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Predictive Technology Group, Inc. (PRED - OTC)

Fertile Grounds for Genetic Testing

Based on our discounted cash flow model which employs 15% discount rate. Revenues represent contributions from both cellular therapy, diagnostic testing and specifically from approved cellular therapy products for osteoarthritis, COPD and diagnostic tests for endometriosis.

Current Price (6/10/2019)	$6.48
Valuation	**$8.00**

INITIATION

Predictive Technologies is developing a suite of diagnostic genetic tests for fertility, endometriosis and degenerative disc disease. The company is also generating revenue from sales of cellular therapy products sourced from amniotic and placental tissue.

Predictive is focused on developing platforms with broad applicability in the genetic testing and cellular therapies spaces. With current revenues, the company is in a strong position to fund development activities in their targeted areas.

Commercialization plans include a focus on select centers of excellence for fertility in the US, allowing for the use of a small sales force and the use of LDTs. For the larger endometriosis market, PRED will initially sell the diagnostic as an LDT and will seek FDA approval for its tests in parallel, allowing for broader use. The strategy for cellular therapies is to identify the most successful indications physicians are treating and use this to design clinical trials for FDA approved use in the future.

PRED turned cash flow positive in 4Q:18 and is able to fund its operations internally. However, capital may be raised to accelerate development.

SUMMARY DATA

52-Week High	**6.91**
52-Week Low	**0.77**
One-Year Return (%)	**561**
Beta	**1.9**
Average Daily Volume (sh)	**366,604**
Shares Outstanding (mil)	**272.5**
Market Capitalization ($mil)	**1,766**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0.0**
Insider Ownership (%)	**20.1**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2018 Estimate	**N/A**
P/E using 2019 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue

(In millions of US$)

	Q1 (Sep)	Q2 (Dec)	Q3 (Mar)	Q4 (Jun)	Year (Jun)
2018	$2.0 A	$3.4 A	$4.2 A	$7.2 A	$16.6 A
2019	$8.1 A	$10.7 A	$11.3 A	$12.0 E	$42.0 E
2020					$66.7 E
2021					$97.2 E

Earnings per Share

	Q1 (Sep)	Q2 (Dec)	Q3 (Mar)	Q4 (Jun)	Year (Jun)
2018	-$0.03 A	-$0.00 A	-$0.02 A	-$0.01 A	-$0.06 A
2019	-$0.01 A	-$0.01 A	-$0.01 A	-$0.00 E	-$0.04 E
2020					$0.03 E
2021					$0.09 E

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INITIATING COVERAGE

Predictive Technology Group, Inc. (OTC: PRED) is a cellular therapy and genetic diagnostic testing company currently commercializing its portfolio of four placental and Wharton's Jelly umbilical cord-derived allografts and two gene-based diagnostics. The cellular therapy division provides products derived from amniotic tissue and Wharton's Jelly that are used by physicians in a variety of healing applications. Genetic diagnostic testing is focused on the women's health market and is expected to commercialize and seek approval for a test specifically for endometriosis.

The Predictive Biotech (PB) segment launched four products in 2017 and is currently generating quarterly revenues in excess of a $40 million annual run rate. Predictive Laboratories (PL) launched ARTguide™ in October 2018 for detecting genetic issues that may impact female fertility, including endometriosis and Fertility Dx in November, which adds a chromosomal microarray to the ARTguide diagnostic. In the future, PL will be responsible for advancing new candidates through the regulatory process. The third operating segment, CellSure (CS), is responsible for obtaining the source material for the cellular therapy segment. The fourth segment is Predictive Labs (PL) and was created with the acquisition of Taueret Laboratories in March 2019. PL will launch genetic tests for endometriosis and degenerative disc disease in the coming quarters.

Predictive's revenues are generated exclusively in the self-pay market which allows for substantial flexibility in availability, pricing and distribution. The company is not required to conduct clinical trials for its cellular therapy products because they do not make efficacy claims. The products are considered minimally manipulated and fall under section 361 where physicians can use them based on their skills and experience. Predictive's lab developed tests (LDTs) are not required to undergo the FDA's premarket review as they can be performed in the company's own facilities. This regulatory structure allows laboratories to provide tests in spaces where FDA-approved diagnostics do not exist. These are appropriate when serving a small market such as that in fertility. However, for larger markets, such as the ones that exist for endometriosis and degenerative disc disease, an FDA-approved test provides the flexibility for broader acceptance and we anticipate Predictive will pursue approval in these cases.

Predictive's commercialization strategy in cellular therapy boasts over 20 sales team members and over 75 distributors that will target the naturopathic physicians, chiropractors, orthopedists, anti-aging, and cosmetic medicine and other specialties that seek to treat pain without surgery.

Predictive anticipates pursuing regulatory approval for specific indications in cellular therapy which will be guided by physicians' treatment success with the current slate of products. The company is expected to pursue FDA clearance for diagnostic tests that are broadly used, such as the one intended for endometriosis.

Predictive is generating cash from operations which can be used for research and development. However, Predictive may seek to raise additional capital in order to accelerate the commercialization process and provide a buffer as investment in product development draws away funds.

While Predictive is currently generating its revenues from cellular therapy, the company will focus incremental efforts on obtaining FDA approval for its suite of diagnostic tests and allogenic cell products. The company may also be a supplier of cellular products to strategic partners that may pursue indications in areas including oncology and orthobiologics as well as provide inventory to tissue banks.

Predictive is expected to be successful as their products serve an unmet need for many conditions where pain medication is problematic or insufficient and surgery is excessive. The demand by patients for alternatives to strong analgesics and surgery has given rise to cellular therapy while the improvement in genetic testing to identify those at risk of suffering from specific diseases has provided an opportunity to apply preventative medicine. Predictive is fortunate in that they are able to commercialize their products immediately, which can provide capital and operating cash flow to support longer term work undertaking registrational studies for promising indications and broadly used tests. The availability of cash flow will provide a foundation that can support development and regulatory approval of additional services and products that can drive substantially faster revenue growth. We initiate on the shares of Predictive Technologies with a target price of $8.00.

INVESTMENT THESIS

Predictive Technologies is growing in a number of underserved areas of the market including cellular therapy and women's health, initially entering the market in the fertility health space. More specifically, the company emphasizes clinical categories of endometriosis, scoliosis, degenerative disc disease and regenerative human cell and tissue products. The common theme that connects currently commercialized products is their reliance on the self-pay market. This is an attractive space as products do not require time consuming approval by formularies or face restrictions by managed care or pharmacy benefit managers that create a barrier between product and patient and layer on substantial distribution costs. Success in cellular therapy and fertility health are expected to support efforts to advance many of the in-development medicines and services through the regulatory process.

In contrast to many development companies, Predictive is free cash flow positive, which provides funds for new launches, research and development efforts and sales initiatives. While we expect the company will consume the majority of operational cash generated to support growth in the sales force for both cellular therapy and genetic diagnostic tests, we see less reliance on capital markets for the company to achieve its objectives than a pure development company.

Both cellular therapy and genetic diagnostic tests are emerging areas in the health care space. For companies that can source, process and provide high quality medicines to the physicians who administer them, there is substantial opportunity. The same goes for genetic diagnostic tests that are developed and backed up by a genealogy database that can accelerate genetic discoveries. Predictive's ownership of a proprietary genealogy database with over 30 million individuals and greater than 300,000 DNA samples provides a valuable resource that can isolate genes that are implicated in disease and generate tests that are highly accurate.

Predictive has identified a growth plan for each of its four segments. Predictive Biotech will continue to grow Section 361 product, which does not make any efficacy claims while Predictive Therapeutics will pursue Section 351 products that require review and approval from the FDA. CellSure will focus on procurement of tissue, optimizing cell yields and quality and offering storage services for new mothers. Predictive Laboratories, which was created and expanded through the acquisition of Taueret, will continue to develop and commercialize genetic diagnostic tests.

Key reasons to own PRED shares:

- **Rapidly growing cellular therapy segment**
  - **Competency in cell and tissue processing**
- **Cash flow from Biotech supports development activities in Therapeutics**
- **Advance of cellular therapy candidates through regulatory approval process in Therapeutics**
- **Library of 300,000 DNA samples and 31 million-individual genealogy database**
- **Multiple new products launching in the Laboratory segment**
  - **ARTguide**
  - **Fertility Dx**
  - **ENDORisk**
- **Transform CellSure into dominant source of tissue product for both internal and exteral markets**
- **Development platform that can be applied to many genetic tests and cellular therapy applications**

In the following sections we discuss Predictive's four segments and the markets that each is pursuing. We provide a discussion of the regulatory environment that the company faces in each of its segments and highlight the portfolio of development projects that we anticipate taking place over the forecast period. We provide additional detail on the endometriosis test and market as we see this as a particularly large driver following a broad and successful launch and also a precursor of other broadly available diagnostic tests. We discuss company specific risk factors and provide a review of peer companies. Our valuation, which employs a DCF model, is described in detail with associated model assumptions in the Valuation section. The product of our work generates a target price of $8.00 per share.

Business Subsidiaries

Predictive Technology Group consists of four segments: Predictive Biotech (PB), Predictive Therapeutics (PT), CellSure (CS) and Predictive Laboratories (PL). Each has a distinct focus with PB commercializing regenerative human tissue products that do not make efficacy claims, PT focused on products that will require FDA approval, CS providing procurement of human tissue for allografts to support both PB and PT and providing tissue storage services and PL developing and commercializing genetic diagnostic tests.

Predictive launched its suite of cellular therapies in 2017 and is has experienced dramatic growth as physicians take advantage of this new category of medicine to improve joint pain. The first diagnostic test, ARTguide, is being commercialized in beta, and is expected to be joined in the future by two additional tests designated FertilityDX and ENDORisk. As sales in these segments expand, Predictive will identify high return indications in cellular therapy and pursue an accelerated route to approval. CellSure is in the process of increasing the number of tissue collection hospitals and implementing a thriving placental tissue storage service offering.

Predictive Biotech

Predictive Biotech was created from the acquisition of ReNovo Biotech in March 2016. The parent company of Predictive acquired the group as a wholly owned subsidiary and obtained ReNovo's cellular, tissue, biomaterial and cellular therapy and product candidates. The company recognized the potential of cellular therapy which has the potential to repair, replace and regenerate cells, tissues and organs to restore impaired function. There exists a gap in between the use of pain medication and invasive surgery to address many common pathologies including arthritis, diabetes, Crohn's disease, spinal cord injuries and other conditions. Cellular therapy has shown an ability to address this gap and there are many outstanding clinical trials currently in progress seeking to show safety and efficacy for this emerging therapeutic area.

A variety of tissue sources exist to provide the portfolio of products available in cellular therapy. Sources include peripheral blood, placental, umbilical cord, bone marrow and adipose tissue. These are used to produce platelet rich plasma (PRP), amniotic derivatives, umbilical cord derivatives as well as bone marrow and lipoaspirates. The products are defined by the presence of a variety of cytokines, mesenchymal stem cells (MSCs) and stem cells that are associated with a variety of medical uses including use for wound healing, sports injuries, ophthalmic procedures, dental procedures and others.

Predictive Biotech has concentrated its efforts on placental and umbilical cord tissue for providing its four commercialized products. The products are processed from donated human tissue from full-term deliveries, in accordance with FDA guidelines and intended for homologous use.[1]

Exhibit I – Commercialized Products



[1] Human cell, tissue or cellular or tissue-based products (HCT/P) is considered homologous if it performs the same basic function or functions in the recipient as in the donor.

