#### **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, 2014
Commission File Number: 000-51310
XTL Biopharmaceuticals Ltd. (Translation of registrant's name into English)
85 Medinat Hayehudim St., Herzliya Pituach, PO Box 4033, Herzliya 4614001, 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 <u>X</u> 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):
Indicate by check mark whether by furnishing the information contained in this Form, the registrant is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.
Yes NoX
If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): 82N/A

Incorporation by Reference: This Form 6-K of XTL Biopharmaceuticals Ltd. dated January 24, 2013 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) filed by XTL Biopharmaceuticals Ltd. with the Securities and Exchange Commission on December 14, 2007, January 18, 2008, and October 28, 2008, respectively.

#### **Re: January 2014 PowerPoint Presentation**

We are furnishing this Current Report on Form 6-K in connection with the disclosure of information in the form of a PowerPoint presentation to be given at meetings with investors and analysts. The PowerPoint presentation is attached as Exhibit 99.1 to this Current Report on Form 6-K. The information contained in the PowerPoint may be amended or updated at any time and from time to time through another Form 6-K, a later company filing or other means. This Current Report on Form 6-K will not be deemed an admission as to the materiality of any information in the Report.

#### **EXHIBIT INDEX**

The following exhibits are filed as part of this Form 6-K:

Description **Exhibit** 

PowerPoint Presentation dated January 2014 "XTL Biopharmaceuticals" 99.1

#### About XTL Biopharmaceuticals Ltd. ("XTL")

XTL Biopharmaceuticals Ltd., a biopharmaceutical company, focuses on the acquisition, development, and commercialization of pharmaceutical products for the treatment of unmet clinical needs. XTL is focused on late stage clinical development of drugs for the treatment of multiple myeloma and schizophrenia.

XTL's lead drug candidate, rHuEPO, for the treatment of multiple myeloma blood cancer, was granted an orphan drug designation from the FDA. rHuEPO has been approved for marketing by the FDA and has for many years been sold for billions of dollars across the world for the treatment of severe anemia.

XTL controls InterCure Ltd. (TASE: INCR), a company which has disrupted the \$42 billion hypertension industry with the world's first FDA-cleared, OTC blood pressure treatment device, RESPeRATE® (www.resperate.com).

XTL is a public company traded on the Nasdaq Capital Market (NASDAQ: XTLB) and the Tel Aviv Stock Exchange (TASE: XTL). XTL shares are included in the following indices: Tel-Aviv Biomed, Tel-Aviv MidCap, and Tel-Aviv Bluetech-50.

#### Contact:

Investor Relations, XTL Biopharmaceuticals Ltd.

Tel: +972 9 955 7080, Email: ir@xtlbio.com, www.xtlbio.com

#### **Cautionary Statement**

Some of the statements included in this Form 6-K may be forward-looking statements that involve a number of risks and uncertainties. For those statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

#### **SIGNATURES**

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

#### XTL BIOPHARMACEUTICALS LTD.

Date: January 24, 2014	By:	/s/ Josh Levine
•		Josh Levine
		Chief Executive Officer





January 2014

# **XTL Biopharmaceuticals**

(NASDAQ: XTLB) (TASE: XTL)

### **Forward Looking Statements**

The following slides contain forward-looking statements that include, but are not limited to, projections about our business and our future revenues, expenses, activities and profitability. Forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause the actual events, results, performance, circumstances or achievements of the Company to be materially different from those expressed or implied by such forward-looking statements due to factors that include, but are not limited to the risk factors set forth in our Annual Report on Form 20-F for the fiscal year ended December 31, 2012, filed with the U.S. Securities and Exchange Commission on April 25, 2013. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this presentation. The Company undertakes no obligation to update any forward-looking statements, to report events or to report the occurrence of unanticipated events that may lead to the actual events, results, performance, circumstances or achievements of the Company being different than as envisaged by such forward looking statements.



### Investment Proposition (NASDAQ: XTLB / TASE:XTL)

- Focusing on the in-licensing and development of late-stage clinical assets to treat serious unmet medical needs in large markets
  - Assets have a well-defined path, quick time to market
  - Partner drug to big pharma after Phase II development
- Three assets in current development pipeline
  - hCDR1 treatment for Systemic Lupus Erythematosus (SLE)
  - rHuEPO treatment for Multiple Myeloma (MM)
  - SAM-101 treatment for schizophrenia
- Experienced management team and advisory board



### **Corporate Snapshot** (Nasdaq: XTLB)

- Headquarters: Herzliya Pituach, Israel
- ADRs trading on the NASDAQ (symbol: XTLB) and on the Tel-Aviv Stock Exchange(symbol: XTL)
- Current Price: \$3.80 (as of 1/22/14)
- Average Volume (3 months): 7,834
- Market Cap: ~\$53 million
- Cap Structure: Common, no debt, no preferred
- Cash: ~\$4 million (as of 12/31/13)
- Cash Burn: ~\$1 million per year



### **Management Team Experience**

### Josh Levine, CEO

CEO, Proteologics Ltd; Senior Director, Teva Pharmaceuticals (Innovative Ventures); Partner, Platinum Neurone Ventures (Israeli VC); Head of Corporate Finance, Patterson Travis; Corporate Attorney, Willkie Farr & Gallagher

