XTL BIOPHARMACEUTICALS LTD
Form FWP
September 26, 2014

September 2014 www.xtlbio.com XTL Biopharmaceuticals (NASDAQ: XTLB) (TASE: XTL) Issuer Free Writing Prospectus Filed Pursuant to Rule 433 Registration No. 333 - 194338 September 26 , 2014

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 , 2013 , filed with the U . S . Securities and Exchange Commission on April 2 , 2014 . 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 .

This presentation highlights basic information about us and the offering. Because it is a summary, it does not contain all of the information that you should consider before investing in the ADSs. We have filed a registration statement (including a prospectus) with the United States Securities and Exchange Commission (SEC) for the offering to which this presentation relates. The registration statement has not yet become effective. Before you invest, you should read the prospectus in the registration statement (including the risk factors described therein) and other documents we have filed with the SEC for more complete information about us and the offering. You may get these documents for free by visiting EDGAR on the SEC website at www.sec.gov . Alternatively, we or any underwriter or dealer participating in the offering will arrange to send you the prospectus if you contact Aegis Capital Corp, Prospectus Department, 810 Seventh Avenue, 18 th Floor, New York, NY 10019 , telephone: 212 813 - 1010 , e - mail: prospectus@aegiscap.com .

Offering Summary Issuer XTL Biopharmaceuticals Ltd. Exchange: Ticker Nasdaq Capital Markets: XTLB Securities Offered American Depositary Shares (ADSs) Offering Size Approximately $4,000,000 of ADSs (100% Primary) Over - Allotment 15% (100% Primary) Use of Proceeds Use of proceeds will be concentrated on the funding of c ontinued development of hCDR1 for SLE/lupus and, to a lesser extent rHuEPO for Multiple Myeloma Sole Book - Runner Aegis Capital Corp.

Investment Proposition 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 receipt of Phase II data Three assets in current development pipeline Experienced management team

Corporate Snapshot Headquarters: Herzliya Pituach , Israel ADRs trading on the NASDAQ (XTLB) and Ordinary Shares on the Tel - Aviv Stock Exchange (XTL) Cash (incl. Short Ter m Deposits): ~$ 3.2 m (as of 6 / 30 / 14) Capitalization (see Appendix): 231 , 772 , 624 Shares Outstanding* ~ 20 million warrants/options No debt or preferred Total Cash Needs/Uses: General corporate: ~$ 1.5 million/year hCDR 1 Phase II trial: ~$ 12 - 14 million rHuEPO Phase II trial: ~$ 1 million Use of proceeds: f unding of continued development of hCDR 1 for SLE/lupus and, to a lesser extent rHuEPO for Multiple Myeloma Headquarters * Each ADS represents 20 Ordinary Shares

Management Team Experience 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 Stanleyworks (NYSE:SWK)); CFO, Lever Israel (division of Unilever (NYSE:UN)); Sr. Associate, PwC, 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

hCDR 1 for the treatment of Lupus

Systemic “Lupus” Erythematosus (SLE) Lupus is a chronic, debilitating inflammatory autoimmune disease, resulting in r heumatologic, dermatological and end - organ manifestations

Lupus: Market Overview Prevalence 1 1.5 million patients in the U.S. (5 million patients worldwide) v a r ying across ethnicities and geographies 90 % are women / majority 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 1 Lupus Foundation of America

Lupus: Competitive Landscape NO completely effective treatments for lupus in the market: Current treatments: corticosteroids, cytotoxic immune - suppressants (palliative care) Problems with current treatments: non specific, severe side effects (hypertension, osteoporosis, bone marrow suppression, increased cancer risk, etc.) Benlysta (HGS/GSK): approved by FDA 3 / 2011 Only approved drug against Lupus in the last 50 + years Unclear correlation between autoantibodies and disease severity Launch is slower than expected (2013 sales of 146 M £ vs. expected blockbuster) Weak pipeline: primarily B - cell inhibitors – like Benlysta

hCDR 1 : General & Mechanism of Action (MOA) hCDR 1 is a peptide that down - regulates the SLE - related autoimmune process; potential to be “first in class” and “best in class” drug Specific upstream immunomodulation through the generation of regulatory T cells Developed by Prof. Edna Mozes of the The Weizmann Institute of Science (Israel) > 40 peer reviewed journal articles; > 200 animal experiments IP: Minimum of data exclusivity (~ 7 years US/ 10 years EU) with plans to extend XTL obtained exclusive license from Yeda Research and Development Co. (1 / 2014) MOA of hCDR 1 : Different than existing late stage pipeline

