Forward-Looking Statement

Statements made in this presentation stating the Company’s beliefs, intentions, and expectations are forward-looking statements. The Company’s actual results could differ materially from those projected. Additional information is contained in the company’s SEC filings such as our Form 10-K and Form 10-Qs filed at www.sec.gov.
Protalex, Inc. (Ticker: PRTX)

**Lead Product**
- PRTX-100

**Market Opportunity**
- ITP (~$1b)
- Rheumatoid Arthritis (>$18B)
- Other Autoimmune Diseases ($Bs)

**Company Structure**
- Experienced Management
- Strong Scientific Advisors
- Low-burn Model
- Funded-to-date by majority shareholder

- Highly-purified natural biologic
- Clinical experience in five human studies
- Demonstrated strong safety profile
- Potential for multiple clinical uses
Protalex Investment Thesis

- PRTX-100 is a novel immunomodulatory biological with potential to be a blockbuster drug in various autoimmune diseases
  - ITP—an orphan disease
  - Rheumatoid arthritis—the largest autoimmune market

- To date, 5 clinical studies conducted demonstrate that PRTX-100 is safe and well-tolerated in humans

- Positive therapeutic effects seen in RA patients and in ITP preclinical models

- Potential efficacy in a number of orphan disease indications

- Validated manufacturing process; significantly lower cost of goods relative to other biologics

- Strong and growing IP position
Preclinical Studies of PRTX-100

+ PRTX-100 inhibits B-cell activation, the expression of CD40 on the surface of B-cells and monocytes, and CD120b and CD16 on monocytes

+ PRTX-100 reduces footpad swelling in the murine CIA model of arthritis

+ PRTX-100 is not immunosuppressive like anti-TNFs
  - Pretreat w drug
  - Challenge w Candida albicans
  - Anti-TNF potentiates infection
Human monocytes were isolated from human blood and human platelets were labeled with PerCP.

Platelets were opsonized with W632 (anti-MHC Class I) and mixed with monocytes that had been treated with PRTX-100 for 48 hours.

Monocytes engulfed platelets and the degree of phagocytosis was assessed by measuring PerCP fluorescence of the monocytes.

Pretreatment of monocytes with PRTX-100 reduced platelet phagocytosis in a dose-dependent manner.
PRTX-100 Treatment of Thrombocytopenia in a Murine Model of Severe ITP

Chow, et al. 2010 model—involves both cellular and humoral immunity

SCID mice receive splenocytes from CD61 KO mice

Mice treated on day 8 after thrombocytopenia is established

PRTX-100 raises platelet counts

Protalex Study 1
PRTX-100 Address Unmet Needs in the ITP and RA Markets

- PRTX-100 reduces immune-mediate platelet destruction; existing therapies do not

- To date, PRTX-100 is safe and tolerable in humans; other ITP and RA drugs carry FDA black box warnings

- The side effects of incumbent RA biologicals are significant:
  - Infusion reactions
  - Mucocutaneous reactions
  - HBV Reactivation
  - PML
  - Renal toxicity
  - Cardiac arrhythmias
  - Etc.
PRTX-100 Clinical Experience

+ 2005 – IND filed for RA
+ 2006 – Phase 1 study completed
+ 2007 – Second Phase 1 using PRTX-100 with improved production/CMC processes
+ 2010-11 – Phase 1b RA Study (PRTX-100-103) in South Africa; presented at ACR Annual Meeting in November, 2012 -- 37 patients enrolled at 3 sites
+ November 2012 – Second Phase 1b RA Study (PRTX-100-104), initiated in US -- 61 patients enrolled at 9 sites.
+ November 2014 – Topline results of PRTX-100-104 cohorts 1 through 4 presented at ACR Annual Meeting; Cohort 5 topline results
+ February 2015 – Phase 1b RA continuation study (PRTX-100-105) initiated in US – 8 patients at one site
+ March 2015 – IND for ITP accepted by US FDA
PRTX-100 Clinical Development Plans

PRTX-100
Immune Thrombocytopenia

2012
Preclinical

2013
Phase 1
So. Africa
PRTX-100-103

2014
Phase 1
in USA
PRTX-100-104

2015
Phase 1/2

2016
Phase 3

2017
Phase 3

-105 Continuation Study

Explore Partnership

Protalex, Inc.

PRTX-100
Rheumatoid Arthritis

2012
Preclinical

2013
Phase 1/2

2016
Phase 3

2017
Phase 3
PRTX-100 in ITP: Study Overview

- Phase 1/2, Open-Label, Single Arm Dose Ranging Study

- Patient Population:
  - Adult patients with persistent/chronic immune thrombocytopenia (ITP) despite adequate therapy
  - Failed at least 1 prior ITP treatment
  - Platelet count < 30,000/µL including patients on corticosteroid, immune-suppressive medications, or a TPO-RA

- Doses being tested
  - 1.0 µg/kg up to 12 µg/kg

- Treatment: 4 weekly doses

- Up to 30 patients at 3 to 5 sites

- Dosing to commence in 2Q15
Doses of 1.5 to 12 µg/kg PRTX-100 appeared well-tolerated and demonstrated no dose-limiting toxicities in RA patients.