### David Kestenbaum, CPA & MBA, CFO

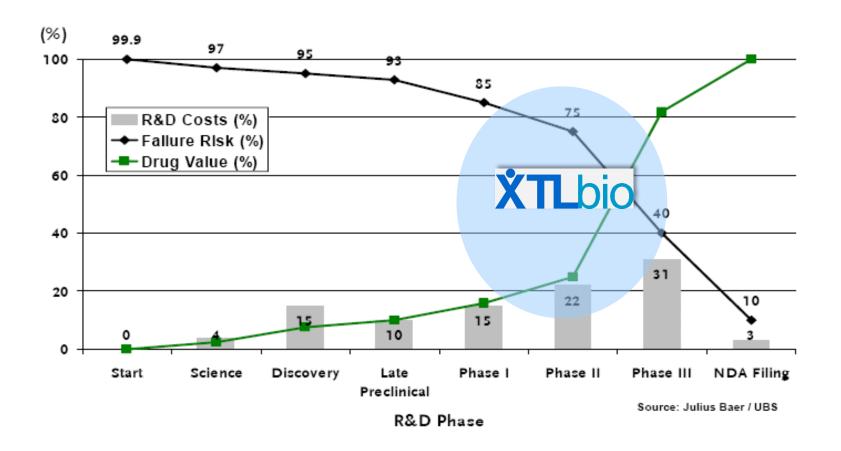
CFO, ZenithSolar Ltd.; Finance Director, Colbar Lifscience Ltd. (division of Johnson & Johnson (NYSE:JNJ)); CFO, ZAG Industries Ltd. (division of The Stanleyworks Inc. (NYSE:SWK)); CFO, Lever Israel (division of Unilever NV (NYSE:UN (ADR))); Sr. Associate – Audit, PriceWaterhouseCoopers, New York

### Prof. Moshe Mittelman, MD, Medical Director

Physician and Scientist, Internationally renowned haematologist. Director, Dept. of Internal Medicine at Ichilov Hospital (Tel Aviv Sourasky Medical Center). Director, Gaon Holdings (TASE: GAON). Formerly Member of the Public Health Reimbursement Committee and Chairman of the Israeli Internal Medicine Association



### Mid to Late Stage Focus: Ideal Investment Opportunity





# **Product Pipeline**

Therapeutic Area	Biologic Agent/ Drug Compound	Preclinical	Phase I	Phase II	Phase IIb	Phase III
SLE	hCDR1					
Multiple Myeloma	rHuEPO					
Schizophrenia	SAM-101					



# hCDR1 for the treatment of Lupus



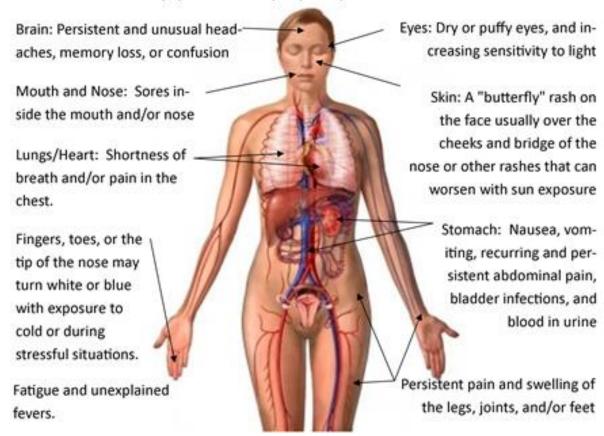


# Systemic "Lupus" Erythematosus (SLE)

**Lupus** is a chronic, debilitating inflammatory autoimmune disease, resulting in rheumatologic, dermatological and end-organ manifestations

### Common Lupus Symptoms

Symptoms of SLE may vary widely between individuals.





### **Lupus: Market Overview**

- Prevalence
  - 1.5 million patients in the U.S. (5 million patients worldwide)<sup>1</sup> varying across ethnicities and geographies
  - 90% are women / 80% between ages of 15 and 45
- Prognosis
  - Dermatologic & musculoskeletal manifestation most common early on
  - End organs become involved as disease progresses
  - Most common causes of death
    - Renal failure
    - Cardiovascular disease
    - CNS disorders
    - Intercurrent infections
  - 10-year survival rate for ~90% of patients (65% rate for patients with renal involvement)



### **Lupus: Competitive Landscape**

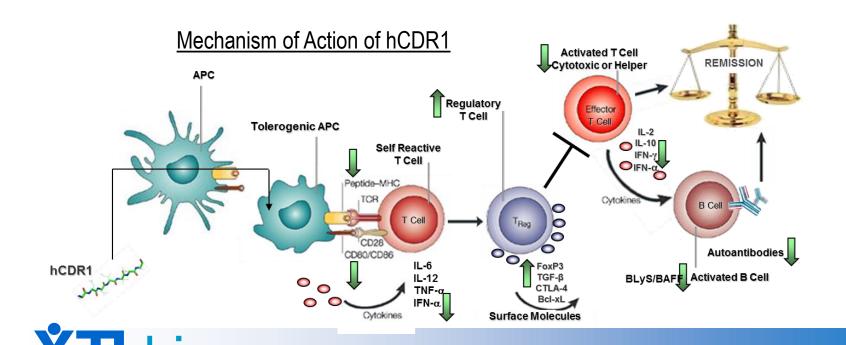
- Current treatments used for Lupus (<u>NO</u> completely effective treatments in market):
  - Corticosteroids, cytotoxic immune-suppressants (palliative care)
    - Non specific, severe side effects (hypertension, osteoporosis, bone marrow suppression, increased cancer risk, etc.)
- Benlysta (BLyS) (HGS/GSK) Approved Mar 2011
  - Only approved drug against Lupus in the last 50+ years
  - Unclear correlation between autoantibodies and disease severity
  - Estimated 15-20% of SLE patients are candidates for Benlysta
  - Launch is slower than expected due to unclear patient selection and cost-effectiveness
    - Original forecast peak annual sales of \$2B with price point of \$35,000 per year
- Weak pipeline: primarily B-cell inhibitors like Benlysta
  - Questionable efficacy and long term safety



