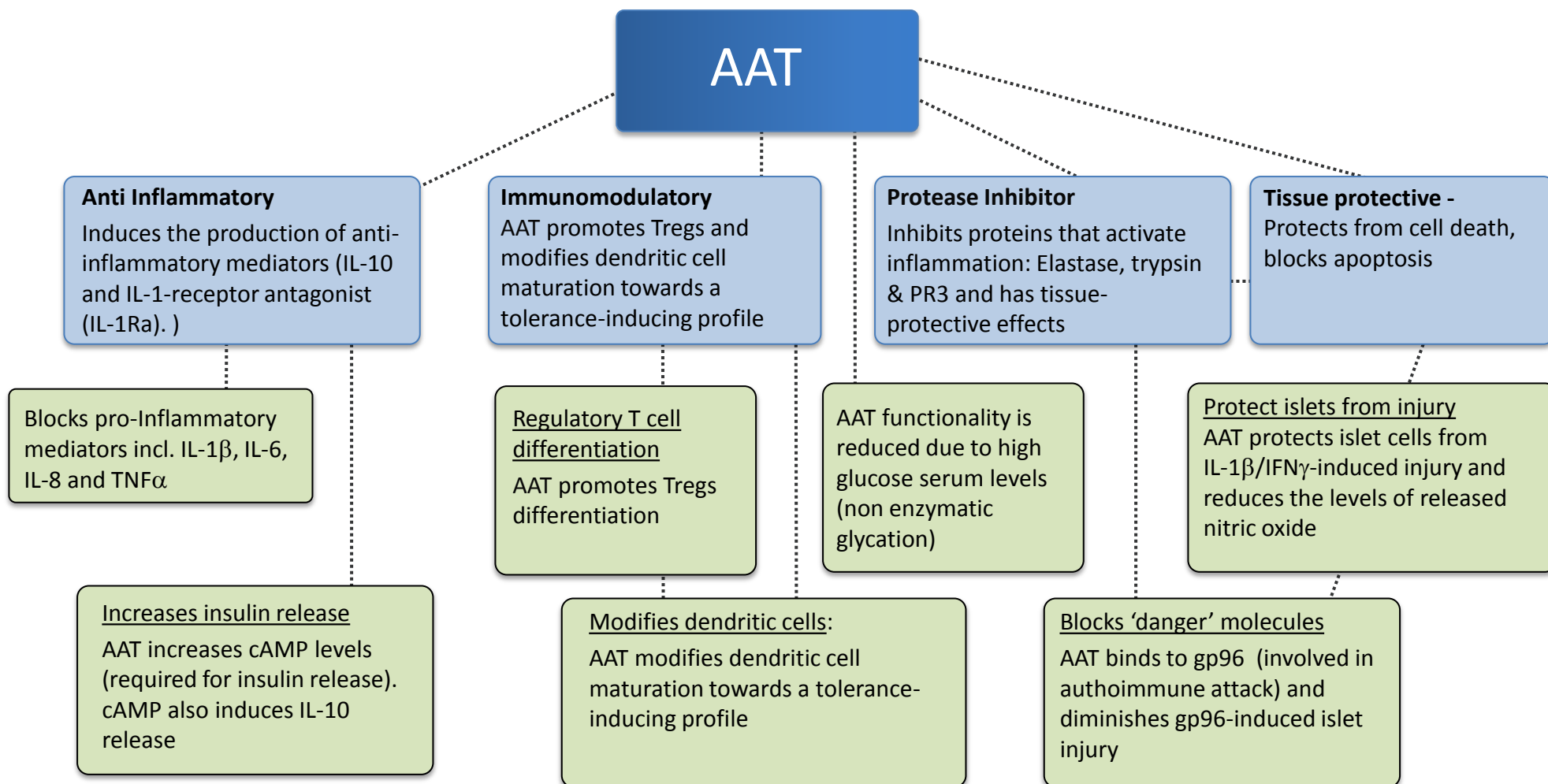
***“We acknowledge the evidence from the DCCT and other studies that have demonstrated clinical benefits in patients who achieve better glucose control, in terms of delaying the chronic complications of diabetes”\*\****

