

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

Form 6-K

Report of Foreign Private Issuer

Pursuant to Rule 13a-16 or 15d-16
of the Securities Exchange Act of 1934

For the month of January, 2017

Commission File Number: **001-36000**

XTL Biopharmaceuticals Ltd.
(Translation of registrant's name into English)

**5 HaCharoshet St., Raanana,
4365603, Israel**
(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.

Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ____

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ____

Incorporation by Reference: This Form 6-K of XTL Biopharmaceuticals Ltd. is hereby incorporated by reference into the registration statements on Form S-8 (File No. 333-148085, File No. 333-148754 and File No. 333-154795) and Form F-3 (File No. 333-194338).

On January 5, 2017, XTL Biopharmaceuticals Ltd. (the “Company”) made available an updated investor presentation on its website. A copy of the investor presentation is attached hereto as Exhibit 99.1 and may be viewed on the home page of the Company’s website at www.xtlbio.com.

Exhibit Index

Exhibit No.	Description
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99.1	Investor Presentation – January 2017
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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

XTL BIOPHARMACEUTICALS LTD.

Date: January 5, 2017

By: /s/ Josh Levine

Josh Levine

Chief Executive Officer



XTLbio

January 2017

XTL Biopharmaceuticals

(NASDAQ: XTLB) (TASE: XTLB.TA)



www.xtlbio.com

Forward Looking Statements

Certain statements in this presentation are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking words such as "anticipate," "planned," "believe," "forecast," "estimated," "expected," and "intend," among others. These forward-looking statements are based on XTL Biopharmaceuticals Ltd.'s current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, the accuracy of our financial forecasts in our product candidates' development activity and the uncertainty regarding the adequacy of our liquidity to pursue our complete business objectives; the timing and cost of the in-licensing, partnering and acquisition of new product opportunities; the timing of expenses associated with product development and manufacturing of the proprietary product candidates that we have acquired, and those that may be in-licensed, partnered or acquired; substantial competition; our need for additional financing; uncertainties of patent protection and litigation; uncertainties of government or third party payer reimbursement; and risks related to failure to obtain regulatory clearances or approvals and noncompliance with applicable drug development regulations. As with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products. There are no guarantees that future clinical trials discussed in this presentation will be completed or successful or that any product candidate will receive regulatory approval for any indication or prove to be commercially successful. Investors should read the risk factors set forth in our Form F-1/A filed with the Securities and Exchange Commission and periodic reports filed with the Securities and Exchange Commission and the Tel Aviv Stock Exchange. While the list of factors presented here is considered representative, no such list should be considered to be a complete statement of all potential risks and uncertainties. Unlisted factors may present significant additional obstacles to the realization of forward-looking statements. Forward-looking statements included herein are made as of the date hereof, and we do not undertake any obligation to update publicly such statements to reflect subsequent events or circumstances, except as required by law.

Highlights

- Developing clinical assets for the treatment of autoimmune diseases
 - Address large markets with high unmet clinical needs
 - Well-defined clinical pathway and relatively quick time to market
 - Partner with large Pharma to help fund late stage development
- Initial focus on hCDR1 asset for the treatment of:

Indication	Preclinical	Phase I	Phase II	Phase IIb	Phase III
SLE (lupus)					
Sjogren's Syndrome					

- Anticipated Key Development Milestones¹:

Indication	2017	2018	2019
SLE	IND Approval	Last Patient In	Final Data
	Phase 2b trial initiation	Interim Analysis	
SS	IND Approval	Last Patient In	
	Phase 2 trial initiation	Final Data	

1 - Future financing may impact development timeline

Corporate Overview

- Lead product candidate (hCDR1 or Edratide): for treatment of autoimmune diseases
 - Novel compound with unique mechanism of action
 - Clinical data in >400 patients with Systemic Lupus Erythematosus (SLE)
 - Demonstrated favorable safety profile and well tolerated by patients
 - “Demonstrated efficacy in ... clinically meaningful endpoints”
(*Lupus Science & Medicine Journal* – August 2015)
 - Encouraging preliminary data in primary Sjogren’s Syndrome (pSS) exhibited, similar to data previously obtained in SLE
- Lead indications represent significant unmet medical needs in area of interest
 - GSK acquired HGS in 2012 primarily for its SLE drug Benlysta for \$3 billion
 - No effective therapeutic on the market for either indication and weak competitive pipeline
- Aim to replicate results achieved in previous Phase 2b trial in SLE
 - FDA supports efficacy endpoint based on the BILAG index
 - Improved trial design for SLE based on previous Phase 2b study; FDA “buy in”