### hCDR1 for the treatment of Lupus

### hCDR1 is a peptide that down-regulates the SLE-related autoimmune process

- Specific upstream immunomodulation through the generation of regulatory T cells
- Developed by Prof. Edna Mozes of the The Weizmann Institute of Science (Israel)
- XTL obtained exclusive license from Yeda Research and Development Co. (1/2014)
- Over 40 peer reviewed journal articles published on hCDR1



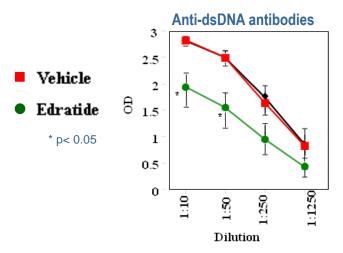
### **Animal Data: Beneficial Effects of hCDR1**

(NZBxNZW)F1 Lupus-prone mice



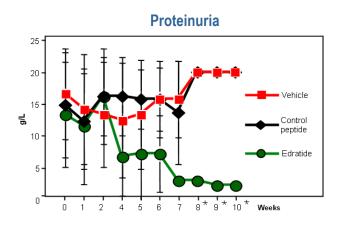
#### BALB/c mice with induced Lupus

10 s.c. weekly injections with Edratide or control peptide (or just vehicle)

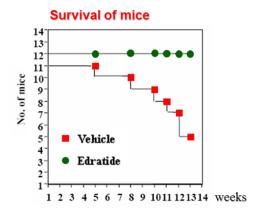


#### **Immune complex deposits**





\* p< 0.05



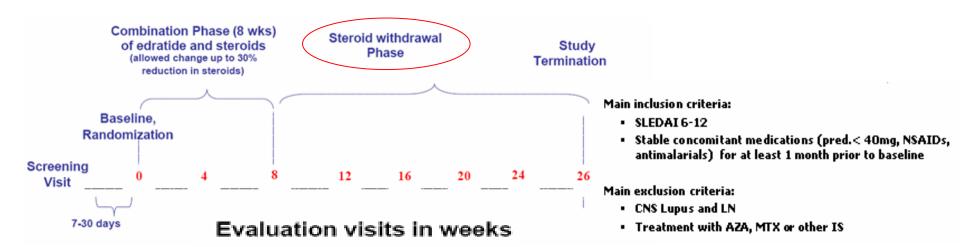


## Clinical Trial History of hCDR1

- Three clinical trials completed (by Teva): Phase Ia, Ib trials and a Phase II (PRELUDE) trial
  - Studies included over 400 patients
  - Demonstrated to be well tolerated by patients and to have a favorable safety profile
- Phase II (PRELUDE) trial
  - Did not meet primary endpoint (SLEDAI) Teva returned hCDR1 to Yeda in 2009
  - Encouraging results in secondary clinical endpoint, the BILAG index
    - 0.5 mg weekly dose showed a substantial effect
- Opportunity for hCDR1
  - FDA published guidelines (2010): secondary endpoint, BILAG (or SRI), should be the correct primary endpoint
    - Similar pathway for approval that Benlysta successfully completed



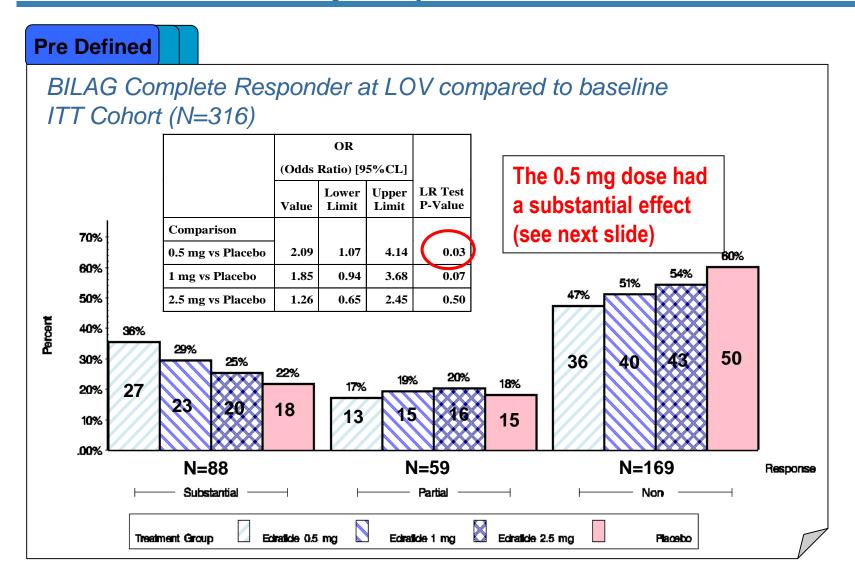
### **PRELUDE Trial Design**



- Primary endpoint (SLEDAI) was not met
- Secondary and Exploratory Endpoints (BILAG, Flares) showed positive trends
- Edratide seems to have a favorable safety profile and is well tolerated