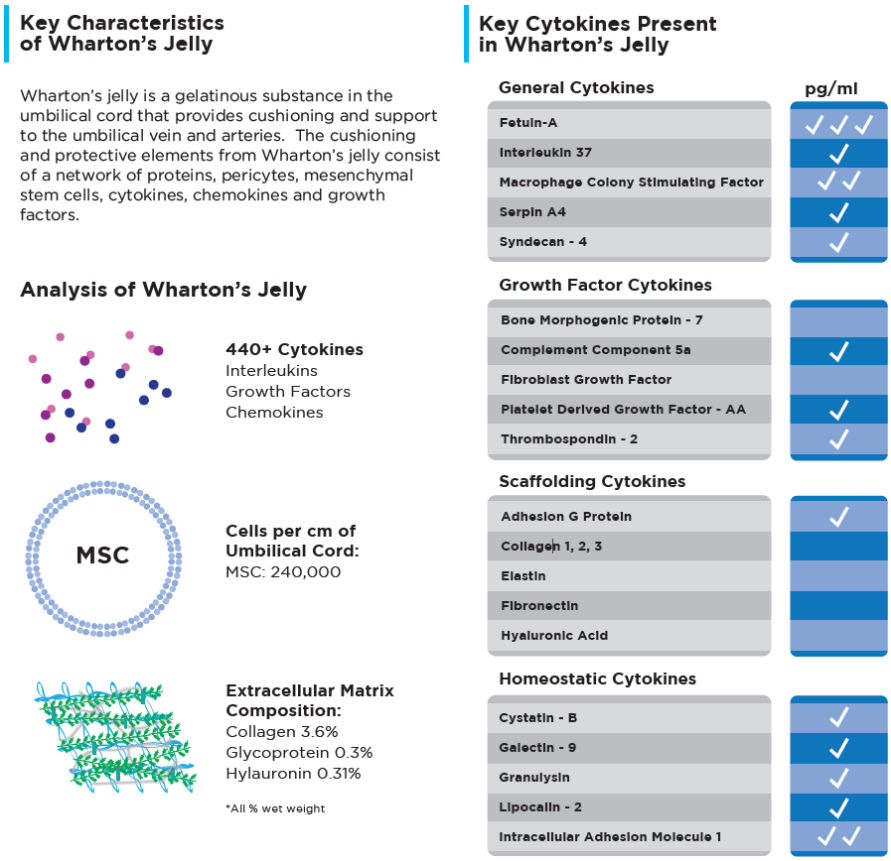
Predictive Biotech's four human cell and tissue products (HCT/P) are collected and handled according to strict criteria observed to maintain functionality and purity. Donors are screened for diseases or behavioral risks, tissues are collected and shipped overnight and sanitized prior to processing, sterility testing is performed while tissue is in quarantine and product is frozen to preserve its favorable characteristics among other protocols. The process follows FDA guidelines and is regulated as a minimally manipulated HCT/P. The regulatory documents that guide its use are 21 CFR part 1271 and Section 361 of the Public Service Health Act. We discuss further in the regulatory structure section.

CoreCyte

The CoreCyte allograft is sourced from the umbilical cord and uses Wharton's Jelly to populate the regenerative factors that make up the product. CoreCyte contains general cytokines such as Fetuin-A and Serpin A4, growth factor cytokine thrombospondin-2, scaffolding cytokines adhesion G protein, a variety of homeostatic cytokines and high levels of mesenchymal stem cells.

CoreCyte is a minimally manipulated human tissue allograft suspension derived from Wharton's Jelly, which is located in the umbilical cord. The product is processed to preserve the biological and structural integrity of Wharton's jelly for homologous use.

Exhibit II – CoreCyte Key Characteristics[2]

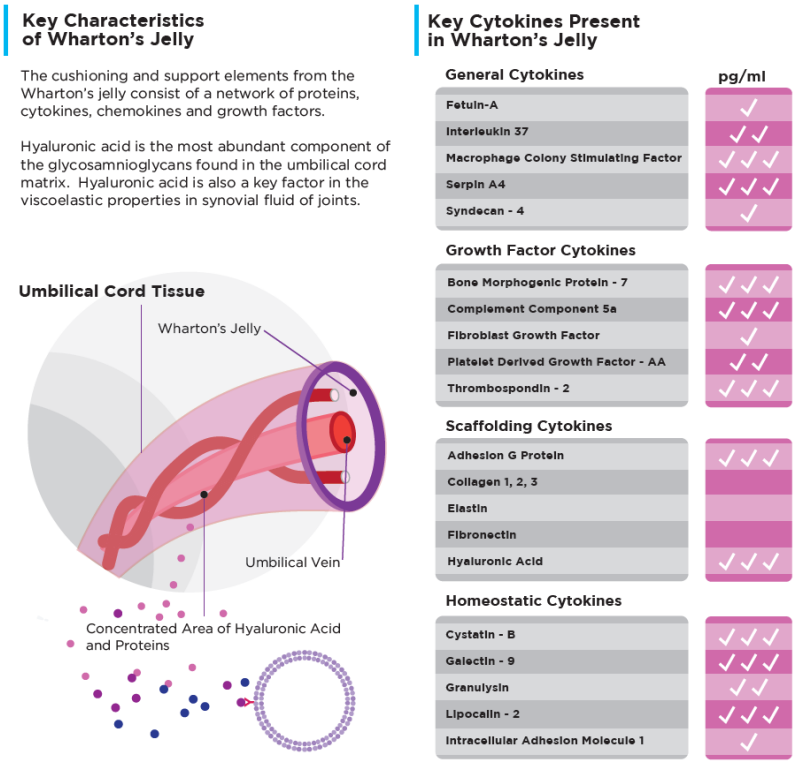


PolyCyte

PolyCyte is also derived from Wharton's Jelly and contains general cytokines, a greater variety of growth factor cytokines compared to CoreCyte, scaffolding cytokines including the adhesion G protein and hyaluronic acid and higher levels of homeostatic cytokines compared to CoreCyte. It is processed to preserve the molecular profiles of cytokines, growth factors and proteins in Wharton's jelly for homologous use.

[2] Number of check marks reflect relative factor amounts as compared to other Predictive Biotech products. All data represented on this grid is informed by either or all available literature, external validation and internal testing. Empty data fields indicate quantities either found in trace amounts, or quantities not specified in literature. Citations and references on file with Predictive Biotech.

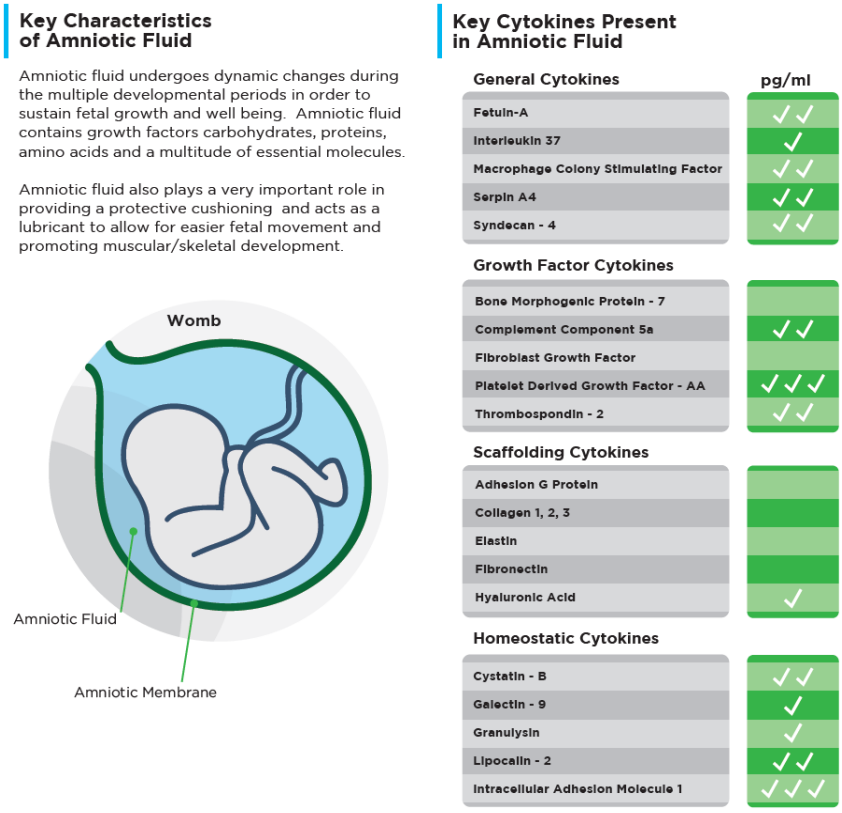
Exhibit III – PolyCyte Key Characteristics



AmnioCyte

AmnioCyte is taken from amniotic fluid and processed to preserve the molecular profiles of cytokines, growth factors and proteins in amniotic fluid for homologous use. It includes a broad selection of cytokines with high levels of Fetuin-A, Macrophage Colony and Lipocalin-2 compared to the other products in the portfolio.

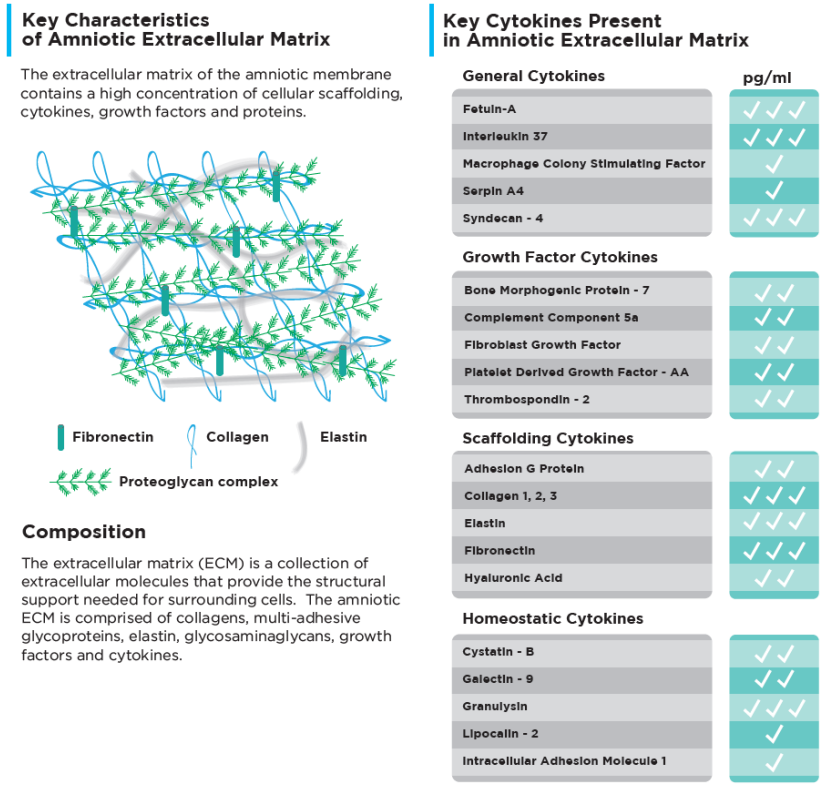
Exhibit IV – AmnioCyte Key Characteristics



AmnioCyte Plus

AmnioCyte Plus is a human tissue allograft suspension derived from the extracellular matrix of the amniotic membrane. The product contains the molecular profiles of cytokines, growth factors and proteins in amniotic fluid for homologous use. More specifically, the extracellular matrix is comprised of fibronectin, collagen, elastin and proteoglycan complexes among other components. AmnioCyte Plus has higher levels of Adhesion G Protein and other scaffolding cytokines, adding Collagen 1, 2 and 3, Elastin, Fibronectin as compared to AmnioCyte. This version also has higher levels of Galectin-9 and Granulysin.