**\*\*FDA Guidance, 2008**

\*Diabetes Control and Complications Trial



# Mechanistic Evidence - Alpha1-Antitrypsin, a Therapeutic Approach for Type-1 Diabetes



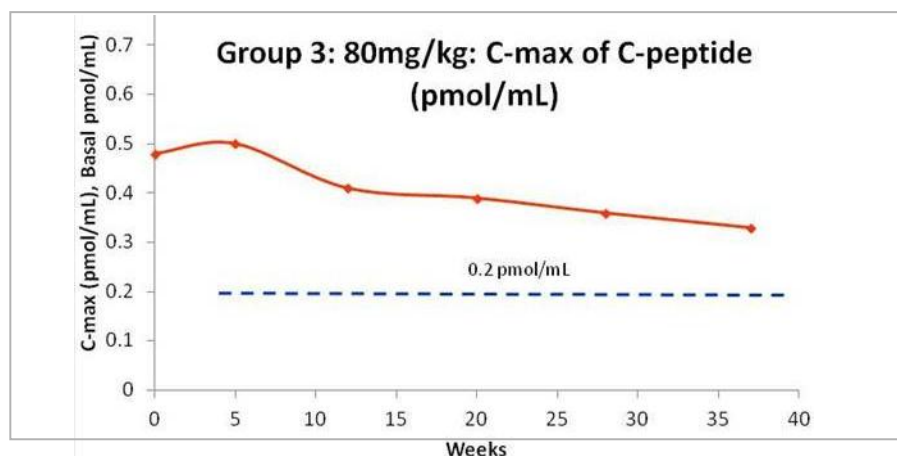
Reference: Fleixo-Lima et al. Mechanistic Evidence in Support of Alpha1-Antitrypsin as a Therapeutic Approach for Type 1 Diabetes. J Diabetes Sci Technol. 2014.



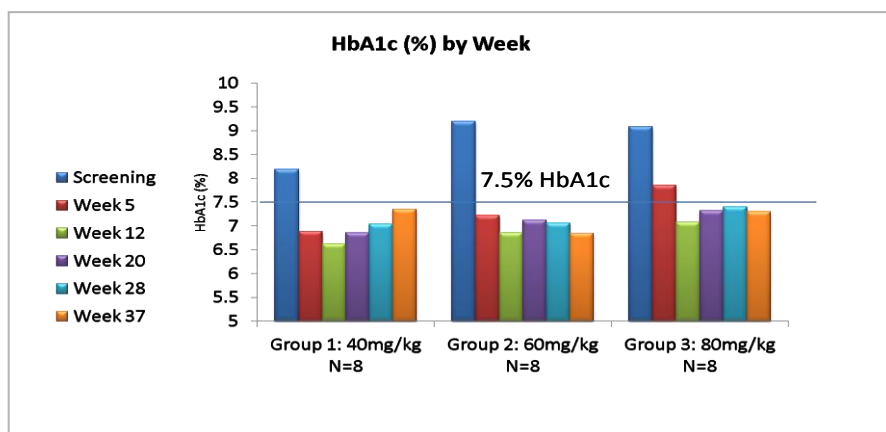
# Clinical Development for Newly Diagnosed Type-1 Diabetes: New Exciting Prospects

*Phase I/II Open Label Study to evaluate the safety, tolerability and efficacy of AAT on beta cell preservation and glycemic control on newly diagnosed T1D pediatric patients.*

End-of-study slope analysis of C-peptide[max] and C-peptide[AUC] revealed no significant changes from baseline



HbA1C data indicated that almost all patients reached glycemic control



- AUC% for C-peptide decreased 23% from baseline vs. ~40-50% expected decrease after 12-15M from diagnosis <sup>(1)</sup>
- Specific diabetes antibody levels decreased in all groups from baseline to study completion, a decrease that may indicate an Immune modulatory effect.
- At end-of-study, 38% of patients decreased insulin dose.
- All subjects completed the study. No Serious AEs occurred. AEs were mild and mostly infusion-related (fatigue, headache)
- On going open label extension interim data: Majority of patients who continued treatment with AAT maintain capability of insulin secretion and attained glycemic targets with HBA1C level below 7.5% for more than 2 years after diagnosis of T1D.