hCDR1: Phase II Ready in Two Autoimmune Indications

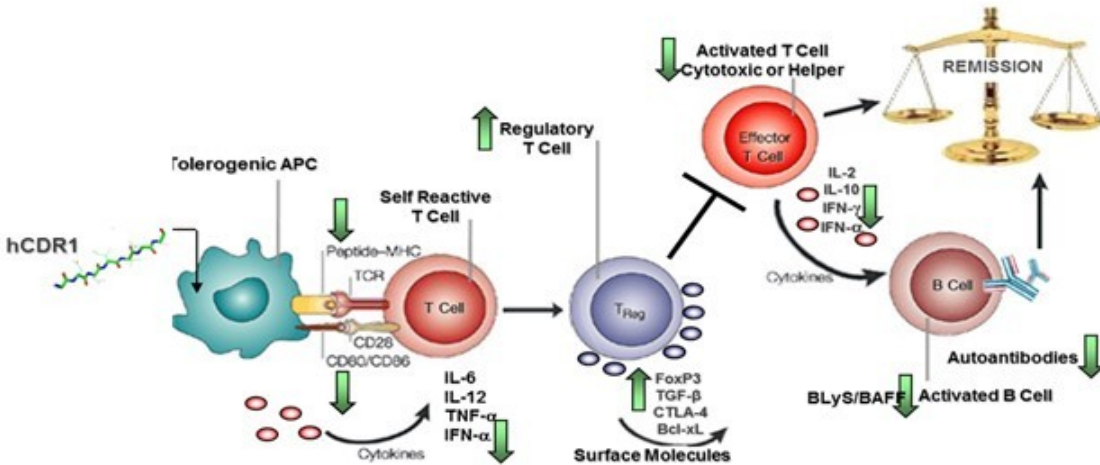
- Peptide that down-regulates autoimmune processes
- Developed by Prof. Edna Mozes from Weizmann Institute of Science (Israel)
- >40 peer reviewed journal articles; >200 animal experiments
- Three clinical studies completed on hCDR1 treating over 400 SLE patients
- Intellectual Property
 - Minimum of data/regulatory exclusivity
 - US: 6.5 - 7.5 years from approval (5 years plus variable litigation time)
 - EU: 10 years from approval
 - Recently filed two new U.S. Patent Applications for treatment of SLE – covering:
 - 0.5 mg and lower doses
 - Specific patient population and/or treatment regimen
 - Recently filed Provisional U.S. Patent Application for treatment of Sjogren's Syndrome

"First in Class" and "Best in Class" Candidate

hCDR1: Unique Mechanism of Action (MOA)