Clinical Trial History of hCDR 1 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 trial Did not meet primary endpoint (SLEDAI) Encouraging results in secondary clinical endpoint, the BILAG index (see below) 0.5 mg weekly dose showed a substantial effect Opportunity for hCDR 1 Teva returned hCDR 1 to Yeda in 2009 Thereafter, in 2010 , FDA published guidelines: secondary endpoint, BILAG (or SRI), should be the correct primary endpoint hCDR 1 has been tested in over 400 patients, is safe and has shown encouraging results on BILAG – one of the FDA's recommended primary endpoints for lupus trials

PRELUDE (Phase II) Trial Design Primary endpoint (SLEDAI) was not met Secondary and Exploratory Endpoints (BILAG, Flares) showed effect/trends Edratide seems to have a favorable safety profile and is well tolerated Non - compliance with Steroid Withdrawal Phase not a protocol violation

BILAG Responder Analysis at LOV Compared to Baseline (Placebo vs. Edratide 0.5 mg) PRELUDE - Secondary Endpoint (Pre - defined/ITT Cohort) n= 83 n= 76 Substantial effect (p= 0.03) even though steroid withdrawal not enforced (see below)

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 - Secondary Endpoint (Post Hoc) n= 69 n= 68 n= 16 n= 13 Clear trend toward even more substantial effect with reduced steroid use

PRELUDE – Trends in other Secondary Endpoints * Predefined: an increase of ≥ 5 mg daily steroids compared to baseline ** Post Hoc: increase of ≥ 5 mg daily steroids vs. lowest previous dose SLE Responder Index* (Post Hoc/ITT Cohort) p= 0.058 Medicinal Flare Analysis (Post Hoc/ITT Cohort) p= 0.04 SRI in PRELUDE trial was composite measure of disease activity based on two validated indices: SELENA - SLEDAI and BILAG *

Clinically Advisory Board Dr. Daniel Wallace, Cedars - Sinai Medical Center Largest lupus practice of its kind in the US; currently running > 30 clinical trials Served as Chairman of the Lupus Foundation of America, receiving the Lupus Foundation of America Award, Achievement Award of the Lupus Research Institute and others " I am privileged to join the team at XTL to help advance what I believe to be one of the most promising Lupus drug candidates in recent history . The data shown in earlier trials is encouraging and could potentially be a disruptive solution to a largely unmet medical need .” Professor David Isenberg, University College London Hospitals Chair of the British Isles Assessment Group (BILAG). President of the British Society for Rheumatology from 2004 – 2006 Chaired the Society’s Biologics Register Committee from 2006 – 2011 Received the 2010 Evelyn Hess Prize from the Lupus Foundation of America and the Rodger Demers Prize (Canada), in 2012 . “I am happy to serve as a consultant for XTL’s Phase II trial testing for hcDR 1 using the BILAG index because it has shown encouraging results when used during the previously conducted PRELUDE trial .” Dr . Murray Urowitz, University of Toronto; Lupus Clinic at Toronto Western Hospital Established the University of Toronto Lupus Clinic and Lupus Databank Research Program . Founding member/president of numerous lupus - related associations and the recipient of numerous awards for his contributions to lupus research. "The continued development of XTL’s hCDR 1 has the medical community eagerly waiting to learn the efficacy of the drug in its planned Phase II trial.”