# Newly Diagnosed Type-1 Diabetes Currently ongoing Phase II/III Clinical Trial

*Pivotal, Phase II/III,  
Double-Blind, Randomized,  
Placebo-Controlled,  
Multicenter study.*

**Study objective:** To evaluate the Efficacy and Safety of Human, Alpha-1 Antitrypsin (AAT) in the treatment of New Onset Type 1 Diabetes.

**Design:** Two doses, placebo controlled, randomized with ~190 pediatric and young adult patients.

**Expected Duration:** Two years.

**Endpoints:** In accordance with FDA / EMA guidance for clinical trials evaluating beta-cell preservation [c peptide parameters, HbA1C, hypoglycemic events and insulin daily dose].



# Graft versus Host Disease (GVHD): The Major Issue in Stem Cell Transplantation

- Donor's immune cells (*the graft*) recognize the recipient (*the host*) as “Non-self”. The transplanted immune cells attack the host's body cells.
- **Deadly side effects:**
  - ~20% of transplanted patients' deaths are caused by GvHD complications
  - ~70% mortality in patients with grade III/IV GvHD
  - ~50% of patients are non responsive to steroids
- **Searching for an effective treatment**
  - Standard of care prophylaxis exhibits poor efficacy/severe AE's (Glucocorticoids)
  - No FDA approved specific drug for GvHD indication
- **Estimated market size: ~ \$700 million**



# Proof-of-Concept Study with AAT (IV) for Graft-Versus-Host Disease (GVHD)

- **Phase I/II study** open label of 24 patients with steroid-resistant GVHD following allogeneic bone-marrow stem cell transplant
- **Dose:** 4 dose groups - 15 day regimen. Doses given on days: 1,3,5,7, 9, 11, 13 and 15
- **Primary End Points:** % of patients at each dosing cohort who experience no toxicity and in whom GVHD is stable or improved
- **Secondary End Points** - AAT levels, cytokine levels, infection rate, progression of GVHD, SAEs.
- In cooperation with Baxter, conducted at the Fred Hutchinson Cancer Research Center in Seattle, Washington

***This proof-of-concept study may serve as a potential platform, to expand the use of AAT beyond GVHD, to other transplantations, based on a similar mechanism of action***



# First Cohort Results Show That AAT May Potentially Exert a Protective Effect on the Bowel Mucosa in Gut GVHD

*Study results have indicated that AAT may potentially exert healing of the bowel mucosa in gut GVHD slowing/stopping the disease progression and re-modulation of the immune attack.*

Continuous administration of AAT as salvage therapy for steroid resistant gut GVHD is feasible approach **without clinically toxicity**

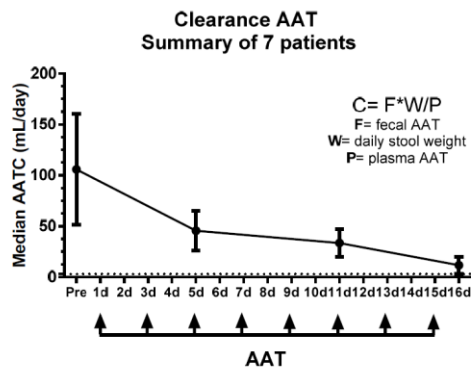
**Preliminary results are encouraging,** and further exploration of AAT therapy in extended phase II and randomized trials as therapy of steroid refractory acute GVHD or as first line therapy are warranted

Stool AAT levels showed a **decrease in intestinal AAT loss**, as measured by AAT clearance and endoscopic evaluation suggesting healing of the bowel mucosa

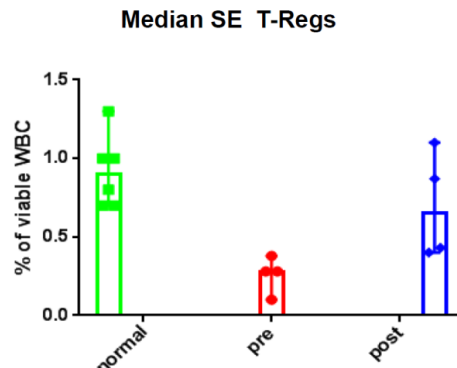
AAT administration during HCT **suppresses serum levels of pro-inflammatory cytokines**, interferes with GVHD manifestation