No treatment-related SAEs and no requirement for expedited reports to FDA.

Most commonly reported AEs were fatigue and flare of RA symptoms of mild to moderate severity.

No laboratory abnormalities associated with PRTX-100 except transient lymphopenia 24 hours post-dose.

37 of 41 randomized patients completed day 85; 2 of 31 PRTX-100-treated and 2 of 10 placebo-treated patients withdrew because of AEs.
Efficacy trends from two phase I clinical studies in RA patients

- PRTX-100-treated patients showed greater response than placebo-treated patients in all common measures of disease activity, including:
  - **ACR20/50/70** (American College of Rheumatology “patient only” index)
  - **CDAI** (Clinical Disease Activity Index, only clinical parameters)
  - **DAS28-CRP** (Disease Activity Score, clinical and blood parameters)

- In most recent US trial, 43% of PRTX-100 treated patients achieved DAS28-CRP < 3.2 (mean pretreatment DAS28-CRP was 4.93)

- Other promising trends with categorical analyses

- Furthermore, the magnitude of the benefit compares favorably to published efficacy data for in-market RA biologicals with “black box” safety warnings
PRTX-100 Increases ACR50 Response in RA Patients on Background MTX Therapy

ACR50 Response Rate

<table>
<thead>
<tr>
<th>Days on Treatment</th>
<th>MTX</th>
<th>MTX + PRTX-100</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>29</td>
<td>5</td>
<td>15</td>
</tr>
<tr>
<td>57</td>
<td>10</td>
<td>30</td>
</tr>
<tr>
<td>85</td>
<td>15</td>
<td>35</td>
</tr>
</tbody>
</table>

Source: Company PRTX-100-104 draft CSR
DAS28 categorical analysis from -104 similar to APPEAL trial data (Enbrel)

Dosing under “maintenance” protocol – apparent safety and reduction in disease

- Trial Cohort 5 included monthly maintenance doses
  - 20 patients, placebo, 240, or 420 ug fixed-dose PRTX-100
  - Five weekly, then four monthly “maintenance” doses

- Analysis of pooled, blinded cohort 5 data presented at ACR 2014
  - Safe and well-tolerated, even in patients w ADAs

- Final, unblinded data announced April, 2015
  - No SAEs
  - Weight-based dosing and monthly maintenance dosing will be considered in future PRTX-100 trials
The biomarker data from the -104 (US) RA phase 1b study indicates that it may be possible to identify patients most likely to respond to PRTX-100.

The biomarker data covers acute phase proteins, adhesion molecules, cytokine-related proteins, growth factors, hormones, matrix proteinases and other proteins.

Findings from the -103 (South Africa) phase 1b study will be studied using insights gleaned from the -104 data set.
PRTX-100-105 Continuation Study

- Enrollment commenced February, 2015
- Open-label, multiple fixed dose open to -104 RA Study patients who indicated a desire for additional treatment
- Up to 12 former participants over a 6-month period at a single site
- Primary endpoint is safety and tolerability of a fixed dose of PRTX-100 administered over an extended period
- Secondary endpoints include immunogenicity, effects on measures of disease activity, evaluation of anti-PRTX-100 antibody presence, and feasibility of biomarkers and joint evaluation with ultrasound
Competitive Advantages of PRTX-100 to Current Biologicals

+ **No FDA Black Box** - Does not suppress the immune system
+ Attractive safety profile may allow use in combination with other therapies
+ Potentially applicable across a broad range of autoimmune diseases
+ Considerably lower cost production
+ Strong intellectual property rights
Patents and Intellectual Property

+ Patents (five issued in US and one in Japan)
  - Initial US patent 7,211,258, “Protein A compositions and methods of use” filed 2002 and issued 2007 for RA, juvenile RA, and systemic lupus erythematosus
  - Continuation patents expanding use were issued for:
    - ITP or autoimmune TP in 2008
    - Acute inflammatory response or inflammation in 2012
    - Psoriasis and scleroderma in 2012
    - MS in 2013
  - Japanese patent issued with 2023 expiration date
    - April 2014 notice of allowance for psoriasis, scleroderma, Crohn’s Disease
+ Other Intellectual Property
  - Considerable know-how in the manufacture and QA of highly purified SPA expected to remain trade secret
Protalex Key Team Members

+ **Arnold P Kling** – President, Director; Principal of Niobe Ventures, LLC, experienced investor in and manager of early stage technology companies

