PROTALEX, INC.

Date of report (Date of earliest event reported): January 11, 2016

PROTALEX, INC.

(Exact Name of Registrant as Specified in Charter)

DELAWARE 000-28385 91-2003490
(State or Other Jurisdiction (Commission File Number) (I.R.S. Employer
of Incorporation) Identification No.)

131 Columbia Turnpike, Suite 1
Florham Park, NJ 07932 07932
(Address of Principal Executive Offices) (Zip Code)

(215) 862-9720
(Registrant’s telephone number, including area code)

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the Registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act of 1933, as amended (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Securities Exchange Act of 1934, as amended (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Securities Exchange Act of 1934, as amended (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Securities Exchange Act of 1934, as amended (17 CFR 240.13e-4(c))
Item 8.01. Other Events.

On January 11, 2016, Protalex, Inc. will be attending the J.P. Morgan Annual Healthcare Conference, being held January 11 -15, 2016 at San Francisco, California, at which it may utilize the presentation attached as Exhibit 99.1 hereto.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<table>
<thead>
<tr>
<th>Exhibit No.</th>
<th>Description</th>
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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 hereunto duly authorized.

PROTALEX, INC.

Dated: January 11, 2016

By: /s/ Arnold P. Kling
Arnold P. Kling
President

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Disclaimer

This presentation highlights certain information about Protalex, Inc. On July 31, 2015, we filed a registration statement, which included a preliminary prospectus, with the U.S. Securities and Exchange Commission (the “SEC”), SEC File No. 333-206008 (the “Registration Statement”) for a registered public offering of shares of our common stock and common stock purchase warrants (the “Offering”). The Registration Statement has not yet been declared effective by the SEC. The Offering may only be made via a final prospectus. Before making an investment in Protalex, Inc., you should read the Registration Statement, including the prospectus contained therein and the documents, and the exhibits thereto, as well as any other documents we have filed with the SEC for more complete information about Protalex, Inc. and the terms of the Offering. A copy of the Registration Statement may be obtained from the SEC’s website at www.sec.gov. You may also obtain a copy of the preliminary prospectus included in the Registration Statement from H.C. Wainwright & Co., LLC, 430 Park Avenue, New York, NY 10022 or via email at placements@hcwco.com. This presentation shall not constitute an offer to sell or a solicitation of an offer to buy, nor shall there be any sale of these securities in any state or jurisdiction in which such an offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.
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. (Symbol: PRTX)

**Lead Product PRTX-100**
- Highly-purified natural biologic
- Clinical experience in five human studies
- Demonstrated strong safety profile
- Potential for multiple clinical uses

**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

Protalex, Inc.
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.
PRTX-100 Inhibits Platelet Phagocytosis

*in vitro*

- 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

PRT raises platelet counts X-100

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 and serious
PRTX-100 Clinical Experience

**Rheumatoid Arthritis (RA)**
- 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
- February 2015 – Phase 1b RA continuation study (PRTX-100-105) initiated in US -- 9 patients at one site

**Immune Thrombocytopenia (ITP)**
- March 2015 – IND for ITP accepted by US FDA
- July 2015 – IMPD for ITP accepted by EMA
- October 2015 – Initiated Phase 1-2 ITP Study in US (PRTX-100-202)
- January, 2016 – Initiated Phase 1-2 ITP Study in Europe (PRTX-100-203)

Protalex, Inc.
PRTX-100 Clinical Development Plans

Immune Thrombocytopenia

2012: Preclinical
2013: EU Phase 1/2
2014: US Phase 1/2
2015: Continuation Study
2016: Phase 2

Rheumatoid Arthritis

2012: Phase 1b in USA
2013: PRTX-100-103 in South Africa
2014: PRTX-100-104
2015: -105 Continuation Study
2016: Explore Partnership

Protalex, Inc.
Orphan Drug Designation in ITP

+ June 2015, FDA's Office or Orphan Drugs Development grants Orphan Drug Designation (ODD) to PRTX-100 in ITP in US

+ October 2015, European Medicines Agency grants ODD to PRTX-100 for ITP in Europe

+ ODD provides:
  ▪ Certain market exclusivity, even beyond patent life (7 years in US, 10 years in Europe)
  ▪ Tax credits
  ▪ Waiver of NDA user fees
  ▪ Potential for receipt of non-dilutive development grants
PRTX-100-202/-203: 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 to 24 µg/kg PRTX-100

