



*“ELIMINATING DISEASE IN  
OUR GENERATION AND  
THE GENERATIONS TO COME”*

## Business Overview – January 2016

### Predictive Therapeutics

#### Address:

2749 East Parleys Way, Ste 100  
Salt Lake City, Utah 84109  
www.predrx.com

#### Management:

Bradley C Robinson,  
CEO/Chairman

Eric K. Olson,  
President and COO

Jack Turner,  
VP Business Development

### Corporate Facts

Year Founded: 2013  
Publicly Traded: PRED

### Investment Overview

#### Industry:

- Stem cells
- Drug development
- Genetic based companion diagnostics

#### Initial Target Markets:

##### Diagnostics:

- Endometriosis
- Preeclampsia
- Carrier screening
- Scoliosis
- Degenerative Disc Disease
  - Block buster diagnostic Market +\$Billion
  - Block buster drug Market +\$Billion

#### Potential Partners:

- In discussions with pharmaceutical and diagnostics firms with major women's health franchises

#### Intellectual Property:

- Strong proprietary positions
- Multiple issued and pending US and International patents

#### Use of Funds: TBD

- Intellectual property:
- Product development:
- Expansion of regulatory team:
- Sales team expansion
- Sales launch
- Working capital

#### Mission:

Revolutionize patient care through novel gene-based companion diagnostics and stem cell/pharmaceutical therapeutics.

*"It is more important to know what sort of person has a disease than to know what sort of disease a person has."*

*Hippocrates, 460-370 B.C.*

Predictive Therapeutics, LLC ("PRx") develops and commercializes discoveries and technologies involved in novel molecular diagnostic and stem cell/pharmaceutical therapeutic products. PRx intends to revolutionize the treatment of serious and debilitating diseases through the commercialization of novel therapeutics leveraged by proprietary gene-based companion diagnostics. PRx has developed and/or acquired a number of technologies that open a window into the origin of human disease and the role that genes and their related proteins play in the disease's onset and progression. PRx uses this information as the cornerstone in the development of new diagnostics that assess a person's risk of disease and stem cell/pharmaceutical therapeutic products designed to effectively prevent and treat the disease.

PRx's utilization of molecular diagnostics focuses on the analysis of genes and their mutations to characterize and assess a patient's inherited risk for developing a particular disease and its progression (predictive health care). Additionally, **PRx believes that advances in the emerging field of molecular diagnostics will improve the ability to determine which patients are subject to a greater risk of developing disease and who, therefore, would benefit from preventive therapies. Molecular diagnostic products may also guide a patient's health care to ensure the patient receives the most appropriate treatment at the most appropriate time (i.e., most effective).**

PRx is well positioned with short and long-term assets in its pipeline to be a leader in the future of preventative, personalized and precision health care that benefits the patient, health care professionals and society at large. Current trends in medicine lie in the creation of new classes of drugs and stem cells that treat the underlying cause, not just the symptoms, of disease and may be useful in disease prevention. By understanding the genetic basis of disease and by working with strategic partners, PRx believes that it will be able to develop medicines and preventative treatments that are more effective, resulting in accelerated and better patient outcomes at significantly lower costs.

#### Development assets of PRx and strategic partners to be utilized in the development of highly actionable genetic tests through use of proceeds:

- DNA – Proprietary genealogy database and over 600,000 DNA samples in library as a result of a birth defect or serious maternity issue:
  - HIPAA compliant
  - Collected from most genetically diverse population in U.S.
  - Believed to be largest DNA library in the world related to women's health
  - Corresponding proprietary genealogy database developed from over 50,000 public sources
  - Appropriate informed consents for DNA samples
  - Proprietary genealogy database used to accelerate genetic discoveries