+ **James W Dowe III** – Vice-Chair of SAB; active investor in biotechnology, computer software and investment management companies

+ **William E. Gannon, MD** – Chief Medical Officer; more than 20 years experience in clinical development and regulatory affairs at Quintiles, PPD, and other companies

+ **Bruce McClain, MD** – Medical Director; more than 20 years experience in clinical development and product safety; senior roles at Aeras Global and MedImmune

+ **Richard Francovitch, Ph.D.** -- VP of ITP Programs; 27 years pharma experience, former Head of Hematology Franchise and Global Commercial Leader for Promacta at GSK

+ **Benjamin R Bowen, Ph.D.** – Senior Advisor; background in pharma and biotech R&D at Genentech, Ciba-Geigy, and Novartis; ten years in investment banking

+ **Michelle Catalina, Ph.D.** – Director of Preclinical Studies; academic research background in immunology, former instructor at U Mass Medical Center
Protalex Milestones

<table>
<thead>
<tr>
<th>Quarter</th>
<th>Event</th>
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<tbody>
<tr>
<td>2Q13</td>
<td>Safety data from first three cohorts of PRTX-100-104</td>
</tr>
<tr>
<td>3Q13</td>
<td>Initiation of Cohort 5 extended dosing study, to investigate monthly maintenance doses</td>
</tr>
<tr>
<td>2Q14</td>
<td>Top-line results of PRTX-100-104 trial, cohorts 1 through 4</td>
</tr>
<tr>
<td>4Q14</td>
<td>Filing IND for PRTX-100 in ITP</td>
</tr>
<tr>
<td>1Q15</td>
<td>Initiation of PRTX-100-105 continuation study</td>
</tr>
<tr>
<td>X 2Q15</td>
<td>Submit end of study report from PRTX-100-104 trial</td>
</tr>
<tr>
<td>X 2Q15</td>
<td>Top-line results from Cohort 5 extended dosing study</td>
</tr>
<tr>
<td>X 2Q15</td>
<td>First dose in Phase 1/2 study of PRTX-100 in ITP</td>
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</tbody>
</table>
Protalex Investment Thesis Summary

+ **PRTX-100 – potentially a blockbuster drug**
  - Multiple clinical indications in both orphan and large markets (ITP, RA)
  - Potentially applicable across a broad set of autoimmune diseases
  - Considerable cost-of-goods advantage over competitors
  - To date, superior safety profile in five human clinical studies

+ **Market Opportunity**
  - ITP = $1 B market
  - RA = $18 Billion annual market size
  - Future expansion into other disease areas

+ **Company Structure**
  - Experienced Management and Advisory Teams with “skin in the game”
  - Committed support from expert Scientific Advisory Board
  - Established IP protection and trade secrets
Appendix

Details on PRTX-100-104 and PRTX-100-103 phase 1b clinical studies
Primary
- Assess safety and tolerability of iv PRTX-100 weekly x 4 doses

Secondary
- Assess immunogenicity after ≥3 doses
- Determine PK and estimate of PRTX-100 plasma exposure after first and fourth dose
- Determine whether a relationship exists between immunogenicity of PRTX-100 and safety and PK
- Assess effect of PRTX-100 on measures of disease activity, e.g., DAS28-CRP and CDAI
PRTX-100-103: DAS28 < 3.2

% of patients with DAS28 < 3.2 at 6 and 10 weeks

Day 42

PRTX-100

Placebo

Protalex, Inc.
PRTX-100-103: Summary

- PRTX-100 was well tolerated
  - 3 mild to moderate infusion reactions, no SAEs related to study drug
  - Anti-PRTX-100 antibodies elicited in majority of patients but neither incidence nor titer was related to dose
  - Patients with antibody response showed increased clearance without increase in AEs. Antibodies do not appear to preclude treatment response

- Relationship between dose and $C_{\text{max}}$ was linear but clearance and AUC were variable

- The higher doses of PRTX-100 resulted in low disease activity, with maximal improvement at 10 weeks after the first dose
PRTX-100-104: Overview

- Multi-center US study initiated 4Q12. Phase 1b randomized, multiple-dose, placebo-controlled, dose-escalation study of PRTX-100 in adults with active RA on MTX
- 41 patients dosed in four dose-escalating cohorts, starting at 1.50 µg/kg, with fifth cohort to investigate extended dosing schedule
- Primary objective: safety and tolerability of PRTX-100 administered by iv injections over five weeks
- Secondary objectives include determining effects on measures of disease activity, assessing immunogenicity, evaluating PK, and investigating durability of response
- Enrollment commenced November 2012 in the US; last dose of cohorts one through four completed July 2013; expansion cohorts completed September 2013; cohort 5 initiated October 2013, last dose August 2014
- Topline data for cohorts 1 through 4 announced June 3, 2014; cohort 5 data November 2014
PRTX-100-104: Study Design

