




# YOUR TEARS CONTAIN CRITICAL INFORMATION

DiagnosTear

tells their story

A close-up of a human eye, looking slightly to the right. The eye is rendered in a dark, monochromatic blue color. A stylized tear drop is positioned in the lower-left quadrant of the eye. The tear drop is composed of a white wireframe mesh that forms a teardrop shape. Inside the tear drop, there is a detailed molecular structure, possibly a protein or a complex of molecules, rendered in various colors including blue, purple, and white. The background is a dark, textured blue, suggesting a close-up of the eye's surface.

**Why aren't we analyzing the composition of our tears to assess the health of our eyes just like analyzing our blood to assess our overall health status?**

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DiagnosTear aims to become the global leader in rapid, tear-based ophthalmologic diagnostics



## DiagnosTear's core platform



**Less than 10 minutes**  
to get an accurate diagnosis  
and prescribe the exact treatment



**1** Microfluidic collection of  
tear liquid



**2** Multifactorial assessment of  
biomarkers in the tear film



**3** Intuitive interpretation of results  
through smart algorithms

# TeaRx™ Dry Eye Syndrome (DES)

Intended for rapid POCT assessment of DES

- Patented tear collector
- Multi-parametric test cassette
- Visual or digital readout
- Smart algorithm for intuitive interpretation (DES score)
- <10 min procedure (3 min hands-on)
- Sensitivity 86.4% | Specificity 86.7%
- CE-IVD and Israeli MoH approved



CE IVD For professional in vitro diagnostic use only

# TeaRx™ DES Parameters

## Parameter

## DES

**Lactoferrin (LF)** Inhibitor of bacterial growth. Possible anti-inflammatory properties. Innate immunity. One of major proteins secreted by the acini of the lacrimal glands. Significantly down regulated in early stages of DES.

[Versura P et al., 2013 ]



**Human Serum Albumin (HSA)** Transportation of free fatty acids, stabilizing the osmotic pressure. most abundant protein in human blood. Leakage from blood vessels imply on severity of DES. marker for the integrity of blood tear barrier.

[Versura P et al., 2013 ]



**Lysozyme (LYS)** Antibacterial enzyme. Innate immunity. produced in the acini of the main lacrimal gland. Significantly down regulated in early stages of DES.

[Versura P et al., 2013 ]



**Immunoglobulin A (IgA)** Major immunoglobulin in tears, essential immune defence factor against infections. Secreted into tears by plasma cells in the conjunctiva adenoid/epithelial layer, or sub-epithelial cells in the lacrimal gland. Significantly down regulated in early stages of DES.

[S. D'Souza and L. Tong, 2014, M. Hoshino et al.,2006]



**Mucins (MUC)** Mucins play an essential role in forming protective mucous barriers on epithelial surfaces that protects from infections. mucins produced by goblet cells. Goblet cell loss and decrease of mucin production are hallmarks in DES.

[P. Argueso et al., 2002]



**Lipocalin (LCNI)** Second to Lysozyme of tears' most concentrated protein. Lipocalin is produced in the lacrimal gland . Recent research implies the lipocalin maintaining tear film stability by acting as a lipid scavenger. Its concentration is significantly decreased in patients with MGD.

[M. Yamada et al. 2004]



(\* ) Specifically, in MGD

# Promising Results from Clinical Trials



4 clinical trials completed  
in Israel & US involving  
>500 subjects

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Overall, both **sensitivity**  
and **specificity** levels  
were **>86%** for detection  
of **high severity** DES



Large clinical trial in India underway  
involving 600 subjects with a  
**wide range of DES severity levels**

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Interim results indicate  
**sensitivity of 79.5%** and  
**specificity of 73%** for TeaRx™  
as a single predictive device

# Ongoing Clinical Trials

As additional data is collected (including post-Rx revisits), DiagnosTear will determine TeaRx™ potential to:



**Predict DES severity & etiology (i.e., MGD)**



**Monitor disease progression**



**Predict & Monitor response to therapy**

# TeaRx™ : Beyond DES Assessment at the Ophthalmologist Office

- TeaRx™ may be used as a single screening test for DES to be primarily used by optometrists and eye care retail chains:
- Stratify eligible patients for **DES-compatible contact lenses** based on Silicone Hydrogel Technology
- Is it DES or chronic allergy? On-site decision support for optometrists and pharmacists recommending **OTC DES medications or OTC Allergy Drops**
- Assessment of MGD – for stratification and monitoring of patients for **Intense Pulsed Light (IPL) Therapy or Thermal Pulsation therapy**
- *Will require FDA 510(k) clearance and CLIA waiver*