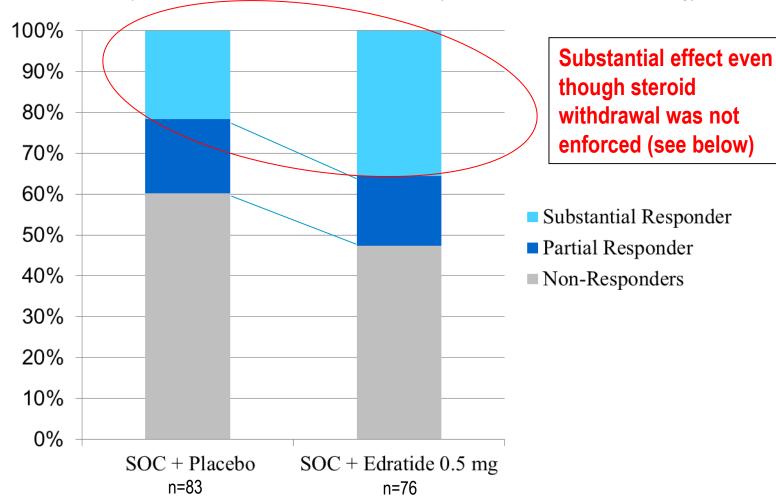
# **PRELUDE - Secondary Endpoint**





# PRELUDE - Secondary Endpoint (Pre-defined)

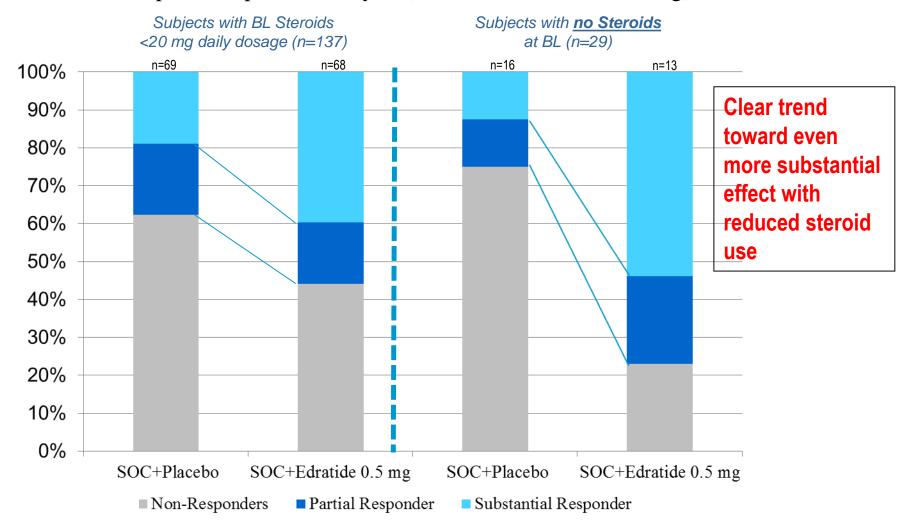
BILAG Responder Analysis at LOV Compared to Baseline (Placebo vs. Edratide 0.5 mg)





## **PRELUDE - Secondary Endpoint (Post Hoc)**

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





# **New Phase 2b Trial: To Improve Probability of Success**

### Proposed trial design is based on:

- FDA guidelines\*
- Benlysta trials as a case study
- Lessons learned from PRELUDE

#### PRELUDE Trial

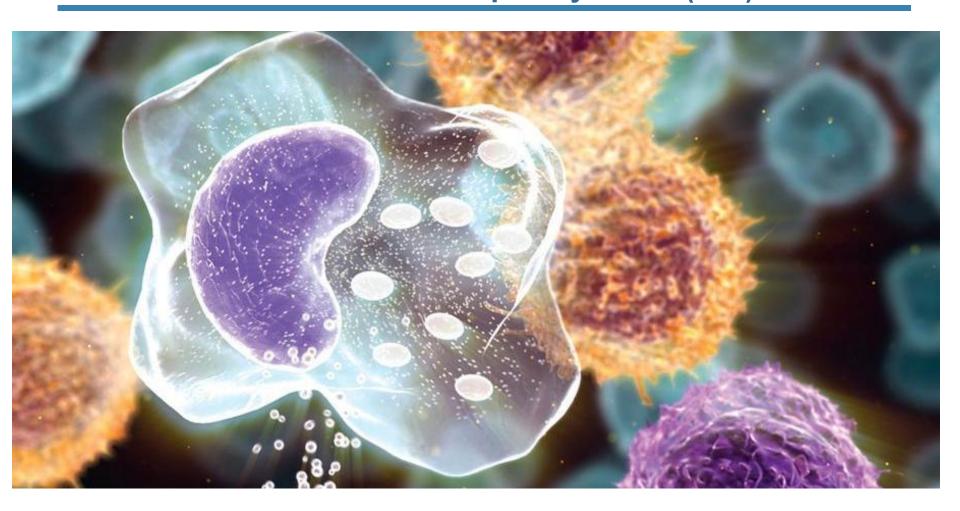
Proposed Phase 2b

Primary endpoint	SLEDAI only	BILAG Substantial Responders
Dose	0.5, 1, 2.5 mg	0.5, 0.25 mg
Steroid Use	Corticosteroids masking Steroid sparing not enforced	Defined regimen of steroids Mandatory and enforced
Trial duration	26 week study	Extend to 52 weeks
Execution Site discrepancies in calculating disease matrices Suboptimal sample & data handling		Training and monitoring Specialized CRO