Exhibit V – AmnioCyte Plus Key Characteristics



Pricing

Cellular therapy is not covered by managed care, Medicare or Medicaid and is a cash-pay product. While this status limits the number of potential customers, it does have the benefit of a near immediate reimbursement of the product, the elimination of a layer of distribution costs, minimal payor risk and a transparent and consistent price not constrained by commercial or government program restrictions. Predictive is selling the product at approximately $1,000 per treatment and is shipping it to physicians following payment with credit card or ACH transfer. Given the troubles with revenue recognition at peer companies in the space, it is important to note that Predictive only recognizes revenue after proof of delivery.

As an incentive to carry the product, physicians and providers who purchase greater than $10,000 of inventory are provided a liquid nitrogen freezer that properly stores the product. Having the freezer onsite provides several additional benefits that increase the number and frequency of touchpoints. The freezer equipment cost is from $700 to $1,000 and liquid nitrogen is provided by Air Products. Having the freezer onsite creates goodwill with the physicians' offices as they now can properly store the strictly controlled allografts, maintaining the viability of the stem cells. It also gives the sales representatives an opportunity to perform an on-site visit during freezer maintenance to determine any emerging needs from the provider and increase the visibility of the company.

Sales Team

Predictive Biotech currently has five Regional VPs of Sales, geographically and strategically placed around the United States. They are supported by 14 geographically situated VP of Sales and one internal salesperson led by Chief Sales and Marketing Officer Michael Herbert. The group can support the many distributors, clinics and providers, or over 1,200 touchpoints with the current team. PB anticipates hiring five to ten additional sales representatives over the next year with target expansion areas on the West coast.

Processing Facility

PB's processing facility is located near the corporate headquarters and contains twelve ventilated hood workstations in a clean room. The processing facility has undergone a successful FDA inspection which found no violations related to the method of extraction for umbilical cord tissue. It has recently upgraded its process to improve the volume of cells extracted.

Cellular Therapy Treatment

Cellular therapy has a role in the broader medical treatment model. Physicians use stem cells to address a variety of joint and soft tissue problems that cause pain and inflammation. The Predictive Biotech salesforce may not promote any specific use of the company's cellular therapy products; however, physicians have the experience and training to determine its appropriate use. According to the literature, cellular therapy and stem cell therapy has been used for joint pain and swelling, osteoarthritis, plantar fasciitis, facial rejuvenation, aesthetics and other disorders. Other acute and chronic conditions include neck pain, back pain, headaches, fibromyalgia and wound healing. Frequently, pain relievers are used to address these conditions including opioid-based approaches. Many of these conditions either do not have effective treatments or require expensive, invasive and risky surgery to address. Cellular therapy may have additional benefits beyond pain and would healing. There is a study now underway at the Duke Center for Autism examining the efficacy and safety of umbilical cord blood in improving outcomes for children with Autism Spectrum Disorder. Cellular therapy offers a middle road that may provide the necessary treatment, which can avoid the risks of both opioid-based treatments and surgery.

Predictive Therapeutics

Following the acquisition of Taueret Laboratories, Predictive created PL and transferred responsibility for genetic diagnostic tests away from PT and to PL. After the separation, PT is exclusively focused on developing Section 351 products that require FDA approval for commercialization.

PT is working on developing drug master files (DMFs) that may be shared with partners for future drug or biologic development and will be in support of current good manufacturing processes (cGMP). When the DMFs are available on file at the FDA they may be reviewed if a new drug application (NDA) is submitted by a partner. The DMF, which frequently includes confidential information, is used as a reference for others to develop products based on another's intellectual property. PT has identified four master file biologic products that will submit for reference which we include below:

- Mesenchymal stem cells derived from Wharton's Jelly;
- Cultured and expanded mesenchymal stem cells derived from Wharton's Jelly;
- Cells derived from placental tissue comprised of hematopoietic and mesenchymal stem cells combined;
- Cultured and non-cultured placental tissue cells

PT has plans to develop several anti-inflammatory cellular therapy candidates that fall under Section 351 of the Public Health Service Act. Predictive Therapeutics expects to advance several of its cellular therapy candidates through the regulatory approval process. Most notably, the products that appear to serve the deepest need and have a clear pathway towards approval will be prioritized, such as those addressing indications in osteoarthritis, inflammatory lung disease, graft vs. host disease (GVHD) and bone marrow replacement.

Regulatory Structure for PT and PB

Sections 351 and 361 of the Public Health Service Act provide authority and requirements for marketing traditional biologics, human cells, tissues and cellular and tissue-based products. Each of these Sections promulgates its own specific definition and requirements for products marketed under its purview.

Section 351

HCT/Ps regulated as biological products and that fall under section 351 of the PHS Act require premarket approval and must undergo clinical trials. A biologics license application (BLA) is required following clinical studies and a determination by the FDA that the product is safe, pure and of appropriate potency is necessary before approval is granted. Section 351 summarizes a list of products that are regulated in this category which includes viruses, therapeutic serums, vaccines, blood and blood components, among other products.

Section 361

The sale of human cellular and tissue products (HCT/Ps) is regulated under section 361 of the Public Health Service (PHS) Act and Code of Federal Regulations (CFR) Part 1271. Products subject to the section do not require premarket approval prior to sale. Certain criteria are applicable to the marketing constraints for HCT/P. The tissue must be minimally manipulated, intended for homologous[3] use, generally not combined with other items, and is either not systemic in its effect or falls under certain constraints if it does have a systemic effect. If the HCT/P does not fall under these criteria, it must be regulated as a drug, device or biologic.

Minimally manipulated tissue:

1) For structural tissue, does not undergo processing that alters the original relevant characteristics of the tissue relating to the tissue's utility for reconstruction, repair, or replacement;

2) For cells or nonstructural tissues, does not undergo processing that alters the relevant biological characteristics of cells or tissues.

Amniotic membrane and umbilical cord are considered structural tissues supporting its categorization as minimally manipulated. The tissue must be original, or present in the tissue of the donor and the processing must not alter "the original relevant characteristics of the structural tissue related to its utility for reconstruction, repair or replacement."[4] The definition of minimally manipulated also allows the extraction or separation of cells from structural tissue that does not change its underlying utility.

While a license is not required for sale of HCT/P under section 361, there are certain requirements that include registration with the FDA, submission to the FDA of each HCT/P manufactured product and compliance with applicable requirements.

Predictive Laboratories

PL develops and commercializes diagnostic tests emphasizing fertility, women's health, spine disorders and other genetically diagnosable diseases. Genetic diagnostic testing was transferred from Predictive Therapeutics following the acquisition of Taueret Laboratories in March 2019 and merged into PL. PL currently has three members on its sales team, which we expect to expand in coming quarters as additional products and markets are launched.

Included in the deal with Taueret, Predictive gained rights to genetic data for preeclampsia and related patents that can be used to develop a test for diagnosing this condition. Treatment for preeclampsia is generally early delivery of the baby; however, early delivery can increase the risk for the newborn and is associated with very high neonatal intensive care unit (NICU) costs. If a successful test can be developed, then early treatment to reduce blood pressure can be administered, improving the health of both mother and child. Predictive has gained the rights to this intellectual property as part of the agreement but may return it to Taueret and avoid the final acquisition payment if they decide not to pursue an indication here.

As part of the creation of PL, Predictive's impressive genetic library and research and development platform that previously resided in PT was transferred to PL. The trove of information will be used to identify genetic markers in a genetically diverse US population. The platform has one of the largest DNA libraries related to women's health and has over 30 million different individuals represented in the collection. This resource will provide the necessary data to develop future fertility tests and other diagnostics where genetic markers can augment early diagnosis.

The subsidiary is developing a suite of genetic diagnostic tests for fertility health and endometriosis and anticipates future tests for scoliosis and degenerative disc disease. In October, the first diagnostic test called ARTguide was launched in conjunction with the American Society of Reproductive Medicine Scientific Conference. This non-invasive test is used to determine the likelihood for endometriosis and other genetic causes of infertility for women who plan to use Assisted Reproductive Technologies (ART) such as In Vitro Fertilization (IVF). The PGx Plus+ test is also being marketed and is used by healthcare providers to anticipate adverse drug reactions that can be determined with genomic information. Looking ahead, we expect a number of additional tests to be launched that leverage the in-house DNA library and genealogy database. This includes Fertility Dx, which is the ARTguide test plus expanded carrier screening and chromosomal microarray that provides a comprehensive test for genetic

[3] As defined in 21 CFR 1271.3(c), homologous use means the repair, reconstruction, replacement, or supplementation of a recipient's cells or tissues with an HCT/P that performs the same basic function or functions in the recipient as in the donor.
[4] Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use. Guidance for Industry and Food and Drug Administration Staff. November 2017.

abnormalities. Another product is ENDORisk, which is specifically targeted towards young women with symptoms of endometriosis.

Exhibit VI – Predictive Labs and Clean Room





Genetic Testing

Genetic testing identifies patterns in chromosomes, genes or proteins that may be used to determine genetic forebears, ancestry and the presence of genetic diseases. There are a wide variety of genetic tests that are used to assist in child bearing, including newborn screening, carrier testing, prenatal diagnosis and predictive testing. This last type can estimate the risk of disorders that appear later in life and is particularly useful when a relative has a certain genetic disorder but physically diagnosable evidence of it does not yet exist. One well known example of this type of test is the BRCA gene test that looks for mutations in the BRCA1 and BRCA2 genes.

Genetic testing is recommended for couples that have failed in-vitro procedures, suffered miscarriages and have a history of genetic disease. The tests allow couples to identify embryos that may have genetic defects and others that have a greater chance for viability when implanted in the womb. Some of the common genetic diseases that are amenable to screening include Cystic Fibrosis, Tay-Sachs and Sickle Cell disease. There are few tests that are commonly offered to couples that are seeking fertility treatment including the preimplantation genetic screening (PGS), preimplantation genetic diagnosis (PGD) and next generation sequencing (NGS). PGS can detect genetic abnormalities related to chromosome number and other genetic diseases that can appear in the baby and other conditions such as Down Syndrome. PGD screens embryos prior to their implantation into the womb and can detect breast cancer genes, Spinal Muscular Atrophy and other conditions. This approach may identify any embryos that may not be viable so the mother has the best chance of delivering a healthy baby. NGS is relatively new and can identify genetic markers for disease and help identify the optimal path forward.

The goal of genetic testing is to provide a tool that helps formulate a plan to conceive. Information from the test can help navigate around obstacles that exist and address conditions that may be causing infertility. The testing can also identify genetic abnormalities that can affect offspring. The market for these services is large and Predictive cites a global fertility services market size of near $17 billion growing at a near 10% compound annual growth rate. Genetic testing can take a material share of this market given its importance in selecting the correct approach for improving fertility.

Laboratory Developed Tests (LDTs)

Most genetic tests are not directly regulated, but there are two entities that hold authority to regulate these tests when it is appropriate: the FDA and the Centers for Medicare and Medicaid Services (CMS). The FDA ensures that the test is safe and effective and assesses its clinical validity. CMS, through the Clinical Laboratory Improvement Amendments (CLIA), ensures that the analytical validity of the test is sound and that the test is accurate in identifying its intended marker.

There are three criteria that are used to evaluate the efficacy of a test which include analytical validity, clinical validity and clinical utility. Analytical validity measures whether or not the test can consistently and accurately detect whether a specific genetic variant is present or absent. Clinical validity relates to the strength of the

relationship between the gene being tested and the risk or likelihood of the patient having the disease being measured. Finally, clinical utility measures whether or not the test results will lead to improved health outcomes.