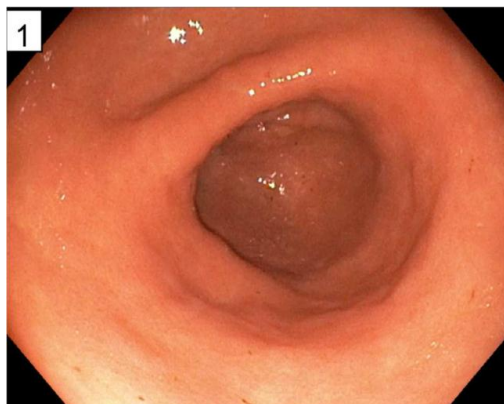
# Phase I/II Clinical Study Interim Report:



Loss of AAT in stool is an expression of intestinal injury.



FACS Analysis pre and post AAT therapy



**Before**  
Duodenitis Suspect severe upper and lower GvHD

Post 8 doses of AAT



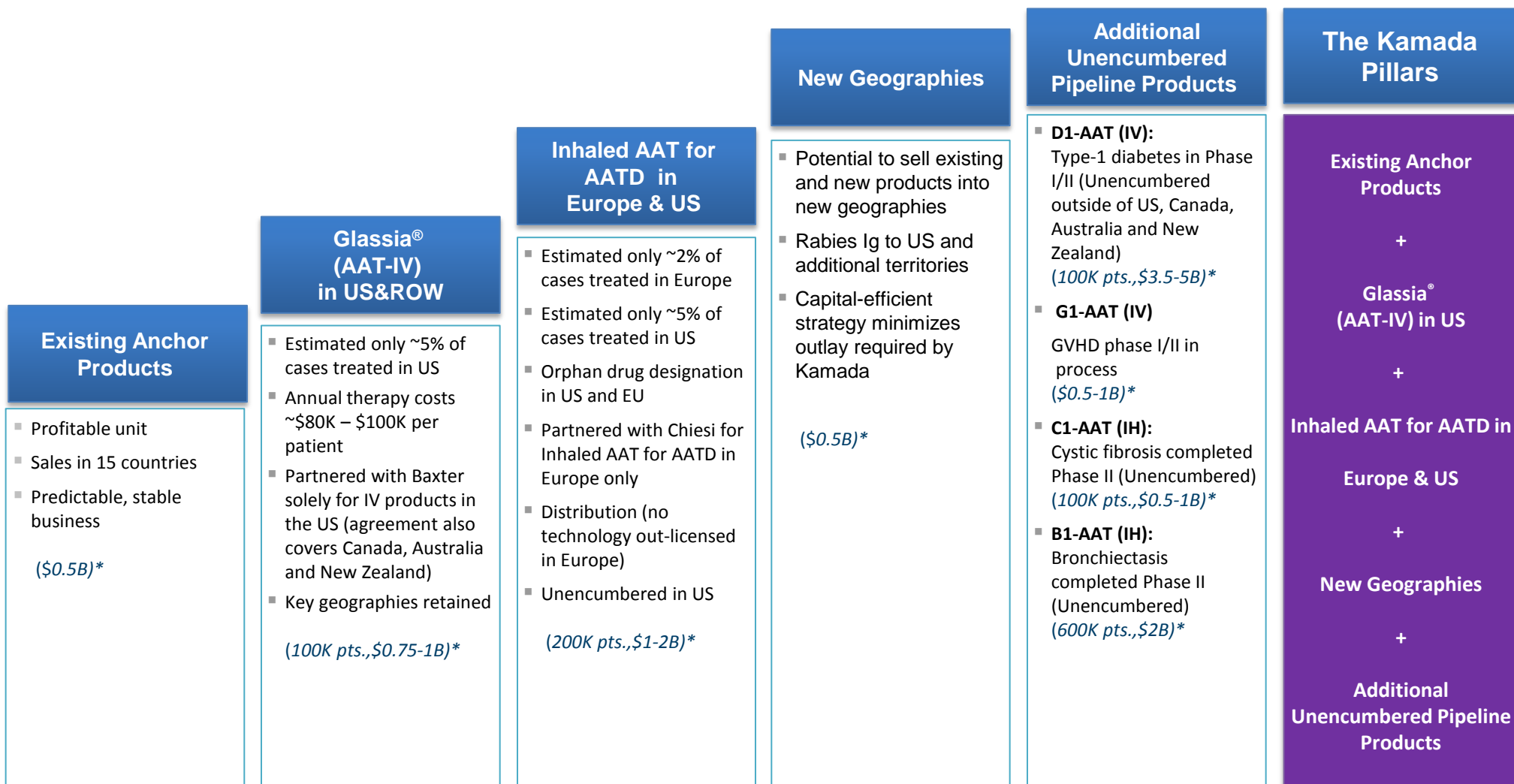
**After**  
Moderate mucosal denudement and edema noted throughout the duodenum.