MOA of hCDR1: Different than existing late stage pipeline candidates

Specific upstream immunomodulation through generation of regulatory T cells

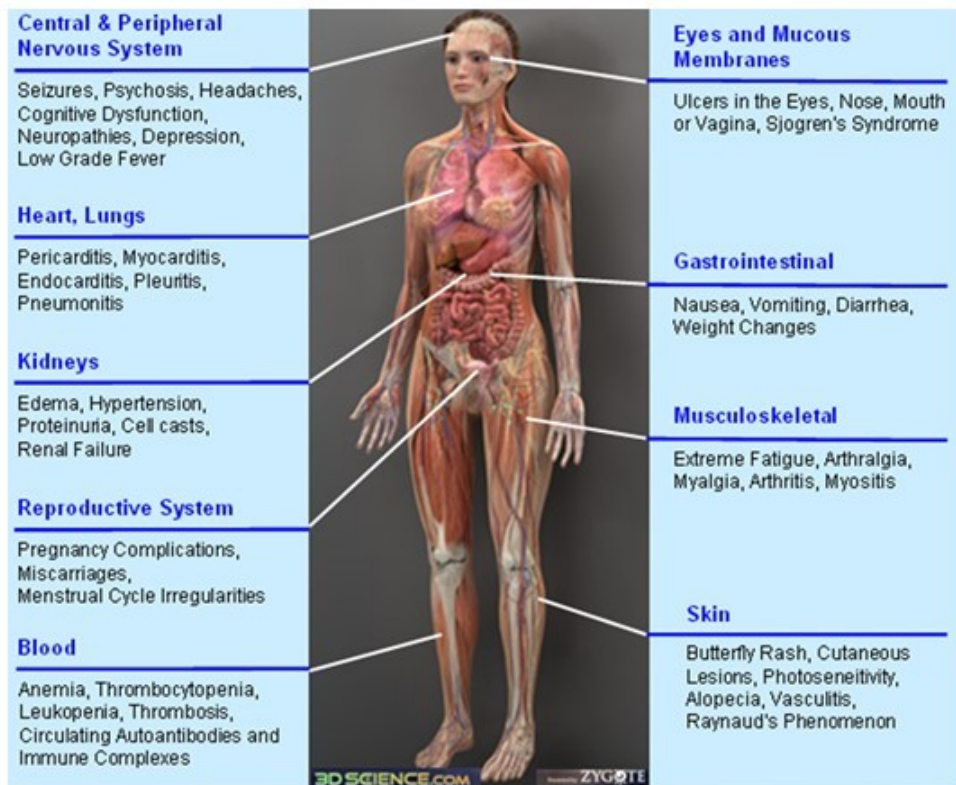


Unique MoA – potential as **standalone** therapy or in **combination** with other lupus drugs



SLE: Affected Organs & Symptoms

- Chronic, debilitating inflammatory autoimmune disease
- Resulting in rheumatologic, dermatological and end-organ manifestations



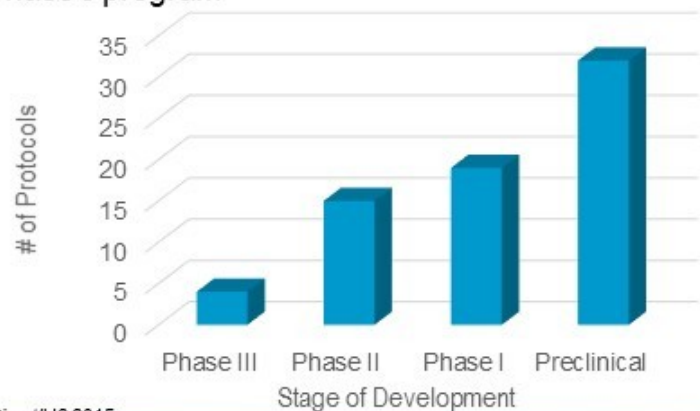
SLE/Lupus: Market Overview

- Prevalence¹
 - 1.5 million patients in U.S. (5 million worldwide) across various ethnicities/geographies
 - Vast majority at onset are women / majority between ages of 15 and 45
- Prognosis
 - Dermatologic & musculoskeletal manifestations are the most common but major organ involvement such as renal, central nervous system and serosal occur frequently
 - Major organs may become involved as disease progresses
 - Most common causes of death
 - Initial – active disease or infection
 - Later - Renal failure, Cardiovascular disease, CNS disorders
 - 80-90% of patients survive beyond 10 years¹
- Market expected to grow dramatically



¹Lupus Foundation of America

- Current treatments: anti-malarials, corticosteroids, immunosuppressants, cytotoxics
 - Problems with current treatments: severe side effects (hypertension, osteoporosis, bone marrow suppression, increased cancer risk, etc.)
- Benlysta (HGS/GSK): approved by FDA March 2011
 - **Only lupus drug approved in the last 50+ years**; 2015 sales of £230m (GSK 2015 financials)
- Current pipeline: primarily B-cell inhibitors – like Benlysta
 - Recent Phase III failures: UCB/Lilly/Anthera
 - Aurinia “success” in Lupus Nephritis: FDA allows single Phase 3 study (following P2b study); recently raised \$28M to fund Phase 3 program