LDTs are developed by hospitals and clinical laboratories using the expertise of physicians and other laboratory professionals located in the lab. These tests can span a broad variety of diagnostic efforts from monitoring basic biomarkers for metabolic diseases to detecting DNA variations in blood samples. New therapies are advancing at a rapid pace and diagnostic tests are critically important for matching the right drug with the right patient. LDTs are regulated under CLIA, which is administered by CMS, and can only be designed, manufactured and used within a single laboratory. This category of test does not require FDA approval but must conform to CLIA standards related to administration procedures, laboratory personnel qualifications, and quality control testing. Requirements for laboratories and their responsibilities under CLIA depend on the complexity of the test. Most molecular genetic tests are classified as moderate to high complexity, and a separate category does not exist for genetic testing. These tests must conform to the basic requirements for high complexity tests and accreditation by an approved organization. In the case of Predictive, the College of American Pathologists (CAP) must accredit the test.

Several individual states also have licensure requirements for laboratory tests that originate in their jurisdiction. Generally the requirements for licensure are for high volume and non-waived tests, but vary depending on state. With the acquisition of Taueret, Predictive gained accreditation from the CAP and CLIA as well as state licensing,[5] which will dramatically accelerate the ability to commercialize offered diagnostic tests that fall under these requirements. PL is in the process of applying for licensure in New York. The state maintains stringent requirements for laboratories and mandates that the laboratory director has a state certificate of qualification. The process to obtain the license usually takes 12 to 18 months. Predictive Labs (under Taueret) applied last year and we anticipate approval could be granted in the near term.

LDTs are intended to fill the gaps where FDA-approved assays are absent or do not satisfy analytical labs' needs. LDTs are also able to apply innovative science and offer it to the public before regulatory agencies can catch up. Both the FDA and CMS regulate genetic tests and provide oversight to ensure the analytical validity of clinical genetic tests; however, they do not validate their clinical utility. The FDA holds enforcement discretion over genetic tests and considers them to be a type of medical device. When a test is designed as an LDT by a single lab and is only used in that lab, the FDA does not require it to undergo the approval process. This may change in the future due to the dramatic growth and prevalence of genetic sequencing. The FDA is now reviewing the regulatory framework for genetic tests but is currently taking a hands-off approach to LDTs that fall into this category.

Despite freedom from the FDA approval process for the LDT, there remain strict regulatory requirements related to collection methods, design controls and quality system requirements. Materials used in the test must be pure and instrumentation used to analyze the data must be robust and capable of precisely measuring critical parameters. LDTs must clearly state that they are not cleared by the FDA and that they do not need to be approved for human testing.

As defined by the FDA, an LDT is an in-vitro diagnostic test that is designed, manufactured and used within a single laboratory. The test can be developed to measure or detect a broad variety of substances taken from the human body, including DNA. If a test is designed or manufactured outside of the lab that offers it, it is not considered an LDT.

CellSure and Procurement Process

CellSure sources all of the human cell and tissue materials for PB. Tissue is collected from umbilical cords and placental material from healthy, full-term deliveries. Predictive's process avoids the use of embryonic or fetal tissue. Donors are given comprehensive medical and social screening which minimizes risks related to disease transmission. Predictive has brought sourcing in-house as it is a critical component of the supply chain and control over collection and handling can improve quality and cells recovered per donation. The segment also performs human leukocyte antigen (HLA) matching to help identify the appropriate allografts for patients.

The segment is organized as a low-profit limited liability company (L3C) and is led by CEO Eric Olson. It is registered as both a public and private storage company that can either hold tissue for individuals who are placing it in storage for themselves (autologous use) or donated tissue that is for clinical trial studies in others (allogenic use). CS received accreditation from the American Association of Tissue Banks (AATB) and the American Association of Blood Banks (AABB).

[5] With the exception of New York

CellSure not only procures tissue for end-market products, but also offers storage of cord blood and stem cells for new mothers. Cord blood is a rich source of stem cells, which can be frozen and later used to treat disease such as leukemia and inherited health disorders. Normal costs for this service range from a few thousand dollars for enrollment, collection and initial storage and then an additional annual fee of ~$100 per year for long term storage. In contrast, Predictive offers collection and five years of storage of cord blood for $199 in conjunction with donation of birth tissue. This provides a compelling benefit for mothers who can store their cord blood and agree to donate their birth tissue for health, science and commercial activities.

The sourcing segment employs a refined process to collect tissue with patient permission for processing and distribution to other users. It uses refrigerated compartments for collection and storage prior to overnight delivery at Predictive's processing facility. The methods used are substantially more efficient compared to competitors' processes due to the focus on temperature and time. Based on Predictive's internal data, the company is able to collect 40 million cells with 80% viability per umbilical cord compared to others in the industry that collect 21 million cells at 66% viability. A simple calculation will show this yields 130% greater volume of useful cells that can be obtained per umbilical cord, attributable to the efficient collection processes and specifically designed refrigeration equipment.

CS' expansion strategy is to develop relationships with hospitals and emphasize their storage bank services that cost substantially less than competing services and become a preferred provider. Efforts in this area are expected to help CS grow to one of the largest tissue procurement entities in the United States that can provide source material to both Predictive and other end users.

Exhibit VII – Procurement & Process for Obtaining Birth Tissue



Purchase of Assets

Taueret Laboratories, LLC

In March 2019, Predictive Technology Group consummated its asset purchase agreement with Taueret Laboratories, LLC and issued warrants for 16.5 million shares of PRED stock. Assets acquired include:

- ~1,000 degenerative disc disease related DNA samples, related family records, relevant clinical records including approximately 600 affected probands and 800 ancestry matched control samples
- Whole exome sequencing data on approximately 300 degenerative disc disease samples, over 800 local controls, and published reference populations, together with initial analysis of the markers
- Project plan, study paperwork, promotional study and materials used in the research study
- Exclusive use of a DNA biobank that has collection over 300,000 samples for multiple diseases that the company may target

In dollar terms, the purchase price was equal to $9.75 million, with $1.2 million paid at closing in Predictive company stock and the remaining balance to be paid on or before December 31, 2020. The assets and personnel that make up Taueret will be consolidated into PL and provide a quality molecular clinical and research facility to support the development and commercialization of predictive analytics and extensive genetic information. PL will be instrumental in developing a portfolio of genetic diagnostic tests for the reproductive health market. In conjunction with the acquisition, Predictive purchased $4.2 million of additional laboratory equipment. The new equipment includes genetic sequencing systems, chromosomal microarrays, DNA extraction and real-time PCR systems among other items.

The acquisition of Taueret provides Predictive with its accreditation from the College of American Pathologists (CAP), the Clinical Laboratory Improvement Amendments of '88 (CLIA) and state licensing requirements. These accreditations and licensing will accelerate Predictive's ability to provide large volume testing services throughout the United States.

Juneau Biosciences

Predictive owns 49% of Juneau and has fully paid for 23% of its interest as of December 2018. The company owes an additional $14.1 million for the remainder of the interest, which is being paid in monthly installments until year end 2020. In November 2015, Predictive acquired LifeCode Genetics which holds an 11.9% share in Juneau Biosciences.

Regenerative Medical Technologies

In October 2018, Predictive entered into an agreement with Regenerative Medical Technologies to acquire certain assets of the company. The assets include a wide variety of genetic testing and collection processes and protocols. The primary assets acquired included:

- Models, methods and protocols for collecting birthing tissue and DNA samples
- Patient registry models, methods and protocols to collect clinical outcomes and electronic medical records
- Designs and methodologies relating to bone marrow aspirate kits, large joint injection kits, degenerative disc disease post-microdiscectomy injection kits, allogenic stem cell products for degenerative disc disease, autism, facet joint and intravenous treatment of opioid addiction

Inception DX

In August 2018, Predictive purchased Inception DX, LLC for 15.5 million shares of common stock. This entity owns laboratory equipment, partial interest in database records for almost 32 million individuals for use in genetic research and 400,000 units in Juneau Biosciences, initial CLIA registration, CLIA lab protocols and other assets. Following the creation of PL, Inception DX was integrated into PL, which already has the CLIA/CAP certifications.

ReNovo Biotech

In March 2016 ReNovo Biotech, Inc. was acquired for its cellular, tissue, biomaterial and cellular therapy products and product candidates. Part of the value of the company is attributed to its protocols to develop amniotic allografts and umbilical cord products.

LifeCode Genetics

LifeCode Genetics, Inc. was acquired in November 2015 for its assay and related services for the prognosis and monitoring of endometriosis in the infertility market. LifeCode was also developing other technologies for women's health issues prior to the acquisition. The company was purchased for 12.3 million shares, equivalent to $30.7 million at the time of the issuance.

Ancestry Database

Predictive acquired an ancestry database that was gathered from over 50 thousand public sources and includes data on over 30 million individuals. The company has been able to use this to de-risk a program before identifying the genetic markers that cause disease. They first worked to identify the markers for endometriosis, and can use it as a platform to identify additional diseases as well.

Access to the database allows the company to query patient characteristics to determine whether or not there are ancestral relationships between people with the disease. For example, when scoliosis is identified in multiple individuals, their lineage is traced back to find similar forebears. They can then sequence the individuals' genomes and identify those markers which suggest the probability that scoliosis will appear.

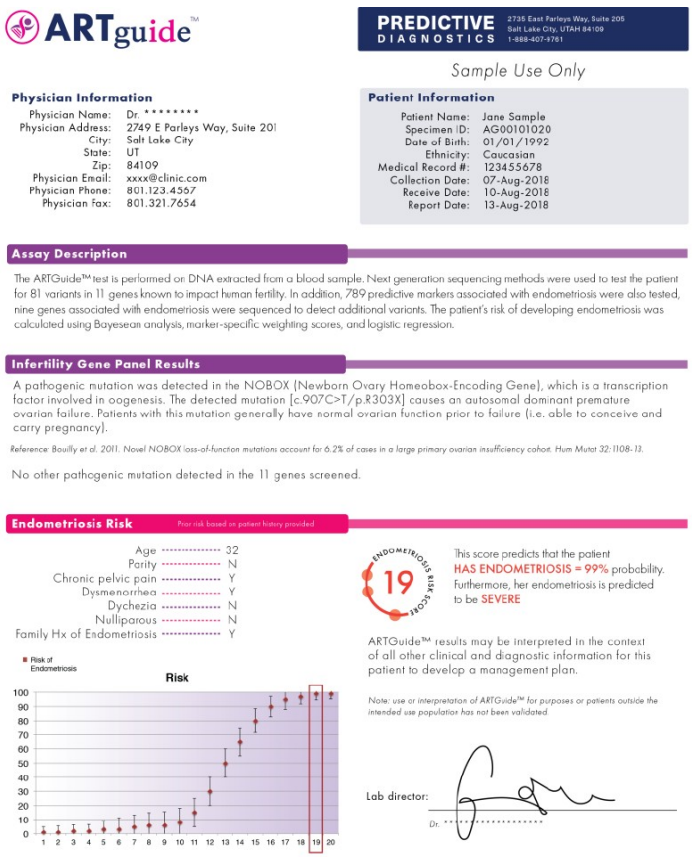
Endometriosis

Endometriosis affects an estimated 200 million women worldwide[6] and is frequently misdiagnosed, preventing its early and proper treatment. While most women affected by the disease are in their 20s and 30s, the first signs appear at puberty. Puberty is also the best time to begin treatment due to the progressive nature of the disorder. While endometriosis can be debilitating if not addressed, it does have a solution: early and accurate diagnosis. And prompt palliative treatment can prevent or delay disease progression. Failing to properly identify and treat endometriosis typically results in irreversible periodic intense pain, infertility, bowel and urinary disorders and other discomfort.