# What's in the Pipeline?

DiagnosTear is Committed to Expanding its Portfolio  
of POCTs for Unmet Ophthalmic Indications

# Conjunctivitis (Red Eye)

Conjunctivitis (red eye) accounts for

**1%** of ALL primary care & emergency room visits

**~80%**

*Of all acute conjunctivitis cases*

Viral

**135/10K**

*Prevalence in the general population*

Bacterial  
(mostly children)

**~15-20%**

*Of all conjunctivitis cases*

Allergic

Azari AA and Barney NP, *Conjunctivitis, A Systematic Review of Diagnosis and Treatment. JAMA* 310(16), 1721-9 (2013)



# Diagnosis is Complex

Therapy is dependent on the etiology.  
Assessment of underlying cause is complex and involves lab workup (not routinely performed)

- **Herpes virus:** (1) may cause scarring of the cornea and permanent vision loss (2) Counterindication for Steroids – **needs to be ruled out!**
- **Adenovirus:** 60-90% of cases – Treatment with Steroids
- **Allergic conjunctivitis:** 15-20% of cases, Treatment with anti-histamines



# DiagnosTear's Solution:

TeaRx Red Eye – A rapid and simple POC test to be used primarily by GPs and pediatricians

	RESULT			
Herpes	+	-	-	-
Adenovirus	+ or -	+	-	-
IgE (Allergy)	+ or -	-	+	-
Management	Urgent referral to Ophthalmologist. No Steroids!	Prescribe topical steroids. Advise patient for proper hygiene and ocular washes	Prescribe topical anti-histamines with or without steroids	Prescribe topical antibiotics No improvement – ophthalmologist

**The commercial model:** Prescription test to be sold at the pharmacy and used at the clinic (like in the case of Strep A rapid test). Patient purchase out of pocket; HMO complement insurance may subsidy

**Incentive to the Patient:** Without using the test, the GP/pediatrician will have to refer the patient to an ophthalmologist. **Incentive to the HMO** – shortening waiting time/referrals to specialists



**This is Us**

# DiagnosTear in a Nutshell

A leading ophthalmic company developing and commercializing disruptive diagnostic solutions for better management of eye diseases



**BioLight Life Sciences (TASE: BOLT)**  
Parent company, majority shareholder



**Elcam Medical**  
Strategic partner and investor

# Our Leading Team



**Yaacov Michlin**

Chairman of the Board

- CEO - BioLight (TASE:BOLT)
- Co-chairman – IATI
- Ex CEO – BrainsWay (Led to NASDAQ IPO)
- Ex CEO - Yissum



**Dr. Shimon Gross**

Chief Executive Officer

- >20 years experience in IVD
- Ex VP Genomics division and Head of R&D – AID Genomics
- Ex VP Sales & Marketing - Savyon Diagnostics
- >25 peer-reviewed publications and patents



**Dr. Amos Sommer**

Chief Technology Officer

- Almost 3 decades experience in IVD R&D
- World expert in developing lateral-flow rapid tests
- Developed the HIV rapid test line for Alere (now Abbott)
- Developed the TearX™ core platform and DES test



**Yiftach Biel**

Chief Financial Officer

- CFO - BioLight (TASE:BOLT)
- Ex BioLight corporate controller
- Ex Delek Global Real Estate (AIM:DGRE) corporate controller
- Certified CPA



**Dr. Oded Yogev**

Head of Innovation

- Extensive experience in developing new methods for the identification of small molecules in human tears
- Ex Head of Lab Operations at AID Genomics.
- Ex Scientific Researcher at TEVA

# Scientific Advisory Board



## Prof. David Zadok

- Director of Ophthalmology at Shaare Zedek MC, Jerusalem, Israel.
- Former Chairperson of the Israel Ophthalmology Society
- Former Head of the Israel Cornea Society
- Fellowship in Corneal Diseases UCSD, San Diego
- Co-authored over 70 scientific publications, 2 book chapters
- Member of AAO, Asia Cornea Society and Israeli Society of Vision and Eye Research
- Current field of work — Cornea and anterior segment, cataract, and ocular surface eye inflammation and dry eye



## Dr. Ron Neumann MD

- Chief Medical Officer of BioLight
- Expert ophthalmologist, specializing in inflammatory eye diseases
- Senior consultant to Maccabi, Israel's leading HMO
- Formerly established a Clinic for Inflammatory Eye Diseases at Sheba Medical Hospital holding this position for nearly a decade
- Ex Global Medical Director for innovative Products – TEVA
- Co chairman – ISOPT
- Founder – FOIS (Foster Ocular Inflammation Society)