## Near-Term Molecular Diagnostic Opportunities:

- **Endometriosis (EndoRisk®) – Genetic diagnostic/prognostic for endometriosis**
  - 1Q 2016 initial launch to fertility clinics
  - 2H 2016 launch to general primary care provider and OB/GYN market
  - Today endometriosis is diagnosed through laparoscopy with costs that exceed \$15,000
  - In over 50% of cases (today’s “gold standard”) diagnoses are NOT confirmed
  - Companion diagnostic for therapeutics
  - 27 million symptomatic women in the U.S. alone.
  - Greater than \$1 billion annual U.S. market
  - Initial base patent issued in January 2015 by USPTO
  - Additional patent applications pending
- **Fertility Dx – Carrier (parents) testing to detect potential diseases passed from parents to child**
  - 1Q 2016 initial launch to fertility clinics
  - 1H 2016 launch to general primary care provider OB/GYN market
  - 385,000 IVF cycles annually in the U.S.
  - Greater than \$1 billion annual U.S. market
  - Carrier testing most common mutations prior to conception
  - Fertility Dx panel to include test for endometriosis and preeclampsia making it the most comprehensive panel to assist parents and health care providers in having the healthiest pregnancies and babies possible
- **Preeclampsia - Cardio-Vascular Risk Assessment Screen (C-VRAS) Test**
  - 1Q 2016 initial launch to fertility clinics
  - 1H 2016 launch to general primary care provider OB/GYN market
  - Up to 8% of 3.9 million U.S. pregnancies are affected by preeclampsia
  - Early identification of women at high risk for cardiovascular disease may lead to primary prevention, earlier diagnosis, more aggressive treatment and improvement in survival.
- **Spinal Deformity – Idiopathic Scoliosis or other Syndromes Genetic Test**
  - 1H 2016 launch
  - 100,000 newly diagnosed cases annually in the U.S.
  - Greater than \$100 million annual U.S. Market
  - Significant revenues in 2016
  - Determines which 80% of children diagnosed with scoliosis will not develop to a “treatable” case of scoliosis.
    - Results in no more unnecessary medical procedures and/or bracing of children, X-rays (tests)
    - Significant cost savings
    - Elimination of stress and stigma on 80% of the children diagnoses with scoliosis
  - Initial patent issued in April 2014 by USPTO
  - Additional patent applications pending
- **Degenerative Disc Disease – Genetic test to determine who will suffer from degenerative disc disease**
  - 2H 2016 estimated launch
  - Approximately 500,000 disc surgeries are performed annually in the U.S.
  - Greater than \$1 billion annual U.S. market
  - Assists in determining which patients will benefit from back surgery and which patients will have better outcomes forgoing back surgeries
  - Patent applications pending

### Near-Term Stem Cell/Pharmaceutical Treatment Opportunities:

- **Allogenic Stem Cell Products** – Immediate Revenue Opportunities
  - Amniotic Derived Injectable Product containing Cells, Proteins, Cytokines, Hyaluronic Acid used for spinal fusion, degenerative disc disease, wound healing and used as an anti-inflammatory for small and large joints.
  - Amniotic Membrane Product used as an anti-adhesion barrier for spinal procedures and for wound healing to reduce pain, scarring and increase healing time for burn victims and diabetic ulcers.
  - Proprietary Stem Cell Product derived from cord blood and tissue. This product is rich in hematopoietic stem cells and used for various applications including potentially endometriosis treatment.

### Mid-Term Opportunities:

- **NHP-07 – First pharmaceutical/therapeutic candidate to be developed by PRx.** Management believes NHP-07 with EndoRisk® as a companion diagnostic/prognostic is the only treatment protocol that can prevent development of endometriosis and, in women experiencing advanced stages of endometriosis NHP-07, stop the progression of the disease while suppressing the debilitating symptoms.
  - Expected launch 2017 - 505(b)(2) expected regulatory pathway
  - Approximately 7,500,000 women suffer from endometriosis in the U.S. with only 2,500,000 currently diagnosed
  - Greater than \$1 billion annual U.S. market
  - Tremendous need for new, more effective/lower side-effect therapeutics to meet this unmet demand
  - Suppresses the symptoms of endometriosis in women diagnosed with endometriosis
  - Prevents the development of the disease
  - Believed to be superior to all competitive pharmaceuticals currently on the market in efficacy, time and cost
  - Combination of two or more existing FDA-approved compounds, whose safety has already been established over decades:
  - Is expected to achieve regulatory approval within 24 months
  - Coupled with EndoRisk® as a companion diagnostic, NHP-07 can be given prior to development of endometriosis or becoming symptomatic to prevent the disease altogether
  - USPTO issued two NHP-07 related patents in October 2015
    - Patent issued for combination of progesterone/progestin and NSAIDs (Non Steroidal Anti-Inflammatory Drugs) as a therapeutics for endometriosis
    - Patent issued for combination of progesterone/progestin and cannabinoids as a possible alternative to the side effects than may result from use of traditional NSAIDs
    - Additional applications are pending
- **Over 25 additional disease targets on development horizon contingent upon funding resources:**
  - Polycystic ovarian syndrome
  - Preterm labor mothers and infants
  - Autoimmune diseases
  - Hypothyroidism
  - Essential hypertension (female early onset)
  - Recurrent miscarriage
  - Morbid obesity (female early onset)
  - Placental abruption
  - Ovarian cancer
  - Gestational diabetes
  - Preeclampsia
  - Intrauterine growth retardation – mothers and infants
  - Birth defects
  - Left cardiac flow lesions