<sup>\*</sup>June 2010 FDA Guidance for Developing Medical Products for Treatment of SLE



# rHuEPO for treatment of multiple myeloma (MM)





### Multiple Myeloma ("MM"): Market Overview

- MM is a severe and incurable malignant hematological cancer of plasma cells
  - Average age at diagnosis is 65-70 years; with a median survival is still: 4-5 years
- MM is the second most common hematological cancer (10%) and about 1% of all cancers
- In the US there are ~75,000\* people living with MM
  - ~20,000\* new cases diagnosed annually
  - ~45,000 new cases in the western world annually
- The disease is progressive with various complications until death:
  - Renal failure, bone pain/fractures, damage to the nervous system, anemia, recurrent infections
- The MM drug market will more than double from \$2.1 billion in 2008 to \$5.3 billion in 2018\*\*



<sup>\*</sup> According to the National Cancer Institute estimation for 2011

<sup>\*\*</sup> According to Decision Resources 2010 report

### **Multiple Myeloma – Competitive Landscape**

- There are several lines of treatment mainly combinations of drugs/treatments
  - IMIDs: Thalidomide ®, Lenalidomide (Revlimid ®), Pomalidomide (Pomalis®)
  - Proteasome inhibitors: Bortezomib (Velcade ®), Carfilzomib (Kyprolis®) (+Steroids)
  - Chemotherapy: Melphalan; Cyclophosphamide; Doxorubicin, etc...
  - Stem cell transplantation (< 65 years of age)</li>
- Patients typically receive 3-4 lines of treatment, until death
- Treatment, if effective, is given until disease progression (usually less than 1 year)
- Patients stop / change treatment because of:
  - Significant side effects or
  - drug resistance (disease progression/relapse)



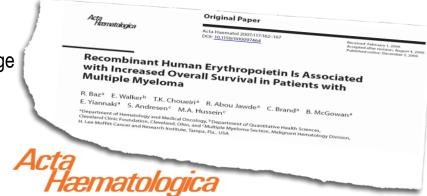
### rHuEPO – Drug Overview

- Recombinant human erythropoietin (rHuEPO) is a hormone, produced by the kidneys, and is responsible for red blood cell production in the bone marrow
- Leading branded medicine forms of rHuEPO, include J&J (Procrit® and Eprex®);
   Roche (NeoRecormon®); and Amgen (Epogen® and Aranesp®)
  - Considered to be a blockbuster drug
  - Approved for anemia only:
    - Chronic renal failure
    - Anemia of cancer
- Black Box warning/FDA alert
- Limited Off-Label use with rHuEPO



# Clinical Trial History of rHuEPO for use with MM Patients

- Clinical observation on advanced MM patients treated with rHuEPO for anemia (1990s; Prof. Mittelman):
  - Corrected the anemia (Hb rise) known effect
    - Reduced blood transfusion requirements
    - Improved quality of life
  - A novel biological effect: Patients lived 38-94 months longer than expected!
- Extensive clinical/basic research with human patients and mice models:
  - rHuEPO has an anti-myeloma effect
    - rHuEPO induces myeloma regression
    - rHuEPO prolongs survival of advanced-stage
       MM patients
  - MOA: stimulation of the immune system
  - Published in medical literature





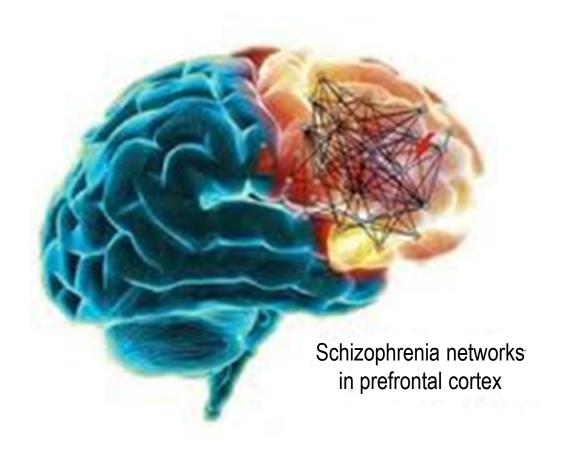


## rHuEPO for MM: Phase 2 Study

- Received patent (in U.S., Europe, Israel, Canada, Hong Kong and Japan) and orphan drug designation
  - Provides 7 years marketing exclusivity in the U.S., from the date of drug approval
- Company already started the regulatory work toward receipt of the IND
  - IND expected for rHuEPO mid-2014
- Study Design: Double blind, placebo controlled, study to assess the safety and effect on survival of rHuEpo) in patients with advanced multiple myeloma



# **SAM-101** for treatment of schizophrenia





### Schizophrenia: Market Overview

**Schizophrenia** is a severe brain disorder in which people interpret reality abnormally, which may result in some combination of hallucinations, delusions, and disordered thinking and behavior.

Estimated market of \$6.4 billion in 2010 (According to Decision Resources).