# FINANCIALS





# Compelling Investment Driven By Multiple Pillars of Growth



\* Estimated market potential



# Strong Financial Profile with Revenue Growth and Expanding Profitability

- Stable, profit generating revenue stream from marketed products
- Strategic partnership model results in efficient operating expenses
  - Baxter purchase obligations provides stable revenue through 2017 and royalties thereafter
  - Kedrion partnership for Rabies Ig expected to increase revenues and profitability from 2017 and on
- Better product mix expected to improve gross margin
- Pipeline products expected to accelerate revenue growth
  - Profits from marketed products to fund part of clinical development programs
- Low capital expenditure to support infrastructure meeting future demand
- Preferred tax treatment under Israeli law



# Sustained and Rapid Growth has Made Kamada EBITDA Positive Within 3 Years of Growth

\$MM	FY2009	FY2010	FY2011	FY2012	FY2013	FY2014
Proprietary Products	10	23	35	47	51	45
<b>Growth</b>		<b>130%</b>	<b>54%</b>	<b>32%</b>	<b>9%</b>	<b>(12%)</b>
Distribution	4	11	24	26	20	27
<b>Growth</b>		<b>187%</b>	<b>110%</b>	<b>8%</b>	<b>(23%)</b>	<b>35%</b>
Total Revenues	14	34	59	73	71	72
<b>Growth</b>		<b>146%</b>	<b>73%</b>	<b>22%</b>	<b>(3%)</b>	<b>1%</b>
<b>Gross Profit</b>	<b>(3)</b>	<b>6</b>	<b>17</b>	<b>23</b>	<b>26</b>	<b>16</b>
R&D	(9)	(9)	(12)	(12)	(13)	(16)
S&M and G&A	(5)	(7)	(7)	(7)	<sup>(2)</sup> (10)	(10)
<b>NET PROFIT (LOSS)</b>	<b>(21)</b>	<b>(14)</b>	<b>(4)</b>	<b>0.3</b>	<b>0.4</b>	<b>(13)</b>
<b>Adjusted EBITDA <sup>(1)</sup></b>	<b>(12)</b>	<b>(6)</b>	<b>1</b>	<b>9</b>	<b>9</b>	<b>(4)</b>

## Note

1. See Appendix for a reconciliation of Adjusted EBITDA to IFRS Net Profit (Loss)
2. Includes one time IPO related expenses of \$1.4 M