Excluding Predictive's offerings, there are no lab tests available to diagnose endometriosis. This has led to misdiagnosis and the attribution of symptoms to other problems such as ovarian cysts, irritable bowel syndrome, normal monthly period pain or other conditions. As a result, patients suffer from ineffective treatment and a decline in health. A system with both an effective early-stage diagnostic and treatment may relieve symptoms and improve both the health and quality of life for a significant segment of the population.

To address this unmet need, Predictive has developed a diagnostic test called Advanced Reproductive Therapy Guide (ARTguide) to test for genetic causes of infertility. ARTguide and its companion for primary care, ENDORisk, examine sequences in the genome that are associated with endometriosis, and along with a clinical questionnaire, can anticipate endometriosis before the symptoms can be observed. The test looks at eleven different genes that predict a similar number of conditions.

Exhibit VIII – ARTguide Tear Sheet


ARTguide™

PREDICTIVE DIAGNOSTICS
2735 East Parleys Way, Suite 205
Salt Lake City, UTAH 84109
1-888-407-9761

Sample Use Only

Physician Information
Physician Name: Dr. ********
Physician Address: 2749 E Parleys Way, Suite 201
City: Salt Lake City
State: UT
Zip: 84109
Physician Email: xxxx@clinic.com
Physician Phone: 801.123.4567
Physician Fax: 801.321.7654

Patient Information
Patient Name: Jane Sample
Specimen ID: AG00101020
Date of Birth: 01/01/1992
Ethnicity: Caucasian
Medical Record #: 123455678
Collection Date: 07-Aug-2018
Receive Date: 10-Aug-2018
Report Date: 13-Aug-2018

Assay Description

The ARTGuide™ test is performed on DNA extracted from a blood sample. Next generation sequencing methods were used to test the patient for 81 variants in 11 genes known to impact human fertility. In addition, 789 predictive markers associated with endometriosis were also tested, nine genes associated with endometriosis were sequenced to detect additional variants. The patient's risk of developing endometriosis was calculated using Bayesean analysis, marker-specific weighting scores, and logistic regression.

Infertility Gene Panel Results

A pathogenic mutation was detected in the NOBOX (Newborn Ovary Homeobox-Encoding Gene), which is a transcription factor involved in oogenesis. The detected mutation [c.907C>T/p.R303X] causes an autosomal dominant premature ovarian failure. Patients with this mutation generally have normal ovarian function prior to failure (i.e. able to conceive and carry pregnancy).

Reference: Bouilly et al. 2011. Novel NOBOX loss-of-function mutations account for 6.2% of cases in a large primary ovarian insufficiency cohort. Hum Mutat 32:1108-13.

No other pathogenic mutation detected in the 11 genes screened.

Endometriosis Risk — Prior risk based on patient history provided

Age 32
Parity ..... N
Chronic pelvic pain ..... Y
Dysmenorrhea ..... Y
Dychezia ..... N
Nulliparous ..... N
Family Hx of Endometriosis ..... Y

Risk of Endometriosis

Risk

100 90 80 70 60 50 40 30 20 10 0

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20

ENDOMETRIOSIS RISK SCORE 19

This score predicts that the patient HAS ENDOMETRIOSIS = 99% probability. Furthermore, her endometriosis is predicted to be SEVERE

ARTGuide™ results may be interpreted in the context of all other clinical and diagnostic information for this patient to develop a management plan.

Note: use or interpretation of ARTGuide™ for purposes or patients outside the intended use population has not been validated.

Lab director:

Dr. ********

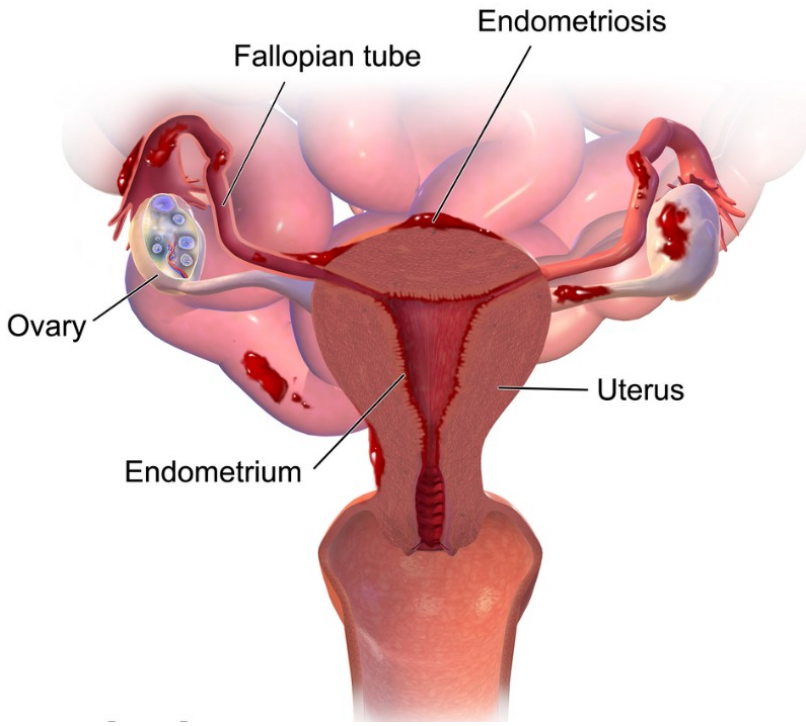
Endometriosis is condition in adolescent to middle-age females where the tissue that lines the uterus begins to proliferate in other parts of the body. This tissue will grow and bleed in response to hormonal changes during

[6] Endometriosis Foundation of America. https://www.endofound.org/endometriosis

ovulation. Women with the disorder are of menstruating age and suffer from a variety of pain related symptoms. According to the American Society of Reproductive Medicine, up to 50% of women with endometriosis suffer from infertility. A similar percentage of all infertile women suffer from endometriosis.[7]

Endometrial tissue, which normally lines the uterus, is sometimes located outside of it. Ectopic endometrial cells are most commonly found on the ovaries, fallopian tubes, and on the bowel and bladder. These cells or lesions inflame and bleed every month in response to the hormonal cycle. Estrogen and progesterone regulate the growth of endometrial tissue by stimulating and inhibiting cell proliferation. With the passage of years, scarring, inflammation and organ dislocation occur causing adhesion between areas where the ectopic endometrial tissue grows.[8] Genetic factors are understood to contribute to the disorder.

Exhibit IX - Location of Ectopic Endometrial Tissue[9]



Endometriosis is difficult to diagnose and can be mistaken for other conditions such as appendicitis, ovarian cysts, fibroids or a number of other disorders. Most women are diagnosed based on the symptoms presented along with a sonogram or MRI, but these results are usually inconclusive. A laparoscopy is frequently performed to provide a conclusive assessment and requires surgery and examination of the uterus and surrounding tissue. This invasive approach is costly and unpleasant.

Genetics plays a role in endometriosis. Studies have shown that sisters, mothers and daughters of those affected are 5 to 7 times more likely to have the disease.[10] Additional work has been performed to identify a genetic signature for predisposed women.

While there is no cure, there is treatment for endometriosis which can include surgery, hormones and the use of painkillers. The combination of birth control and NSAIDs is one common approach and in more serious circumstances laparotomy or hysterectomy may be performed. If taken early, hormone treatments can prevent the endometrial tissue from proliferating and limit the damage. The hormones can inhibit ovulation and reduce estrogen levels. Progesterone specifically can decrease the activity of estrogen receptors, which has several beneficial effects on the disease through growth inhibition of endometrial tissue as well as reducing blood vessel growth, reduction of inflammation and moderation of the menstrual cycle.

[7] https://www.fertstert.org/article/S0015-0282(12)00585-7/pdf
[8] http://endometriosis.org/endometriosis/adhesions/
[9] Blausen.com staff (2014). "Medical gallery of Blausen Medical 2014". WikiJournal of Medicine 1 (2). DOI:10.15347/wjm/2014.010. ISSN 2002-4436
[10] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4346178/

Diagnostics

The approved and in-development products for endometriosis are good news for Predictive. The ARTguide test assists in-vitro fertilization (IVF) specialists and patients in determining the optimal course of care for fertility treatment, accounting for the effects of endometriosis and other genetic causes of fertility. ENDORisk is focused on identifying patients at a high risk for endometriosis and can guide the prescription of one of the FDA-approved treatments available.

Apart from a laparoscopy which is invasive and may cost from $8 to $20 thousand per procedure, there are no tools to diagnose early stage endometriosis. The lack of an inexpensive and non-invasive test has left many women undiagnosed and a large population with an unmet need. Following the launch of ARTguide, we anticipate that Predictive Therapeutics will seek out partnerships with peers offering endometriosis therapies to the non-infertility markets. We highlight the importance of having an effective diagnostic tool for any disease that can be easily misdiagnosed. The lack of a proper evaluation can result in a patient being denied timely treatment or being given potentially toxic and improper medications.

Exhibit X – ARTguide Fertility Panel

Gene Symbol	Gene Name	Condition(s)
FOXL2	Forkhead Box L2	Primary Ovarian Insufficiency
FSHR	Follicle Stimulating Hormone Receptor	Ovarian Dysgenesis 1, Ovarian Hyperstimulation Syndrome, Ovarian Response to FSH Stimulation
LHB	Luteinizing Hormone Beta Polypeptide	Hypgonadotropic Hypogonadism
LHCGR	Luteinizing Hormone/Choriogonadotropin Receptor	Luteinizing Hormone Resistance, Female: Leydig Cell Hypolasia with Hypergonadotropic Hypogonadism
NOBOX	NOBOX Oogenesis Homeobox	Premature Ovarian Failure 5
NR5A1 (SF1)	Nuclear Receptor Subfamily 5 Group A Member 1	Multiple associated syndromes of sex reversal, POF, POI
PATL2	PAT1 Homolog 2	Oocyte Maturation Defect 4
POF1B	POF1B, Actin Binding Protein	Premature Ovarian Failure 2B
ZP1	Zona Pellucida Glycoprotein 1	Oocyte Maturation Defect 1
ZP3	Zona Pellucida Glycoprotein 3	Oocyte Maturation Defect 3
FMR1	Fragile X Mental Retardation 1	Fragile X Syndrome; Premature Ovarian Failure

The ability to accurately diagnose women with the disorder is critical for treating the population with the unmet need. It is also important from a payor's perspective and can improve the likelihood of formulary inclusion. Payors value a diagnostic test that can identify the appropriate population for treatment, as they are only providing medicine for patients that will respond, resulting in lower but more appropriate usage and better outcomes.

Predictive's plan to launch ENDORisk is expected to be followed by a treatment option. The company is planning to develop a pipeline of therapies from both internal efforts and external partnerships to treat early to advanced stages of the disease. One potential therapy being pursued is a combination of progesterone/progestin with a non-steroidal anti-inflammatory.

The strategy for commercialization of ARTguide is to target the top ten metropolitan areas for infertility services and offer it in these high volume areas. Over the last couple decades, infertility services have gravitated towards centers of excellence in a few major metropolitan areas, and patients have been willing and able to travel to the locations with the best reputations. This concentration of fertility clinics has made it efficient for companies with fertility and women's health products to communicate and educate providers about their value. Predictive believes it can effectively develop the ARTguide and Fertility Dx line of diagnostics with an eight to ten person salesforce and effectively penetrate 80% of the United States market.

To discover the potential for a diagnostic test in the infertility markets, Predictive commissioned a study targeting infertility specialists to gauge interest in prescribing ARTguide. It found that there was significant interest in the test and a third of the physician respondents would offer the test to all of their new patients on their first visit. Based on company estimates assuming penetration into just 12 of 480 US clinics, each with nine physicians, ARTguide and Fertility Dx could generate over $150 million in revenues.