- Juvenile onset diabetes
- Fetal macrosomia
- Dizygotic twins
- Other pregnancy complications
- **Additional therapeutic opportunities:** These products are expected to be discovered as a result of knowledge gained in the development of genetic tests for the diseases listed above.
  - Many therapies may be repurposing of existing FDA approved pharmaceuticals

### Long-Term Opportunities:

- New DNA-based diagnostics
- New Stem Cell Products cleared for endometriosis and degenerative disc disease
- New drug discoveries cleared for endometriosis and degenerative disc disease

### Genetic Diagnostics Regulatory Clearance

Genetic diagnostics do not require approval by the FDA in order to go to market if the tests are Laboratory Developed Tests (“LDTs”), which are regulated under the Clinical Laboratory Improvement Amendments (“CLIA”). It is estimated that of the 2,000 genetic tests commercially available, less than a dozen were reviewed by FDA. The American Clinical Laboratory Association (“ACLA”) filed a citizen petition on June 4, 2013 challenging the FDA’s authority to regulate LDTs as medical devices under the federal Food, Drug, and Cosmetic Act (FDCA). The ACLA stated, “CLIA allows laboratories the flexibility to develop and validate LDTs quickly to respond to public health needs.” The ACLA also wrote, “Laboratories are able to update LDTs regularly as medicine advances, so that patients have access to the most advanced testing.” LDTs are laboratory services, not products, and are not distributed, nor delivered or placed into market, noted the petition. “They are proprietary procedures for performing a diagnostic test using reagents and laboratory equipment, **essentially know-how.**”

### Stem Cell and Pharmaceutical Therapeutic Regulatory Clearance

Allogenic stem cell products do not require approval by the FDA. These products are regulated under the American Association of Tissue Banks (AATB). If stems cells are manipulated for specific treatment applications the product is regulated by the FDA as a drug. Development of pharmaceutical products is subject to regulation by the FDA and foreign regulatory authorities and requires approval before they may be clinically tested and commercially marketed for human therapeutic use. Through the knowledge gained from understanding the genetic cause of a disease, PRx endeavors to identify, modify or combine existing commercially available FDA-approved compounds for new uses. PRx will use NHP-07, its first therapeutic candidate for the treatment of endometriosis, as a model for the creation and discovery of new drug opportunities. As it is a long and costly process to get new drugs approved, PRx will endeavor to develop these new opportunities through strategic partnerships with large pharmaceutical companies.

### Securing Intellectual Property Rights

Patent protection in the U.S. and major foreign jurisdictions for synthetic genes, proteins, antibodies, drug targets, drug compounds, diagnostic markers, technologies, methods, processes and other inventions are in progress, and may be used in the development of novel therapeutic and molecular diagnostic products.

The products listed in this document have patents issued and/or patents pending with the U.S. Patent and Trademark Office (“USPTO”) and internationally by filing applications under the Patent Cooperation Treaty (“PCT”) and nationally at appropriate times. To further protect trade secrets and other proprietary information, employees and consultants are required to enter into confidentiality and invention assignment agreements.

No attempts will be made to patent DNA sequences (isolated or otherwise) via composition claims. Instead, patents will be filed for the application of knowledge of particular DNA sequences via method claims. More specifically, PRx plans to patent methods for detecting particular DNA sequences discovered to have an association with a particular disease and the resultant treatment of the patient (e.g. administration of a particular drug) based on the discovery of such DNA sequences in the patient.