# Consistent Track Record of Execution

US FDA approval for Glassia®

Strategic agreement with Baxter & First Glassia® sale in the US

Strategic agreement for Rabies in the US with Kedrion

Anti-Snake Venom launch

Strategic agreement with Chiesi for Inhaled AAT for AATD in EU

Newly diagnosed type-1 diabetes Phase II trial completed

Initiation of Phase II/III for type-1 diabetes

Initiation of US Phase II for Inhaled AAT for AATD

Initiation of US Phase I/II study of Glassia in GVHD

Completion of EU Phase II/III Inhaled AAT for AATD trial

Completion of US Phase III Rabies Ig

US Orphan Drug Designation for Glassia to treat GVHD

Increased sales, profitability and production capacity

2010



December 2014



# Future Milestones and Value Creation

	Milestone Date
Phase III Rabies Ig trial (US) results	1H15
Phase II/III Inhaled AAT for AATD (EU) presentation at ATS	2Q15
Interim data from GVHD trial	2015
<b>MAA submission for Inhaled AAT for AATD</b>	<b>2015</b>
<b>BLA submission for the Rabies Ig in the US</b>	<b>2015</b>
<b>Completion of Phase II for Inhaled AAT for AATD trial (US)</b>	<b>2015</b>
Strategic agreements	2015
Initiation of Phase III for intravenous AAT for GVHD	2016
<b>Rabies product launch in the US (if approved)</b>	<b>2016</b>
<b>Inhaled AAT for AATD launch (EU) (if approved)</b>	<b>2016/7</b>
Interim report for Phase II/III for type-1 diabetes trial	2016
<b>Reaching \$100 million of annual revenues</b>	<b>2017</b>
<b>Double number of Glassia patients WW</b>	<b>2018</b>
AAT IV for newly diagnosed type-1 diabetes launch in ROW (if approved)	2017/18



# Kamada Investment Highlights



## **Rapidly Growing, Globally Positioned Biopharmaceutical Company**

- Focused on Orphan Diseases and Plasma Derived Protein Therapeutics



## **Flagship Product Glassia® Approved for Alpha-1 Antitrypsin Deficiency Disorder**

- Has a Unique and Differentiated Product Profile and Represents an Exciting Growth Opportunity



## **Valuable R&D Pipeline Focused on Various Orphan Indications**



**Significant Opportunity for Intravenous AAT for Type-1 Diabetes and Graft vs Host Disease and for Novel Inhaled AAT for Alpha-1 Antitrypsin Deficiency**



**Validating Strategic Partnerships with Industry Leaders Baxter, Chiesi, Kedrion and Pari Pharma**



**Integrated, Efficient and Scalable Best-in-class Patented Platform Technology and Know-How**



**Strong Financial Profile with Increasing Profitability**



# THANK YOU

[www.kamada.com](http://www.kamada.com)

# APPENDIX





# Conditional Approval Guidance & Precedence

## EMA Guidance

EMA/509951/2006

**GUIDELINE ON THE SCIENTIFIC APPLICATION AND THE PRACTICAL ARRANGEMENTS NECESSARY TO IMPLEMENT COMMISSION REGULATION (EC) No 507/2006 ON THE CONDITIONAL MARKETING AUTHORISATION FOR MEDICINAL PRODUCTS FOR HUMAN USE FALLING WITHIN THE SCOPE OF REGULATION (EC) No 726/2004**

## Precedence for Conditional Approval

Arzerra - GSK

<http://www.bloomberg.com/apps/news?pid=newsarchive&sid=aaAMTmwslwq4>

Cometriq – Exelixis

<http://www.exelixis.com/investors-media/press-releases>

Translarna PTC Therapeutics

<http://ir.ptcbio.com/releasedetail.cfm?ReleaseID=888466>

Deltysba - Otsuka

[http://www.otsuka.co.jp/en/company/release/2013/1125\\_02.html](http://www.otsuka.co.jp/en/company/release/2013/1125_02.html)

Sirturo - Johnson & Johnson

<http://www.investor.jnj.com/releasedetail.cfm?ReleaseID=831021>



# Inhaled AAT Is A Significant Opportunity

## Inhaled AAT Highlights

- First and only Inhaled AAT product for AATD
  - Device and drug combination enable optimal size particles delivered directly to diseased tissue
- Positive data to date in AATD and strong safety profile
- Potential to expand AATD market, particularly in Europe
- Potential Inhaled AATD launch in Europe not before 2016 , pursuing conditional approval based on phase 4 commitment.
- US pathway to be discussed with FDA beginning 2015

## Strategic Partnership with Chiesi

- Chiesi distribution agreement as of August 2012
- Agreement: Chiesi responsible for S&M, patient ID, and reimbursement
- Product: AAT for AATD Inhaled only
- Territories: EU and Turkey
- Milestone revenues: \$60MM upfront, regulatory and sales
- Distributor price
- Minimum purchases from 2nd yr following receipt of regulatory and reimbursement approvals, ~\$120MM for first 4 years, subject to actual price after regulatory approval