In-Vitro Fertilization

Since the first successful birth in 1978 using IVF treatment, the procedure has become commonplace and it is estimated that by 2012 approximately 5 million children had been born using these techniques.[11] According to Grand View Research the IVF market was approximately $17 billion in 2018 and is forecast to grow at about 10% per annum. The Grand View report identifies 6.7 million women in the US suffering from infertility, or 11% of women of reproductive age. Another factor contributing to the increased need for IVF and other fertility services is that women are bearing children later in life as compared to previous generations. Fertility declines with age, which results in increasing numbers of individuals who want to have children seeking IVF treatment.

The cost of IVF treatments can be high with expenses of $12,000 to $15,000 per IVF cycle, plus additional medication costs of another $3,000 to $5,000. Total costs average around $20,000 per cycle, which are usually out of pocket and not covered by insurance. Success rates of IVF treatment vary by age, but on average range from 30% to 40%, suggesting that the average woman pursuing this route will need about three attempts to take a baby home. With difficult success rates and high costs, potential parents have every incentive to use every tool at their disposal to ensure their baby is healthy.

These statistics outline an attractive market that has space for a higher quality competitor that can offer less expensive and more comprehensive diagnostic testing. With the large out of pocket expenditure that individuals and couples expect and a strong desire to take all the precautions ensure a successful pregnancy, there is little sensitivity to the cost of additional tests which may increase the likelihood of taking a healthy baby home.

NASDAQ Uplisting

Predictive currently trades on the over the counter (OTC) markets and has submitted an application to the NASDAQ. The company received comments back from the NASDAQ in late May and expects to file responses in June. This action was preceded by the necessary prerequisite of filing of Form 10 in December 2018 and subsequent filings of the second and third quarter 10-Qs. The NASDAQ has several requirements regarding number of shareholders, market makers, market value, asset value and share price among others. Predictive satisfies all of the requirements and may be uplisted to the exchange this month.

[11] Adamson, G.D.; Tabangin, M.; Macaluso, M.; Mouzon, J. de (2013). "The number of babies born globally after treatment with the assisted reproductive technologies (ART)". Fertility and Sterility. 100 (3): S42. doi:10.1016/j.fertnstert.2013.07.1807.

Corporate Strategy

Predictive has launched an exciting portfolio of companies that are on the leading edge of cellular therapy and diagnostic testing. Consumers' needs are evolving and the company has developed a strategy to identify high-impact products and distribute them to physicians and patients. Each business segment has its own defined objectives summarized below.

Predictive Therapeutics:

- Utilize data from cellular therapy use to identify the optimal clinical pathway to pursue FDA approval
- Seek indications that can be easily commercialized and rapidly approved
    - Endometriosis and other women-focused indications
    - GVHD
    - Osteoarthritis
    - Lung Disease

Predictive Biotech:

- Educate market on offerings in cellular therapy/Recognition as thought leader
- Expand salesforce to penetrate West coast and other regions
- Pursue providers in diverse areas
    - Osteopaths
    - Orthopedics
    - Chiropractors
    - Integrated practices
    - Group purchasing organizations
    - Industry conferences

Predictive Laboratories:

- Identify high density fertility markets and launch targeted marketing to these providers
    - ARTguide
    - Fertility Dx
- Commercialize ENDORisk
- Develop additional diagnostics that leverage IP and databases

CellSure:

- Provide tissue collection and cord blood storage services in partner hospitals
- Seek additional hospitals and birthing centers to provide services
- After satisfying PT and PB tissue needs can sell surplus

Key Events

- Launch of ARTguide – October 2018
- Acquisition of Regenerative Medical Technologies – October 2018
- Acquisition of DNA & Ancestry Assets – October 2018
- Acquisition of Inception Dx – September 2018
- Acquisition of Taueret Laboratories – March 2019
- Launch of Fertility Dx – 2019
- Launch of EndoRisk – 2020
- Clinical Trials for selected cellular therapy indications - 2020

RISKS

All investments contain an element of risk which reflects the uncertainty of the business and what it will ultimately achieve. Some investments exhibit higher predictability, with current cash flows and established sales. These enterprises will have a lower level of perceived risk while other companies that are betting on an emerging technology will have a much higher level.

The biotechnology space includes companies at both ends of the spectrum, from mega-cap pharmaceutical powerhouses that have multiple products currently generating revenues, to small operations with a handful of employees conducting pre-clinical studies. Many of the risks faced by the large pharmaceutical companies and smaller biotechnology-focused firms are similar; however, there are some hazards that are particular to smaller companies that have not yet established themselves or their products.

For smaller early-stage companies, investing in commercialization and drug development is an extended process. The timeframe for conducting pre-clinical research to eventually marketing a biologic can take from 12 to 15 years or even longer given market conditions. And with, on average, only one in one thousand compounds eventually making it to the market, the risks are substantial. Commercialization is also fraught with risk. Hiring a sales force is expensive and costs are upfront. Success relies on distributors and sales representatives, many of which are outside the control of the company. Other risks are faced in areas where government regulation is not clearly defined. Predictive Technologies is now commercializing cellular therapy products and diagnostic tests which are only lightly regulated by the FDA and CMS/CLIA. If additional regulations are promulgated, Predictive may have to withdraw its revenue-generating products and tests and pursue regulatory approval, which may be time consuming and expensive.

Currently, Predictive Technologies is commercializing human cellular and tissue products and diagnostic tests. A variety of entities regulate these products and tests including the FDA, CMS (via CLIA) and accrediting agencies. Additional regulatory requirements may emerge, requiring additional time and expense to meet new obligations. Predictive also anticipates seeking approval for specific indications for members of its cellular therapy portfolio, which will require clinical trials and a biologics license application (BLA) with the FDA. Based on the data provided in Clinical Development Success Rates,[12] NDAs and BLAs have about a 10% chance of ultimate approval when in Phase I, increasing as they move through the subsequent phases. Predictive will have access to real world data regarding the safety and efficacy of their cellular therapy products, which may improve the likelihood of success compared to industry averages.

Predictive's current portfolio of cellular therapy and diagnostic tests do not require FDA approval as they fall under exemptions for minimally manipulated tissue and LDTs. Despite this current status, the FDA may change the requirements for qualification under Section 361 or mandate regulation for LDTs. If implemented, these requirements could result in a halt and/or delay of product sales until they are granted approval by the relevant regulatory authority.

FDA or other governmental regulatory approvals are a material uncertainty to which all drugs and biologics must submit before they are legally marketed. Substantial expense is undertaken to bring a molecule or compound through clinical trials and address all of the regulatory agencies' concerns. Isolating companies that have a long history of research success in drug development, with opinion leaders and experts in the field are key elements that can help mitigate this risk. Companies that have had previous success with the FDA or other regulatory agencies also are more attractive than those who may be new to the process. Some accelerated pathways to approval have been put forth such as the Orphan Drug Act; however, changes in sentiment or perceived safety of pharmaceuticals or drugs could change the regulatory environment to demand a more thorough process and these pathways may be extended or additional requirements may be put in place.

Even under a scenario of growing revenues, emerging companies need to invest in many areas to continue their trajectory. This requires funding which may be difficult to secure. Access to financing comes and goes in cycles. During periods of improving confidence, capital may be easy to access; however, during a liquidity crisis or a period of heightened risk perception, even companies with bright prospects may be in trouble if they are dependent on the financial markets to fund their growth. If capital is needed to sustain the company and it is not readily available, it may be forced to suspend operations, sell equity at a substantial discount to previous valuations and dilute earlier

[12] Clinical Development Success Rates 2006-2015. David W. Thomas, Justin Burns, John Audette, Adam Carroll, Corey Dow-Hygelund, Michael Hay.

shareholders. A lack of funding may leave potentially promising products without a viable route to move forward or force a company to accept onerous terms.

Contract research organizations (CROs) maintain a large role in the development of drug candidates in an environment of high complexity and cost. Finding appropriate populations to participate in clinical trials has become increasingly difficult due to the shift to personalized medicine and orphan indications that address only a small population. This shift has escalated the dependence on these specialized CROs for enrollee sourcing, project management and clinical monitoring services which add additional risks and dependence on third parties. We anticipate Predictive will face these risks as they move their cellular therapy portfolio into the clinic.

Drug price inflation has gained increased attention over the last several years and has contributed materially to the increase in health care costs over the last decades. As new therapies have been approved, drug prices have set new records and increased at a substantial rate. Predictive is somewhat insulated from a backlash from these trends since managed care, government programs or other payors do not mediate their products and services. The absence of these intermediaries for Predictive's product set reduces the distortion that occurs from opaque pricing, tempering extremes that allow prices to exceed what an individual could be reasonably expected to pay. This allows market forces to play a role in near-term commercialization both of the cellular therapy and diagnostic testing markets.

While regulation many times creates an expensive hurdle that requires time and funding to address, it does more thoroughly identify risks of using a specific drug or biologic. Some view regenerative medicine as the "wild west" of treatment where physicians lack FDA-approved indications to guide their efforts. LDTs are another area where concerns have been raised regarding interpretation and quality of results that have not traversed the formal regulatory review process that more broadly used tests have. Predictive's currently marketed products do fall under a lighter regulatory aegis; however, the company plans to pursue regulatory approval for new indications in cellular therapy and for broadly used diagnostic tests such as the one for endometriosis.

While we have discussed a broad variety of risks above, we believe that our forecast parameters, discount rates, success probabilities and valuation metrics address these eventualities and our target price reflects an assumption of these risks faced by Predictive Technology Group and others in the biotechnology industry.

PEERS AND COMPETITORS

The cellular therapy and diagnostic testing spaces are fragmented with a broad cross section of companies vying for a foothold. With fewer regulatory constraints than approved pharmaceuticals, quality control can be a risk, allowing companies with strict controls and standards to differentiate themselves. The industry includes companies that are developing stem cell therapies, cellular immunotherapies, direct cell reprogramming, cellular scaffolds and matrices, gene therapies, tissue engineering and other related efforts. Diagnostic testing spans both consumer and physician end-market testing. While they emphasize different markets, consumer desire to understand their genetic predispositions will be a favorable tailwind for companies in the space. One of the larger and more favorable markets for testing is the fertility and newborn market. There is an inelastic desire for parents to understand how best to conceive and what risks their offspring may face. We include a list of the most relevant peers and competitors below in cellular therapy and diagnostic testing, ranked by market capitalization for public companies. Private companies comprise a large portion of this market, contributing to its fragmentation. As cellular therapy and diagnostic testing become more accepted, we anticipate consolidation of the strongest players.