Atypical antipsychotics have improved schizophrenia treatments with a better side-effect profile

### **Five Key Unmet Needs Remain Un-answered:**

Compliance improvement



**Poor patient compliance (20-40%)** - preventing effective management and contributing to relapse – poor compliance is inherent to the disease and due to side effects

Negative symptoms treatment



Current treatment have little benefits; negative symptoms continue to limit patient recovery

Cognitive symptoms treatment



Among current atypical antipsychotics **none show statistically significant efficacy** 

Treatment for partial responders



Up to 25% of the schizophrenia population appear to become more resistant to current therapies along with the development of the disease

Better sideeffect profile



No ideal balance between efficacy and side-effect profile (weight gain, risk for metabolic syndrome, sedation, impotence)

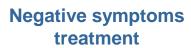


### SAM-101 for Schizophrenia: Drug Overview

- SAM-101 is a combination therapy: existing antipsychotic drug + minocycline (acts synergistically to provide an optimal treatment of schizophrenia)
- Minocycline is a commonly prescribed anti-microbial and anti-inflammatory drug
  - Effectively crosses the blood-brain barrier
  - Neuro-protective activity in animal models of various neurodegenerative diseases
  - Mild and rare side effects, most of them reversible
- MinoGuard successfully completed a phase 2a, 70-patient randomized, prospective, double blind, placebo controlled clinical trial
  - Improved positive signs and cognitive signs
  - Reduced negative symptoms and side effects
- XTLbio has a worldwide exclusive license for SAM-101 from MinoGuard for the treatment of psychotic disorders focusing on Schizophrenia



### SAM-101: Addresses unmet needs





SAM101 showed significant improvement in negative symptoms

Cognitive symptoms treatment



SAM101 showed significant improvement in various cognitive symptoms

Better sideeffect profile



Less patients in treatment group showed weight gain and more remained stable

Treatment for partial responders



SAM101 was effective in treatment of acute, stabilized and treatment-resistant patients

**Compliance** improvement



Due to better efficacy and less side-effects, SAM101 may improve compliance

Could treat anxiety, the main schizophrenia co-morbidity



### **SAM-101: Independent Clinical Studies: Schizophrenia Patients**

### Independent studies demonstrate efficacy of combination therapy, SAM-101

Location	# of pat. (C/R)	<b>Duration</b> (months)	Daily Dose (mino)	Stage of disease	Type of trial	Study Endpoints
Israel <sup>1</sup>	21/54	6	200 mg O.D	First episode - acute	Double-blind, placebo-controlled	Primary: negative Secondary: cognitive symptoms, function, positive
University of Manchester	100/120	12	200 mg O.D	First episode - stabilized	Rater-blind, placebo-controlled	Primary: negative and cognitive symptoms. Secondary: positive
Japan <sup>2</sup>	22	1	150 mg T.I.D	Treatment- resistant	Open label	Positive and negative symptoms (PANSS)

C: completers R: randomized

Levkovitz Y, Mendlovic S, et al. J. Clinical Psychiatry (In Press)<sup>1</sup> Miyaoka T et al. Clinical Neuropharmacology 31, October 2008<sup>2</sup>

Other clinical observations support the hypothesis<sup>3,4,5</sup>

Prog Neuropsychopharmacol Biol Psychiatry. 2007 Jan 30;31(1):304-7
 CNS Neurol Disord Drug Targets. 2008 Oct;7(4):376-81.



<sup>&</sup>lt;sup>3</sup> Prog Neuropsychopharmacol Biol Psychiatry. 2007 May 9;31(4):968-9.

# **SAM-101: Independent Clinical Study Results**

Israeli Study	Manchester Study Results
Reduced Negative Symptoms (SANS): flattening, apathy, alogia, asociality, disturbance in attention	Reduced Negative Symptoms (PANSS Negative): flattening, apathy, alogia, asociality, disturbance in attention
Improved Cognitive Signs (CANTAB): improved performance in spatial working memory, attention set shifting abilities, and executive function	Improved Neuropsychological Measures: Stroop word, Stroop Color Word
Improved General Function (GAF): social and occupational functioning, Quality of Life, community ability	Reduced Side Effects: study group gained less weight than placebo group
Reduced Side Effects: less patients showed weight gain	No difference in positive symptoms as compared to the placebo group
No difference in positive symptoms compared to the placebo group	



### SAM-101: Potential for Phase 2b

- Ongoing market research is currently being conducted with KOLs (Defined Health)
- KOLs interviewed to date agree that SAM101 promises to address a major unmet need in the treatment of schizophrenia
- Key points of KOL interest in the SAM-101 program:
  - MoA combines anti-inflammatory and neuroprotective properties)
  - Addresses negative and positive symptoms across various stages/subpopulations of the disease (early phase, stabilized, treatment-resistant)
  - Results are replicated across three independent clinical studies
  - Phase 2a data on improvement in negative and multiple cognitive endpoints look promising and warrant further analysis and investigation
  - Clean side effect profile and reduction of weight gain associated with baseline antipsychotic therapy



# Summary and Next Steps



## XTLbio – Next Steps<sup>1</sup>

- hCDR1:
  - Finalizing CAB/Protocol ongoing
  - Regulatory work including CMC for 0.25 mg dose
  - "First Patient In" Phase IIb expected end 2014/beginning 2015
  - "Last Patient In" expected 12 months later
  - Interim data (mid-2016)<sup>2</sup>
- rHuEPO for MM
  - Regulatory process with FDA ongoing
  - IND and "First Patient In" expected mid-2014
- SAM101 for Schizophrenia
  - Formulation development (for combination) for Phase IIb trial of SAM 101