hCDR1 (Edratide): Clinical Trial History

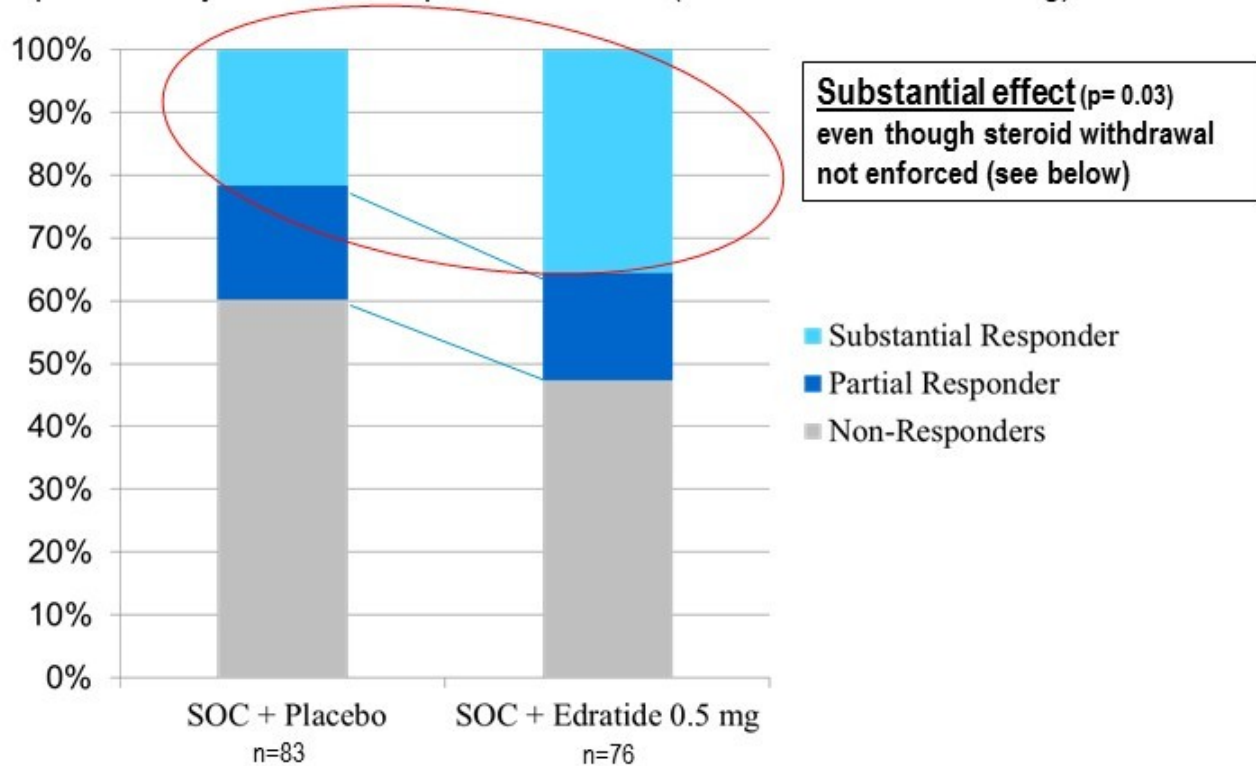
- Three clinical trials completed (by Teva): Phase Ia, Ib and IIb trials
 - Over 400 patients enrolled in prior trials
 - Well tolerated and demonstrated favorable safety profile
- Phase IIb (PRELUDE) trial (conducted by Teva)
 - Did not meet primary endpoint (SLEDAI)
 - Did not enforce steroid withdrawal algorithm
 - Encouraging results in secondary clinical endpoint, BILAG index (see below)
 - 0.5 mg weekly dose showed a substantial effect
- Opportunity
 - Teva returned to Yeda in 2009 and XTL in-licensed in 2014
 - FDA published revised guidelines in 2010 with BILAG as preferred primary endpoint

Encouraging Phase IIb results based on secondary endpoint (BILAG index)

Primary endpoint confirmed by FDA pre-IND written response for planned XTL sponsored trial

PRELUDE - Secondary Endpoint (Pre-defined/ITT Cohort)

BILAG Responder Analysis at LOV Compared to Baseline (Placebo vs. Edratide 0.5 mg)