Exhibit XI – Peer and Competing Companies[13]

Ticker	Company	Price	MktCap (MM)	EV	Therapeutic Area
ABBV	AbbVie Inc.	$76.95	$113,757	$147,150	Markets Orilissa, a non-peptide small molecule gonadotropin-releasing hormone antagonist for women with endometriosis pain.
MYOV	Myovant Sciences	$9.20	$824	$649	Developing relugolix for endometriosis
NVTA	Invitae Corp	$19.91	$1,790	$1,540	Reproductive health, proactive health, diagnostics via genetic testing. Analyzes patient specific genetic variation & generates test reports
OFIX	Orthofix	$52.76	$1,010	$944	Stem Cell Development
AXGN	AxoGen Inc	$19.32	$756	$703	Nerve grafts. Surgical soft tissue allografts. Touch and strength measurement devices.
VCEL	Vericel	$15.26	$670	$637	Stem cell development. Markets autologous cell therapy products including MACI & Carticel, both intended for cartilage repair.
OBSV	ObsEva SA	$11.33	$515	$402	Developing linzagolix for endometriosis
MESO	Mesoblast Ltd.	$5.10	$506	$512	Allogeneic cellular medicines. Cell therapy platform based on specialized cells known as mesenchymal lineage adult stem cells.
MDXG	MiMedx Group	$4.80	$522	$553	Allogenic stem cell. Develops and markets regen biologics with human placental tissue allografts
ATHX	Athersys	$1.61	$241	$190	Development of MultiStem, adult-derived allogenic stem cell product platform, for multiple disease indications in various disease areas.
ONVO	Organovo	$0.57	$74	$23	Bioprinted human tissue
PSTI	Pluristem Therapeutics	$0.59	$89	$81	R&D & manufacture cell of therapeutic products & related technologies for treatment of ischemic, inflammatory, and hematologic conditions
RNUGF	ReNeuron	$3.08	$101	$119	UK-based stem cell research company targeting peripheral arterial disease, strokes, and retinal diseases
ISCO	International Stem Cell Corp	$0.74	$5.5	$7.0	human parthenogenetic stem cells (hpSC) to treat severe diseases of the central nervous system, joints and liver
CUR	Neuralstem	$0.37	$7.4	$3.5	Stem Cell Development. Human neuronal stem cells and small molecule compound products.
PRED	Predictive Tech Group	$6.48	$1,766	$1,764	Develops & commercializes novel molecular diagnostics & HCT/Ps

[13] Price and market capitalization data is as of June 10, 2019

Company	Therapeutic Area
Aegle Therapeutics	MSCs for dermatological disorders
BlueRock Therapeutics	Use Cell+Gene platform to develop, manufacture and deliver native cell and engineered cell therapies; produce native cell therapies to replace damaged or degenerated tissue
DiscGenics	RM for alleviating pain & restore function for degenerative spine diseases
Micromatrix	Development of fully biological human organs utilizing its patented perfusion decellularization/ recellularization technology
Nohla Therapeutics	Ex-vivo stem cell expansion & directed differentiation based on the density-dependent Notch ligand platform that uses purified CD34+ cord blood stem and progenitor cells
Orbsen Therapeutics	Use of allogeneic stromal cells for foot ulcers & kidney disease
Invitrix Therapeutics	Stem cell regenerative medicine developing autologous tissue grafts for burn patients; cord blood stem cells, amniotic tissue & fluid and Wharton's Jelly
Burst Biologics	RM, fluid allografts for I-O, CNS diseases
Regenerex LLC	Allogeneic cell therapy product to induce tolerance in organ transplants
DotLab	micro-RNA biomarker test; women's healthcare; endometriosis diagnostics
ReceptivaDx	Biopsy of endometrium tissue
Regenerative Patch Technology	Cell-based implant technology for the treatment of retinal diseases
SCM Lifescience	Provides stem cells and CMO services. Pursuing several indications in GVHD, acute pancreatitis, atopic dermatitis & liver cirrhosis.
Semma Therapeutics	Curative use of stem cells in regenerative medicine for Type 1 Diabetes
Sentien Biotechnology	Combines MSCs within an approved blood-filtration device. They are natural bone marrow cells that have anti-inflammatory properties
StemBioSys	Produce cell culture systems for stem cells
Unicyte	RM program for chronic kidney disease in 3 platforms: human liver stem cells, functional pancreatic islets, nano-extracellular vesicles
ViaCyte	Differentiates stem cells into pancreatic beta cell precursors for insulin production
Helix	consumer DNA testing
Sure Genomics	Personal genome testing company. Sequence & store genome.
ORIG3N	Genomic testing. Genetic repository.
Atlasbiomed	DNA & Microbiome testing
Pathway Genomics	Retail & physician testing in fitness, nutrition, skin, mental health, pain, cardiac and carrier status testing.
Counsyl	Genetic test & DNA screening for baby & family
Color Genomics	Analysis of genes for risk of disease (breast cancer)
Centogene	Genetic testing & whole genome sequencing; genetic database of rare diseases
CiceroDx	ReceptivaDx endometriosis test. biopsy of endometrium tissue
Veritas Genetics	Genetic sequencing & interpretation. requires provider order before genetic sequencing
Xcode Life Sciences	Personal genomics. Preventative healthcare focus.

MANAGEMENT PROFILES

John E. Sorrentino, Chairman of the Board and Chairman of Scientific Advisory Board

Mr. Sorrentino is Vice-President and Chief Operating Officer of Vaccine Research and Development at Pfizer. During his more than 35 years of senior management experience in the life sciences industry, Mr. Sorrentino has held leadership roles in private and public companies, as well as government and non-profit institutions, with a focus on improving public health. Prior to joining Wyeth (later acquired by Pfizer) in 2004, Mr. Sorrentino held executive positions in several organizations that provided neonatal screening and related clinical services. Mr. Sorrentino's expertise has had him appear before state legislators, the US Congress and professional societies on a variety of healthcare and policy issues.

Mr. Sorrentino brings significant leadership experience in R&D, commercialization and clinical laboratory management that are valuable additions to the Company's Board of Directors.

Bradley C. Robinson, President and Chief Executive Officer / Director

Mr. Robinson was appointed CEO of Predictive in March, 2015. Mr. Robinson brings operational, business development and financing experience developed during early stage structuring of ventures in the areas of pharmaceuticals, medical device and information technology. He was a founding member of LifeCode Genetics, LLC in 2011 and Predictive Therapeutics, LLC in 2013, both of which are now wholly owned subsidiaries of the Company. Mr. Robinson has been a founding member of other ventures in healthcare, one of which, Specialized Health Products International, Inc., was publicly traded until its acquisition in March of 2008 by C.R. Bard. Mr. Robinson was the CEO and co-founder of Infusive Technologies, LLC from November, 2004 until September, 2008 when it was acquired by Sagent Pharmaceuticals, Inc., a specialty injectable pharmaceutical products company. As part of the acquisition, Mr. Robinson became President of the medical device division of Sagent Pharmaceuticals. He left Sagent Pharmaceuticals in 2010 to become Vice President of Business Development of Juneau BioSciences, which develops and commercializes genetic tests related to women's healthcare. He was responsible for developing strategic partnerships and the company's capitalization. Mr. Robinson studied accounting at the University of Utah and earned an MBA/MIM from the Graduate School of International Management (Thunderbird).

Michael Dey, Ph.D, CEO of Predictive Therapeutics / Director

Michael Dey, Ph.D., was elected as a member of the Board and CEO of Predictive Therapeutics in June of 2016. Prior to joining Predictive Therapeutics, Dr. Dey was an executive at Wyeth where he was the President of Scientific Affairs for Wyeth's Women's Health Care business. Previously, Dr. Dey was the President of Wyeth Women's Health Care which he managed for 7 years. Dr. Dey had worldwide responsibility for this consolidated unit of more than $3 billion in annual revenues that included all of Wyeth's Women's Health Care resources. Prior to his leadership role in women's health care he served as Vice President, General Manager of ESI Pharma, Inc. In 1995, with Wyeth's acquisition of American Cyanamid and Lederle Standard Products, Dr. Dey became President of ESI Lederle, Inc. where he directed one of the largest generic drug companies in the U.S. with more than $500 million in sales, approximately 150 employees in R&D and 100 employees in Marketing and Sales. ESI Lederle sold both oral and injectable products that included Tubex, the prefilled syringe delivery system. Dr. Dey received a BS in Biology/Chemistry from Western Washington University, a Pharmacy degree from the University of Washington, a MS degree in Pharmacology-Toxicology from the University of California, Davis, and a PhD in Pharmacology-Toxicology from Washington State University.

Eric Olson, Executive Vice President and CEO of Predictive Biotech

Mr. Olson is Executive Vice President and the founder and Chief Executive Officer of Predictive Biotech, Inc. since he joined the Company in 2016. His previous experience includes over 25 years developing and commercializing innovative technologies in devices, diagnostics, biologics and biomaterials. During the last 8 years of his career, Mr. Olson has served in the role of either President, CEO or Board Member. Prior to joining Predictive Technology Group, Mr. Olson was the President and CEO for Cupertino, CA based Skeletal Kinetics where he developed and commercialized synthetic bone substitute products for Orthopedic and Spinal applications. Previous to that, Mr. Olson was the President, CEO and Board Member for Amedica Corporation. Amedica manufactured and distributed cortical and cancellous silicon nitride ceramic interbody devices for spine. In addition, the company distributed a line of HCT/Ps designed to work in conjunction with the ceramic biomaterial. Mr. Olson took Amedica Corporation public in 2014. Mr. Olson began his career with Smith & Nephew and has worked with Johnson & Johnson, Medtronic and Wright Medical in Sales and Marketing leadership roles. Mr. Olson earned his BS in Behavioral Science and Health Administration degrees from The University of Utah.

Paul Evans, Chief Operating Officer

Mr. Evans was appointed Chief Operating Officer of Predictive in June of 2018. Prior to joining the Company, Mr. Evans was Vice President of Intellectual Property at Vivint, Inc. from 2014 to 2015, where he led the development, management, and enforcement of Vivint's intellectual property portfolio across the company's entire platform of smart home solutions, including security and surveillance, smart home control, wireless internet, and cloud storage. From 2010 to 2013, Mr. Evans was General Counsel, Executive VP of Corporate Development, and Chief Governance and Compliance Officer at InTouch Health, a leading provider of telehealth enterprise network and managed services to hospitals and healthcare systems for the delivery of specialty clinical care to patients. Prior to joining InTouch Health, Mr. Evans was an attorney with Stoel Rives LLC from 2008 to 2010. From 2000 to 2008, he was General Counsel, VP of Business Development, Chief Governance and Compliance Officer of Specialized Health Products International, Inc., a medical device company acquired by C.R. Bard in 2008. Mr. Evans earned his BS in Mechanical Engineering, JD, and MBA degrees from The University of Utah.

Simon Brewer, Chief Financial Officer and Treasurer

Mr. Brewer was appointed as Predictive's Chief Accounting Officer in January of 2018, and Chief Financial Officer in July of 2018. Prior to joining Predictive, Mr. Brewer served as CFO of Norbest, LLC from 2016 to 2017, where he was responsible for finance, accounting, HR and IT functions. Previously, Mr. Brewer was Vice President, Finance and IT for Wilson Electronics, LLC from 2013 to 2016. Mr. Brewer oversaw significant growth for the electronics company operating in all 50 states and internationally in several countries. Mr. Brewer assisted heavily in building scalable processes, modernizing the business, international growth in Asia, and an acquisition of a main competitor. Before that, he was Senior Director and Corporate Controller for Backcountry.com, Inc. from 2009 to 2013. Mr. Brewer implemented Sarbanes Oxley when Backcountry.com was purchased by a publicly traded company, Liberty Interactive, as well as started the FP&A function for modernizing data driven decision making. Mr. Brewer started his accounting career as a CPA for KPMG LLP from 2005 to 2009, working on audits, IPOs, bankruptcies, divestitures, and acquisitions. Mr. Brewer received his BA and Masters of Accounting degrees, along with a minor in Russian, from The University of Utah. Mr. Brewer is a CPA licensed in Utah and Nevada.

Dr. John C. Nelson. M.D., M.P.H, Chief Medical Officer

John Nelson, M.D., was appointed Chief Medical Officer of the Company in January, 2018. Dr. Nelson, MD, MPH is an obstetrician and gynecologist from Salt Lake City, Utah. Dr. Nelson has served as President of the American Medical Association, Salt Lake County Medical Society and the Utah Medical Association. He was also chair of the Finance and Planning Committee of the World Medical Association. He served on the Advisory Committee to the Director of the National Institutes of Health (NIH) as well as on the advisory committee for the Agency for Healthcare Research and Quality (AHRQ). He has been a lecturer on detecting and preventing interpersonal violence having served as spokesperson for the American Medical Association Alliance. He was a charter member of the Prospective Payment Assessment Commission (ProPAC) now known as MedPAC.