<sup>&</sup>lt;sup>2</sup> Subject to regulatory approval



<sup>&</sup>lt;sup>1</sup> Subject, in some cases, to necessary financing

### XTLbio – Summary

- Company has three Phase II assets
- Each addresses a significant unmet medical need
- Each has interesting and/or compelling clinical data
- Each has a game plan that, if successful, should result in significant value appreciation
- Such game plan should result in significant clinical data in a reasonable amount of time
- Such game plan can be achieved by XTL
  - Finance requirements are reasonable/manageable
  - XTL can manage the two proposed clinical trials simultaneously





# Thank you!



# **Backup Slides – hCDR1 for Lupus**



### PRELUDE – Secondary Endpoint; BILAG Responders

#### **Pre Defined**

### BILAG Responder Definition:

**Substantial Responder (SR)** - All systems at LOV are either C or D/E provided that at least one system was either A or B at baseline.

**Partial Responder (PR)** - At least one system improved and at least one system without improvement from A or B to C or D/E at LOV, and no deterioration from C or D/E at baseline to A or B at LOV in other systems.

**Non Responder (NR)** - Same BILAG score in LOV as in baseline in all systems or new A or B in at least one system compared to baseline (other systems may improve or deteriorate).

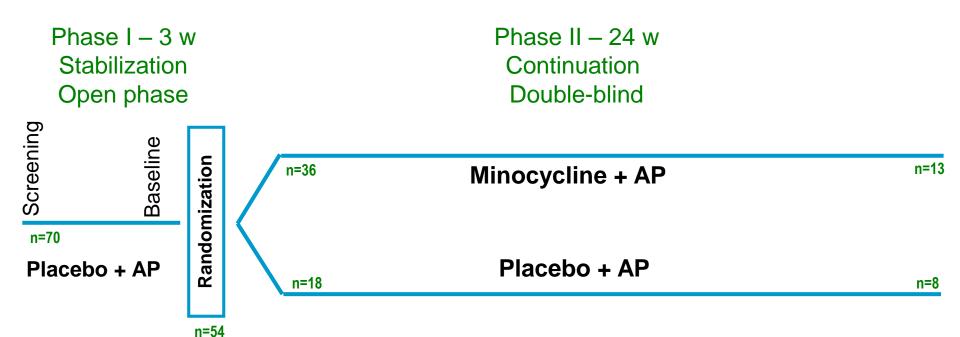


# Backup Slides – SAM 101



### Israeli Phase IIa SAM-101 Study Design

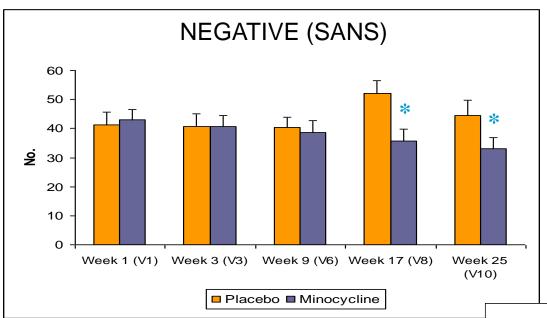
# Large-scale (54 randomized patients), prospective, double blind, placebo control trial

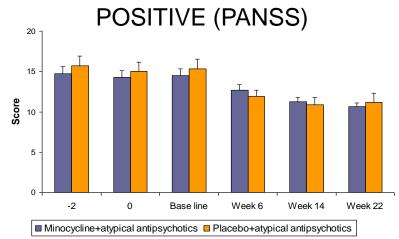


Parameters Tested Primary: Negative (SANS) Secondary: Cognitive (CANTAB), Function, Positive (PANSS)