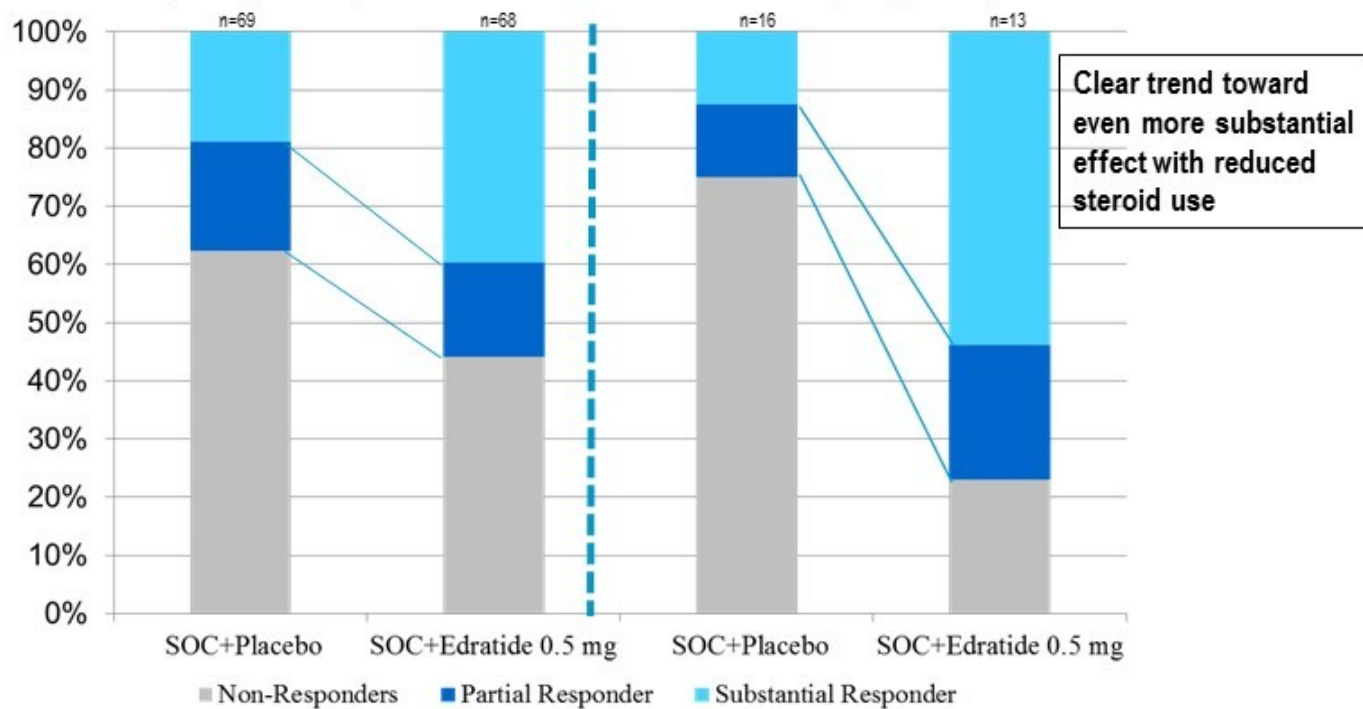


PRELUDE - Secondary Endpoint (Post Hoc)

BILAG Complete Responder Analysis (Placebo vs. Edratide 0.5 mg)

Subjects with BL Steroids <20 mg daily dosage
(n=137; p=0.007)

Subjects with **no Steroids** at Baseline
(n=29; p=0.05)



PRELUDE: Peer-Reviewed Publication (August 2015)

Safety and efficacy of hCDR1 (Edratide) in patients with active systemic lupus erythematosus: results of phase II study



Murray B Urowitz,¹ David A Isenberg,² Daniel J Wallace³

KEY MESSAGES

- ▶ Edratide demonstrated efficacy in one and possibly more clinically meaningful endpoints.
- ▶ Dose ranging studies demonstrated the 0.5 mg subcutaneous weekly was the most effective dose.
- ▶ There were no safety signals in this 26 week study.