- Treatment: 4 weekly doses

- Up to 30 patients at 6 sites in Europe

- Up to 36 patients at several sites in the US

- Dosing commenced in both US and Europe
PRTX-100-202: Adult ITP patients refractory to TPO-RAs

Dosing: IV infusion weekly for 4 weeks

- PRTX-100 1 µg/kg
- PRTX-100 3 µg/kg
- PRTX-100 6 µg/kg
- PRTX-100 12 µg/kg
- PRTX-100 18 µg/kg
- PRTX-100 24 µg/kg

Primary objective:
- Platelet response

Secondary objectives:
- Time to response
- Quality of response
- Duration of response
- Reduction in concomitant ITP medications
- Safety
- Immunogenicity
- PK
- Biomarkers

Screening ≤ 21 days

Treat up to 36 patients at 5-6 US sites; up to 13 study visits

- Treatment 4 weeks
- Weekly Follow-up 4 weeks
- Monthly Follow-up 8 weeks
- Long Term Follow-up 24-48 weeks
PRTX-100-203: Adult ITP patients who have received one prior treatment

Dosing: IV infusion weekly for 4 weeks

- PRTX-100 24 µg/kg
- PRTX-100 18 µg/kg
- PRTX-100 12 µg/kg
- PRTX-100 6 µg
- PRTX-100 3 µg/kg

Primary objective:
- Safety

Secondary objectives:
- Platelet response
- Time to response
- Quality of response
- Duration of response
- Reduction in concomitant ITP medications
- Immunogenicity
- PK,

Screening ≤ 21 days

Treatment 4 weeks

Weekly Follow-up 4 weeks

Monthly Follow-up 8 weeks

Long Term Follow-up 24-48 weeks

Treat up to 30 patients at 5-6 trial sites in Europe; up to 13 study visits
PRTX-100-104: Overall safety in RA

- 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.
PRTX-100 Increases ACR50 Response in RA Patients on Background MTX Therapy

**ACR50 Response Rate**

- **MTX + PRTX-100**
- **MTX**

**PRTX-100 + MTX**

- Trial PRTX-100-104: 41 patients w active RA randomized 3:1
- Baseline MTX vs MTX + PRTX-100, five weekly i.v. doses, 1.5, 3, 6, or 12 mcg/kg
- Last PRTX-100 dose at day 29
- No drug-related SAEs

Source: Company PRTX-100-104 draft CSR
PRTX-100-105 Continuation Study

- Enrollment commenced February, 2015; last dose/visit expected in 1Q16
- Open-label, multiple fixed dose open to -104 RA Study patients who indicated a desire for additional treatment
- Eleven former participants enrolled 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
Patents and Intellectual Property

- Patents (five issued in US and one in Japan, one EU intention to grant)
  - 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 more claims issued for psoriasis, scleroderma, Crohn’s Disease
  - In September, 2015, European Patent Office issued an intention to grant claims relating to treatment of numerous autoimmune diseases
- Additional patent applications pending in Europe, Canada, Japan, and US

- 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, Inc.
## Protalex Milestones

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<th>Milestone Description</th>
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<tr>
<td>4Q14</td>
<td>Filing IMPD and IND for PRTX-100 in ITP in Europe &amp; US</td>
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<tr>
<td>1Q15</td>
<td>Initiation of PRTX-100-105 continuation study</td>
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<tr>
<td>2Q15</td>
<td>Complete PRTX-100-104 study (US Phase 1B in RA)</td>
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<tr>
<td>2Q15</td>
<td>Orphan Drug Designation for PRTX-100 in ITP in US</td>
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<tr>
<td>3Q15</td>
<td>Submit end of study report from PRTX-100-104 trial</td>
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<tr>
<td>4Q15</td>
<td>Orphan Drug Designation for PRTX-100 for ITP in Europe</td>
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<tr>
<td>4Q15</td>
<td>First dose in US Phase 1/2 study of PRTX-100 in ITP</td>
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<tr>
<td>1Q16</td>
<td>First dose in European Phase 1/2 study of PRTX-100 in ITP</td>
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<td>1Q16</td>
<td>Top line findings from PRTX-100-105 continuation study</td>
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<tr>
<td>2H16</td>
<td>ITP trial top line results</td>
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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
Thank you