### SAM101 Reduces Negative Symptoms (Israel trial)

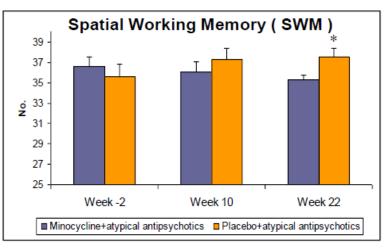


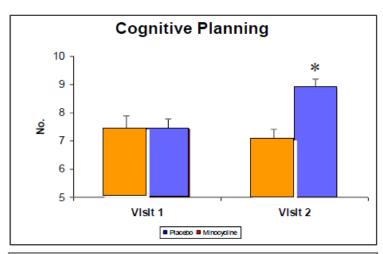


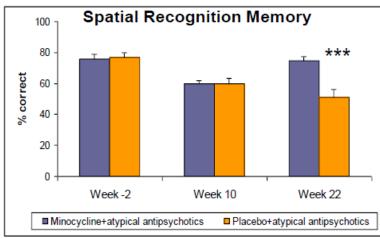


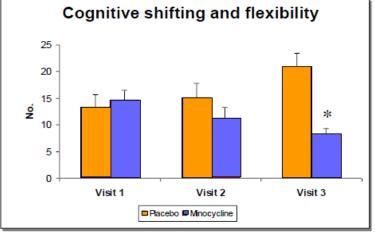


### SAM101 in Cognitive Functions (Israel trial)



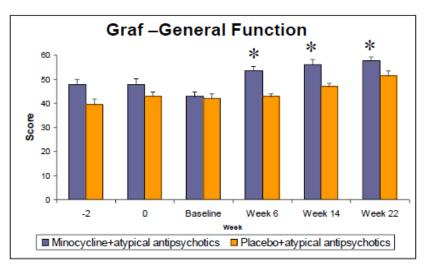


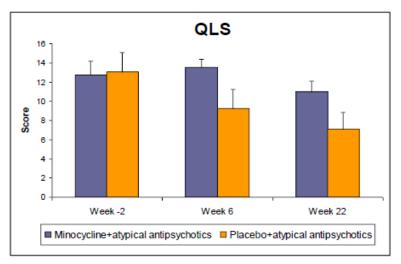


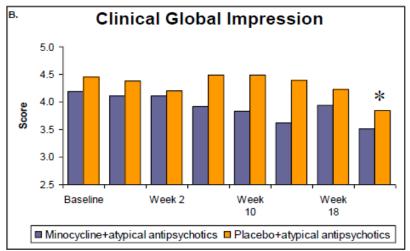




### SAM101 Improves General Function (Israel trial)

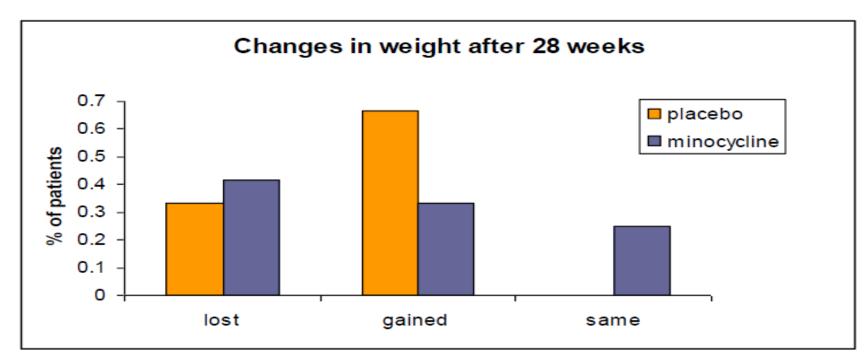








### SAM101 Prevents Weight Gain (Israel trial)



0.2 = 20% of patients



# Safety and Tolerability (Israel trial)

### Minocycline-related Adverse Events:

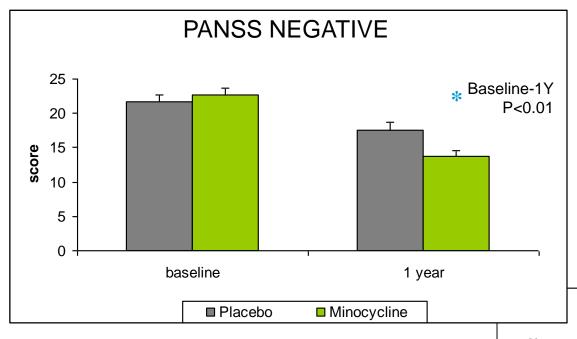


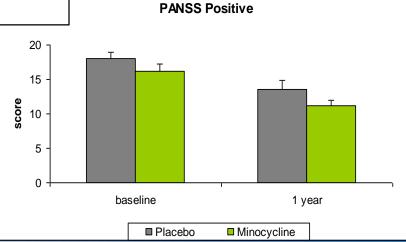


Minocycline (200 mg/day for 6 months) is well tolerated and safe for patients suffering from schizophrenia



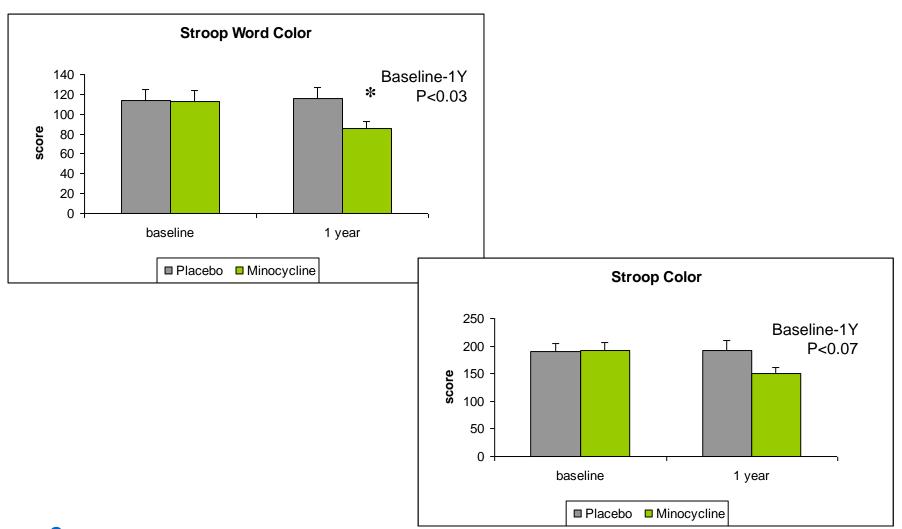
### SAM101 Reduces Negative Symptoms (Manchester trial)





No significant difference in positive symptoms

### SAM101 Improves Cognitive Functions (Manchester trial)





### Combination Therapy Reduces Weight Gain (Manchester trial)