Urowitz MB, Isenberg DA, Wallace DJ. *Lupus Science & Medicine* 2015;2:e000104. doi:10.1136/lupus-2015-000104



5-Jan-17

XTL Sponsored Trial: Improve Probability of Success

Proposed trial design based on: (1) FDA written guidance; (2) Benlysta trials; and (3) clinical data from PRELUDE - especially the 0.5 mg results in BILAG endpoint

	PRELUDE Trial	<i>Proposed Trial</i>
Primary endpoint	SLEDAI only	BILAG Substantial Responders
Dose	0.5, 1, 2.5 mg	0.5 mg and lower
Steroid Use	< 40 mg daily dose at baseline Steroid sparing not enforced	Lower daily dose at baseline (<15 mg) Defined steroid reduction regimen
Trial duration	26 weeks	26 weeks
Execution	Site discrepancies in disease matrices Suboptimal sample & data handling	Training and monitoring Specialized CRO

FDA Guidance (written response dated January 19, 2016)

- Phase 2 study with a primary efficacy endpoint to be based on BILAG index
- Reduced steroid usage and elevated anti ds-DNA levels in patient population (and other inclusion/exclusion criteria)
- Reasonable number of patients required to prove safety for marketing approval

hCDR1 for SLE: Development Milestones

Milestone	2016	2017	2018
Pre-IND Meeting ✓			
Finalize phase 2b trial design ✓			
CMC – Drug Product production & testing ✓			
New Patent Applications filed ✓			
IND Approval			
Trial Enrollment			
Initial Clinical Data			

hCDR1: treatment of Sjögren's Syndrome (SS)

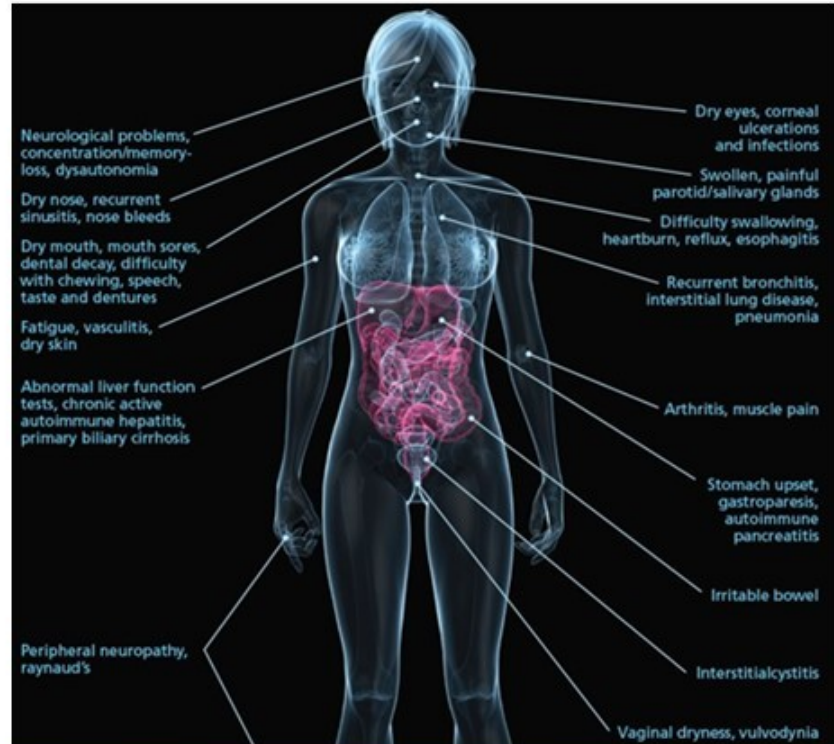


SS: Affected Organs & Symptoms

Chronic autoimmune inflammatory disorder characterized by diminished lacrimal and salivary gland function that may affect multiple organs/systems

Two types of SS (~50/50):

- **Primary SS (pSS):** SS patient who does not have another major rheumatic and/or autoimmune disease
- **Secondary SS:** secondary to another autoimmune disease