- Patients with RA:
  - ≥ 4 swollen and ≥ 5 tender joints (28 joint count)
  - Positive RF or anti-CCP
  - Stable dose of MTX or leflunomide

- Treatment
  - Randomized in blocks (3:1)
  - PRTX-100 at 1.5, 3.0, 6.0, or 12.0 µg/kg iv, five weekly doses

- Measurements
  - PK at 1st and 4th doses; antibodies at day 1, 22, 57 and EOS; safety at screening and day 15, 29, 57, and EOS; CBCs at 1, 2, 15, 22, 29, 57, 85, 113, and EOS; components of ACR20/50/70 and DAS28CRP at screening, day 1, 8, 15, 22, 29, 57, 85, 113, and EOS
### PRTX-100-104: Patient Demographics

<table>
<thead>
<tr>
<th>PRTX-100 dose</th>
<th>1.5 µg/kg</th>
<th>3.0 µg/kg</th>
<th>6.0 µg/kg</th>
<th>12 µg/kg</th>
<th>All</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>No. of patients(^a)</strong></td>
<td>6</td>
<td>9</td>
<td>9</td>
<td>5</td>
<td>29</td>
<td>8</td>
</tr>
<tr>
<td><strong>Mean age, years (SD)</strong></td>
<td>61.2 (13.3)</td>
<td>57.6 (11.8)</td>
<td>63.3 (9.7)</td>
<td>62.6 (6.8)</td>
<td>61.1 (10.3)</td>
<td>59.9 (9.4)</td>
</tr>
<tr>
<td><strong>Age range, years</strong></td>
<td>47–76</td>
<td>30–72</td>
<td>42–71</td>
<td>51–72</td>
<td>30–72</td>
<td>46–71</td>
</tr>
<tr>
<td><strong>Male, %</strong></td>
<td>66.7</td>
<td>44.4</td>
<td>33.3</td>
<td>57.1</td>
<td>48.4</td>
<td>30</td>
</tr>
<tr>
<td><strong>Caucasian, %</strong></td>
<td>83.3</td>
<td>88.9</td>
<td>77.8</td>
<td>85.7</td>
<td>83.9</td>
<td>80.0</td>
</tr>
<tr>
<td><strong>Weight, kg (SD)</strong></td>
<td>74.6 (4.3)</td>
<td>91.4 (20.6)</td>
<td>81.0 (16.2)</td>
<td>86.0 (16.9)</td>
<td>83.9 (16.9)</td>
<td>82.3 (14.0)</td>
</tr>
<tr>
<td><strong>Day 1 DAS28-CRP (SD)</strong></td>
<td>4.9 (0.55)</td>
<td>5.3 (0.62)</td>
<td>4.8 (0.67)</td>
<td>4.65 (0.88)</td>
<td>4.93 (0.68)</td>
<td>5.30 (0.87)</td>
</tr>
<tr>
<td><strong>Day 1 DAS28 swollen joint count (SD)</strong></td>
<td>10.2 (4.54)</td>
<td>13.0 (6.4)</td>
<td>8.9 (4.23)</td>
<td>13.6 (5.18)</td>
<td>11.2 (5.32)</td>
<td>12.8 (5.50)</td>
</tr>
<tr>
<td><strong>Day 1 CDAI (SD)</strong></td>
<td>37.9 (10.7)</td>
<td>44.7 (12.4)</td>
<td>34.7 (11.3)</td>
<td>37.6 (14.0)</td>
<td>39.0 (12.1)</td>
<td>43.6 (13.2)</td>
</tr>
<tr>
<td><strong>Day 1 CRP (SD)</strong></td>
<td>0.86 (1.02)</td>
<td>0.29 (0.24)</td>
<td>0.25 (0.18)</td>
<td>0.69 (1.01)</td>
<td>0.49 (0.69)</td>
<td>0.74 (0.66)</td>
</tr>
<tr>
<td><strong>RA disease duration, years (SD)</strong></td>
<td>10.0 (2.93)</td>
<td>15.9 (11.7)</td>
<td>15.6 (11.1)</td>
<td>8.1 (3.9)</td>
<td>13.0 (9.7)</td>
<td>8.4 (6.8)</td>
</tr>
</tbody>
</table>
PRTX-100 treatment reduces CDAI<14 for three or more consecutive visits (-104 trial)

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Percent (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MTX only</td>
<td>13%</td>
</tr>
<tr>
<td>MTX + PRTX-100 All Doses</td>
<td>31%</td>
</tr>
<tr>
<td>MTX + PRTX-100 6 and 12 mcg/kg</td>
<td>36%</td>
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