New Phase 2 b Trial: Improve Probability of Success Proposed trial design is based on: (1) new FDA guidelines; (2) Benlysta trials; and (3) clinical data from PRELUDE - especially the 0.5 mg results in the secondary endpoints 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 disease matrices Suboptimal sample & data handling Training and monitoring Specialized CRO

rHuEPO for the 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 m edian survival of ~ 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 K* new cases diagnosed annually; ~ 45 K new cases in the western world annually The MM drug market is expected to more than double from $ 2.1 b in 2008 to $ 5.3 b in 2018 ** The disease is progressive with various complications until death: Renal failure, bone pain/fractures, nervous system damage, anemia, infections Patients typically receive a number of lines of treatment, until death Patients stop / change treatment because of: Significant side effects or Drug resistance (disease progression/relapse) * According to the National Cancer Institute estimation for 2011 ** According to Decision Resources 2010 report

rHuEPO – Drug Overview Recombinant human erythropoietin (rHuEPO) is a hormone, produced by the kidneys, and is responsible for red blood cell production in 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 results in limited “Off - Label” use of rHuEPO Based on clinical results (see below), XTL received use patent (US, EU, Israel, Canada) for the use of rHuEPO for the treatment of MM Received orphan drug designation (7 years market exclusivity in US)

Clinical observation on advanced MM patients treated with rHuEPO for anemia (1990 s; Prof. Mittelman) : Corrected the anemia (Hb rise) – known effect A novel biological effect: Patients lived ~ 36 - 90 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 Clinical Trial History of rHuEPO for Use with MM Patients

rHuEPO for MM: Phase 2 Study Study Design : Study to assess the safety and effect on survival of rHuEpo in patients with advanced multiple myeloma ~ 30 patient, open label study to be conducted primarily in Israel Company already started the regulatory work with the FDA Regulatory approvals for start of trial expected 1 H 2015

2014 2015 2016 XTLbio – Next Steps 1 hCDR 1 rHuEPO Finalize CAB/ Protocol Regulatory/ CMC Begin enrollment Phase II trial Complete Enrollment Phase II trial Interim data Phase II trial End of trial Begin enrollment Phase II trial Regulatory Complete Enrollment Phase II trial 1 Subject, in some cases, to necessary financing and regulatory approval SAM 101 development subject to necessary financing and follows other two products Use of Proceeds of Current Funding

XTLbio – Summary XTL has three Phase II assets; current focus on two of the assets (hCDR 1 / rHuEPO) Both address a significant unmet medical need Both have compelling clinical data hCDR 1 has robust data on > 400 patients on the FDA recommended endpoint rHuEPO for MM has shown significant survival benefit XTL plans should result in clinical data in a reasonable amount of time If either trial is successful, should result in significant value appreciation XTL believes game plan is achievable Finance requirements believed to be reasonable/manageable XTL believes it can manage the two proposed clinical trials simultaneously

Appendix

Summary Financial Outlook $ 3.2 M in cash and short term deposits at June 30 , 2014 Capitalization Ordinary Shares Issued & Outstanding (excluding ~ 4.4 m treasury shares) 231 , 772 , 624 Warrants Series 2 (until 10 / 28 / 14 @ $ 0.28 *) 12 , 217 , 106 Warrants Series B (until 3 / 17 / 15 @ $ 0.30 *) 1 , 926 , 727 Options 5 , 933 , 862 Fully Diluted 257 , 245 , 022 Authorized 700 , 000 , 000 • Converted at fixed exchange rate of 3.611 NIS/US$ Ordinary Share to ADS Ratio = 20 : 1

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). PRELUDE Secondary Endpoint: BILAG Responders

SAM - 101 for the Treatment of Schizophrenia Schizophrenia networks in prefrontal cortex

SAM - 101 is a combination therapy: existing antipsychotic drug + minocycline 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 2 a, 70 - patient randomized, prospective, double blind, placebo controlled clinical trial Reduced negative symptoms/side effects; improved cognitive signs Results replicated in two other studies (UK/Japan) on different patient populations XTLbio has a worldwide exclusive license for the treatment of psychotic disorders IP: 2026 (Combined therapies of antipsychotic drugs and tetracyclines in the treatment of psychiatric disorders); new IP upon formulation SAM - 101 for Schizophrenia: Drug Overview