SS: Market Overview

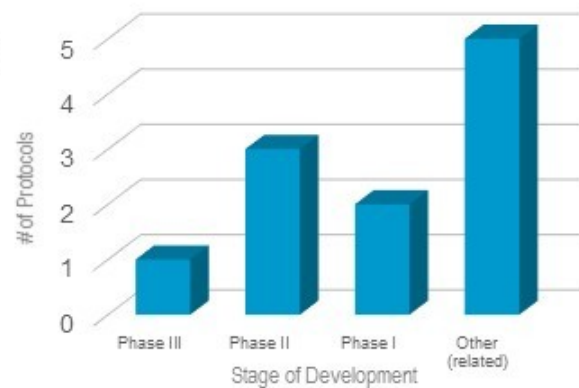
- Prevalence
 - ~0.7%¹ of U.S. population— estimated 2.5 to 4 million patients²
 - Vast majority at onset are women (at least 9:1)²
 - Average age at diagnosis: 40-50 years²
 - Market expected to grow to 3.5 million cases globally by 2024¹
- Prognosis
 - Hallmark symptoms are dry eyes/mouth, fatigue and joint pain
 - May impact other organs (extra-glandular): kidneys, gastrointestinal system, blood vessels, lungs, liver, pancreas and nervous system
 - Increased risk of non-Hodgkin's B cell lymphoma (relative risk: 13x chance of developing disease vs. general population)¹
 - ~70% of patients have anti-Ro (SS-A) ; ~40% of patients have anti-La (SS-B)²

¹ Global Data Research 2016

² Sjogren's Syndrome Foundation

SS: Competitive Landscape

- **No approved treatment for the systemic manifestations of the disease**
- Two approved symptomatic treatments
 - Salagen (pilocarpine; Eisai, 1998) and Evoxac (cevimeline; Daichi, 2000)
- Immunomodulatory treatments (usually for extra-glandular disease)
 - Cyclosporine (ocular inflammation)
 - Hydroxychloroquine (mild inflammatory symptoms of joints, muscles & skin)
 - Corticosteroids (for serious symptoms)
 - Immunosuppressive agents: used to treat serious internal organ manifestations
 - Biologic agents: rituximab (off-label use)
- Competitive pipeline: only 1 Phase III product
 - Orencia (BMS) approved for Rheumatoid Arthritis
 - 1 open-label proof-of-concept study and then straight to Phase 3
 - Other trials – off-label use of drugs approved for other autoimmune diseases

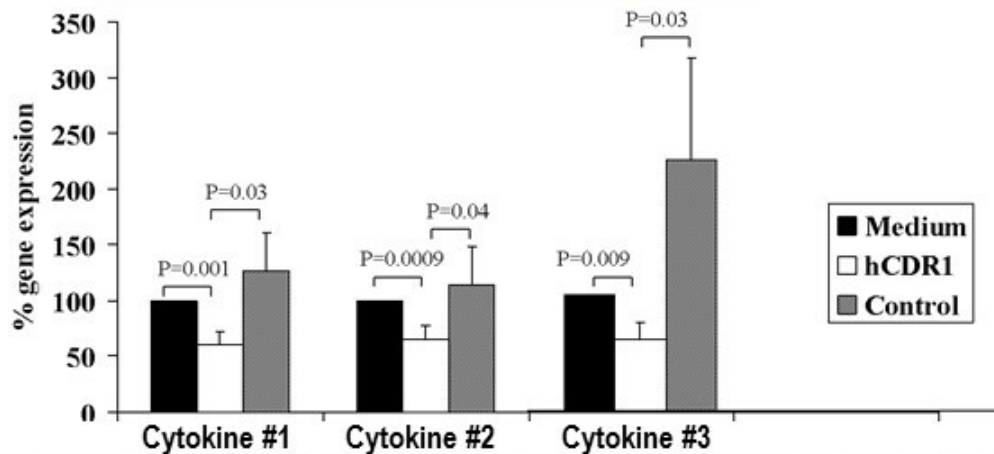


Source: Global Data Research 2016

hCDR1: Pre-clinical Study Data on pSS Patients

- Blood mononuclear cells (PBMC) from blood samples of patients with pSS incubated *in-vitro* with hCDR1 and a control peptide
- Promising *in-vitro/ex-vivo* study results:
 - Significant reduction in gene expression of 3 cytokines considered to be pathogenic in SS
 - Similar to results in SLE patients using same method
- Similar studies in PBMCs of RA and APS patients yielded no significant effect

Reduction in Gene Expression of 3 Cytokines



* P values calculated from % responses of all tested patients (responders and non responders) as compared to medium=100%.