## Management/Advisors

**Proven and Experienced Team** – An experienced team that has completed similar product ventures from conception to commercialization through internal sales and marketing and/or major strategic partnerships. The key executives have a track record of successfully developing and marketing high volume products in the health care field. As a result, PRx will be able to benefit from and leverage valuable relationships with industry and thought leaders. Discussions have already commenced with significant companies that have major women’s health franchises. PRx is in serious discussions with additional, well-known and respected health care industry Advisors and Executives beyond those listed below that are expected to join the team in the next several months:

## Comparable Companies

- Genetic Diagnostic Companies:
  - o Roche Diagnostics
  - o Becton Dickinson
  - o Novartis
  - o Abbott
  - o Hologic
  - o Cepheid
- Allogenic Stem Cell Companies
  - o Mimedix
  - o BioD, LLC
  - o Allosource
  - o Nutech
- Stem Cell Development Companies
  - o Osiris
  - o NeoStem
  - o Orthofix
  - o NuVasive
  - o Vericel Corporation
  - o Bioheart
  - o Neuralstem
  - o Ocata Therapeutics

## Summary

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## INTELLECTUAL PROPERTY SUMMARY

### ENDOMETRIOSIS THERAPEUTIC – NHP-07

Owned by Predictive Therapeutics, Inc. (No contingencies or royalty obligations)

Title	Ser #, Patent # or Pub #	US	1 <sup>st</sup> Named Inventor	Status
Progestin Cannabis Therapeutic and Method of Use	14/281,172 US 9,149,499	US	Bradley C. Robinson	Issued
Progestin NSAID Therapeutic and Method of Use	14/281,127 US 9,161,941	US	Bradley C. Robinson	Issued
Progestin NSAID Therapeutic and Method of Use	PCTUS2014386018	US	Bradley C. Robinson	National Filing Stage
Progestin NSAID Therapeutic and Method of Use	14/875,656 US 2016/0022696	US	Bradley C. Robinson	Pending
Method of Treating Endometriosis	62/275,413	US	Bradley C. Robinson	Pending
Additional filings in process				

### ENDOMETRIOSIS GENETIC DIAGNOSTIC

Licensed from Juneau Biosciences, LLC (profit sharing)

Title	Ser #, Patent # or Pub #	US	1 <sup>st</sup> Named Inventor	Status
Genetic Markers Associated with Endometriosis and Use Thereof	12/765,643 US 2010/0272713	US	Kenneth Ward	Pending
Genetic Markers Associated with Endometriosis and Use Thereof	13/159,132 US 2015/0361494	US	Kenneth Ward	Pending
Method of Determining Predisposition of Endometriosis	13/603,284 US 2015/0363558	US	Kenneth Ward	Pending
Method of Determining Predisposition of Endometriosis	13/788,913 US 8,932,993	US	Kenneth Ward	Issued
Method of Testing for Endometriosis and Treatment Thereof	13/789,082 US 2015/0368714	US	Kenneth Ward	Pending
Method of Testing for Endometriosis and Treatment Thereof	14/594,266 US 2015/0133382	US	Kenneth Ward	Pending
Additional filings in process				



**SPINE TECHNOLOGIES**

**Owned by Predictive Therapeutics, Inc. (No contingencies or royalty obligations)**

<b>Title</b>	<b>Ser #, Patent # or Pub #</b>		<b>1<sup>st</sup> Named Inventor</b>	<b>Status</b>
Apparatus and Method for Dynamic Scoliosis Orthosis	12/145,959 US 7,967,767	US	Ogilvie	Issued
Method of Treating Scoliosis Using a Biological Implant and Determining Predisposition	12/341,289 US 8,123,787	US	Ogilvie	Issued
Method of Treating Scoliosis Using a Biological Implant and Determining Predisposition	13/357,800 US 8,641,738	US	Ogilvie	Issued
Method of Treating Scoliosis Using a Biological Implant and Determining Predisposition	14/170,691 US 2105/0127105	US	Ogilvie	Pending
Genetic Markers Associated with Degenerative Disc Disease and Uses Thereof	13/364,378 US 2105/0337373	US	Chettier	Pending