hCDR1: Upcoming (Phase 2) Study in pSS

- Safety of hCDR1 in humans already established in SLE patients
- First clinical trial in pSS will be a controlled Phase 2 study
 - Study objectives: Safety & efficacy of different doses of hCDR1 in pSS patients
 - 3-arm study – 2 doses plus control
 - Study duration: 3 months active treatment
 - N≈50 patients

Milestone	2017	2018
Patent Application Filed	*	
IND Approval	*	
Trial Initiation (FPI)		
Clinical Data		*

Management Team



Josh Levine, CEO

CEO, Proteologics; Senior Director, Teva Pharmaceuticals (Innovative Ventures); Partner, Platinum Neurone Ventures; Corporate Finance Head, Patterson Travis; Attorney, WF&G



David Kestenbaum, CPA & MBA, CFO

CFO, ZenithSolar; Finance Director, Colbar Lifescience (division of J&J (NYSE:JNJ)); CFO, ZAG Industries (division of The Stanleyworks (NYSE:SWK)); CFO, Lever Israel (division of Unilever (NYSE:UN)); Sr. Associate, PwC, New York



Dr. Daphna Paran, Medical Director

Senior lecturer: Tel Aviv University; Head of Day Care unit/Deputy Head of the Department of Rheumatology; Tel Aviv Medical Center (Ichilov Hospital); Trained at Rayne Institute, St. Thomas Hospital, London; Published/co-authored >60 articles on rheumatology and lupus



Monique Ben Am, MSc, Clinical Development Lead

VP Clinical Development, BioCancell; Director, Teva Pharmaceuticals Ltd.; VP Clinical, Topspin; Associate Director, Novartis (development of Gleevec™)

Clinical Advisory Board

- **Dr. Daniel Wallace, Cedars-Sinai Medical Center;** Largest lupus practice of its kind in the US
 - Former Chairman of the Lupus Foundation of America (LFA), received LFA Award, Lupus Research Institute Achievement Award and others
- **Professor David Isenberg, University College London Hospitals**
 - Chair of the British Isles Assessment Group (BILAG), President of the British Society for Rheumatology (2004–2006) and Chair of its Biologics Register Committee (2006–2011)
- **Dr. Murray Urowitz, University of Toronto; Lupus Clinic at Toronto Western Hospital**
 - Established University of Toronto Lupus Clinic and Lupus Databank Research Program.
 - Founding member/president of numerous lupus associations and recipient of numerous awards for his contributions to lupus research.
- **Dr. Lee Simon, Former Division Director, US FDA**
 - Former US FDA Division Director of Analgesic, Anti-inflammatory and Ophthalmologic Drug Products and practicing Rheumatologist for 36 years.
 - Awarded 2003 ACR Distinguished Service Award and Scientific Leadership Award of the Lupus Research Institute.

Corporate Snapshot

- Headquarters: Raanana, Israel
- Member: Corporate Advisory Council of the Lupus Foundation of America
- ADRs trading on NASDAQ (XTLB) and Ordinary Shares on TASE (XTLB.TA)
- Capitalization (as of December 31, 2016):
 - 274,205,799 Shares Outstanding*
 - Warrants to purchase 961,111 ADRs*
@ \$2.25 (expire March 2020)
- Member, Corporate Advisory Council, Lupus Foundation of America

* Each ADS represents 20 Ordinary Shares



Summary

- Lead candidate (hCDR1): for treatment of autoimmune diseases
 - Novel compound with unique mechanism of action
 - Ready for two Phase 2 studies in different autoimmune indications
 - Clinical data in > 400 SLE patients
 - "Demonstrated efficacy in ... clinically meaningful endpoints"
 - Encouraging preliminary data in primary Sjogren's Syndrome (pSS)
 - Similar to data previously obtained in SLE
- Lead indications represent unmet medical needs in areas of interest
 - GSK acquired HGS/Benlysta in 2012 for \$3 billion
 - No effective therapeutic on the market for either indication
 - Weak competitive pipeline
- Aim to replicate results achieved in previous Phase 2b trial
 - FDA supports efficacy endpoint based on the BILAG index





Thank You

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