Michael Herbert, Chief Sales and Marketing Officer

Michael Herbert was appointed Chief Marketing Officer in February of 2017 and assumed the additional role of Chief Sales Officer in April 2019. Prior to joining Predictive, Mr. Herbert was Chief Marketing Officer at Flagship Health Group 2011 to 2017, where he worked with many of the top insurers on their go-to-market strategies. Mr. Herbert's focus has been on strategic brand building, channel alignment, product development and positioning across a broad spectrum of health care and consumer companies. He has held senior leadership and ownership positions in early through mid-stage companies, including Bianchi (SVP Sales and marketing 1984 – 1996), Castelli (CEO, 1996 – 2004), Shock Doctor (Chief Sales and Marketing Officer 2004 – 2009), and DreamGuard (Chief Sales and Marketing Officer 2009 – 2011), leading to multiple successful transactions.

Christine Seward, Vice President, Sales, Predictive Laboratories

Christine Seward was selected as Vice President of Sales for Predictive Laboratories in April 2019 where her responsibilities will emphasize the commercialization of ARTguide and follow-on diagnostic tests that are developed by the business segment. Ms. Seward's background includes roles as Product Director and Director of Marketing at Myriad Genetic Laboratories where she assumed a wide variety of responsibilities including negotiation of contracts, development of study design or clinical validity and executing launch plans for EndoPredict, BRACAnalysis and other diagnostic products. Her latest efforts were focused on improving operational efficiencies across the various organizations at Myriad, directly reporting to the Chief Financial Officer. Ms. Seward is a graduate of California State University, Northridge and the highly esteemed Texas A&M University in College Station, Texas.

Financial Results

Predictive Technology Group filed its fiscal third quarter 2019 financial statements on May 20, 2019 for the three month period ending March 31, 2019. The company reported revenues of $11.3 million, which was comprised almost entirely from the human cell and tissue products (HCT/Ps) segment. $10 thousand was generated in the Diagnostics and Therapeutics segment. Revenues increased 167% over 3Q:18 levels. After cost of goods sold, gross profit was $6.5 million, representing a gross margin of 57.7%. Total operating expenses were $9.2 million, a 61% increase over the prior year. Operating loss fell to ($5.0) million from ($4.8) million in 3Q:18 on increased headcount and higher research and development costs. On a per share basis, loss was ($0.01).

Cash balance as of March 31 was $1.8 million and no debt was carried on the balance sheet. For the first nine months of the fiscal year, cash from operations was $3.1 million, a sharp improvement from the ($2.6) million deficit in the prior year. Property and equipment investments equaled $2.7 million, bringing free cash flow to $0.3 million for the first three quarters of FY:19. Cash from financing activities was $1.7 million, resulting in a net increase in cash over the nine months of $0.6 million.

VALUATION

Predictive Technology Group has made tremendous progress launching its cellular therapy portfolio and has just begun sales of its diagnostic tests. We anticipate continued strong growth in the coming quarters, as growth in HCT/Ps continue to advance and revenues from diagnostic testing grow.

We use a discounted cash flow model to determine our valuation. Predictive is growing rapidly and is making heavy investments into its current and future product set. Our forecasts anticipate over 100% growth in 2019 and over 50% growth in 2020.

We see near term revenue addition from increased penetration into the cellular therapy market as products become better known in the target physician communities including naturopathic physicians, chiropractors, orthopedists, anti-aging, and cosmetic medicine and other specialties that seek to treat pain without surgery. The addition of sales representatives is expected to have a direct relationship with increasing revenues.

Last October, PL launched its first diagnostic test, ARTguide, and we are anticipating launches in the near future of Fertility Dx and ENDORisk. While ARTguide and Fertility Dx have a narrow audience in the fertility market, ENDORisk has the potential to experience broad penetration, helping diagnose a very common condition in young women which may generate substantial revenues. The DNA and ancestry database maintained by PL provides the opportunity for future diagnostic tests in degenerative disc disease, scoliosis, preeclampsia and others.

We value ENDORisk individually as it is a priority for PL, pursues large markets and will seek FDA approval, increasing the perception of efficacy. The addressable market for endometriosis is approximately 7.5 million and with the inclusion of those with pelvic pain, it grows to approximately 27 million women. We see the most likely target market as a subset of young women from their early teens to early 20s who can benefit most from treatment that limits the progression of the disease. Our estimates call for initial sales as an LDT in 2020, growing to ~250,000 tests per year by 2025, then holding a steady market share. Pricing for tests is forecast to be approximately $1,500 growing with inflation, which we see as reasonable given the incentive of competing pharmaceuticals to find those who will best benefit from treatment. Gross margin will be in the low 70% range after direct costs and sales commissions. The NPV of ENDORisk, assuming a 15% discount rate and 70% probability of ultimate approval is $1.0 billion.

PT will pursue products that require FDA approval and is in the process of submitting drug master files to the FDA for support of internal and partnership development. PT has the benefit of a history of use of its products in many anti-inflammatory indications which may be submitted in an IND. With substantial patient data already available, especially in osteoarthritis (OA) of the knee, PT may be able to immediately start a registrational trial in this indication. PT has identified lead candidates in OA and chronic obstructive pulmonary disease (COPD), which we value individually using NPV analysis.

OA affects an estimated 30 million adults according to the CDC and has a higher rate of prevalence in older adults. Treatment ranges from pain medication to therapy and surgery; however, OA remains an unmet need. Based on

observations of efficacy from physicians using cellular therapy to address OA, PT will pursue clinical trials and ultimate approval of an indication in OA. Given the availability of safety data from Section 361 use, we anticipate PT will be able to launch a Phase II trial in the next year and obtain approval by 2023. Initial penetration into this market is estimated to be 60 basis points, or 190,000 treatments, growing to 180 basis points of penetration or near 600,000 treatments by 2027. R&D is expected to be about $75 million spread over four years. Cost for treatment is forecast to be approximately $3,000 and gross margin is forecast to be in the low 70% range after procurement & processing and sales & distribution cost. The NPV of the OA indication using a 15% discount rate and 15% probability of ultimate commercialization is $770 million.

Data from the American Lung Association estimate that COPD affects about 11 million persons in the United States. Current treatment includes medications such as bronchodilators or glucocorticosteroids, oxygen therapy and surgery. However, there is no cure. The lack of effective treatment or a cure has opened a space for cellular therapies to be used to address the disease. Similar to PT's pursuit in OA, we see the availability of safety data from Section 361 use as advancing clinical studies and enabling efforts to begin with a Phase II trial by next year. Cost for the trial is estimated to be approximately $75 million, providing registrational data by 2022. Approval and first sales are expected by 2023. We anticipate ~57,000 treatments in the first year at ~$3,000 per treatment. Penetration is expected to grow to over 200,000 treatments per year by 2027. The NPV of the COPD indication using a 15% discount rate and 15% probability of success is $270 million.

We see development in graft vs. host disease (GVHD), lung disease and other anti-inflammatory indications to be additional indications that can be pursued either following the lead candidates discussed above or in parallel as capital availability permits.

CS is not expected to generate material revenues as it is predominantly a source of supply for PB and PT. Revenues from tissue storage will be used as an offset to cost. However, if the segment is able to become dominant and displace some of the weaker participants in tissue collection, it may collect more tissue than is needed internally and generate revenue on sale of the surplus. We do not model revenue from this segment; however, it contributes to the favorable margin profile and availability of source material.

PB is rapidly growing its cellular therapy revenues and several smaller volume diagnostic tests focused on the fertility market including ARTguide and Fertility DX which we anticipate will continue to grow revenues in the near term. We forecast gross margin at approximately 65% in FY 2019 and FY 2020, anticipating similar profitability profiles from both the HCT/P and Diagnostics and Therapeutics segments. As volumes increase our estimate for gross margin also will rise to the low 70% range reflecting efficiencies in collections, processing, pricing and fixed costs in cost of goods sold. Sales and marketing expenses will rise over time as additional sales representatives are added to the roster for both segments. General and administrative expenses are forecast to increase markedly to $10.5 million in FY 2019 and grow at normal inflationary rates after. Research and development expenses will also increase in FY 2019 to reflect increased spending on both HCT/Ps and diagnostic test development and we forecast spending in the $3 to $4 million range annually over the next few years. As additional information becomes available regarding specific R&D efforts we will include both the anticipated revenues and costs in our valuation model. We anticipate that Predictive will exhaust its accumulated net operating losses by fiscal year 2022 and will begin paying corporate taxes of 21% and state taxes of 5%.

Predictive turned cash flow positive in the fourth quarter of FY 2018, and now has four consecutive quarters of positive cash from operations. The company may decide to raise capital through a debt or equity issuance to fund development activities and accelerate growth; however, our estimates do not include any capital raises or the associated accelerated growth from additional funds. We will adjust accordingly when and if announced.

Our approach values the company's core products and layers on additional value from specific products and indications. We probability adjust products in development and use a 15% discount rate for forecasted cash flows. The net of all our assumptions is a net present value of $8.00 per share.

CONCLUSION

Predictive Technology Group is in an enviable position with current and rapidly growing revenues from cellular therapies and a full pipeline of diagnostic tests and other candidates that are expected to layer on revenues in the coming quarters. The company has also made significant strides to source its own tissue that is used in its commercialized and in-development cellular therapies which should both increase the volume of tissue per collection and reduce the cost of goods sold.

Predictive Therapeutics is the longer term play in the company and is expected to file INDs for several new indications in the broader area of inflammation and other promising conditions such as OA and COPD. The clinical studies conducted here are expected to provide a halo effect for Section 361 product and also command a position for approved product on payor formularies. Predictive has recognized the shift in medicine to cellular therapy and genetic testing an analysis and has gathered the data necessary to develop products that can improve health with targeted therapy.

The company's selected niche of fertility medicine is an attractive one. While many of the products and services that are offered in this area are not covered by health insurance and government programs, there are fewer barriers to providing and distributing a self-pay product which has allowed for a rapid ramp up in sales for the company. The Section 361 products are allowed to forgo clinical trials and begin marketing immediately as they are minimally manipulated products for which no claims are made. Predictive also plans to pursue several indications that fall under Section 351 and will use information already available from patients to help guide candidates through the approval process.

Key reasons to own:

- **Rapidly growing cellular therapy segment**
  - **Competency in cell and tissue processing**
- **Cash flow from Biotech supports development activities in Therapeutics**
- **Advance of cellular therapy candidates through regulatory approval process in Therapeutics**
- **Library of 300,000 DNA samples and 31 million-individual genealogy database**
- **Multiple new products launching in the Laboratory segment**
  - **ARTguide**
  - **Fertility Dx**
  - **ENDORisk**
- **Transform CellSure into dominant source of tissue product for both internal and exteral markets**
- **Development platform that can be applied to many genetic tests and cellular therapy applications**

In summary, we believe that Predictive Technology Group has identified several underserved areas in medicine that can benefit from advancing technology. Not only does the company have strong growth in the current period, but it also has a diverse pipeline of diagnostic tests and cellular therapy products that are expected to generate growing revenues in the years to come. The company's vertical integration into hospitals and other birthing centers provides a high quality source of tissue that can be used both internally and with other companies that develop cellular therapy and regenerative medicine products. Based on our forecasts and DCF model assumptions, the shares are undervalued relative to their potential and we initiate Predictive Technology Group with a target price of $8.00.

PROJECTED FINANCIALS

Predictive Technology Group, Inc. - Income Statement

Predictive Tech. Group, Inc.	2018 A	Q1 A	Q2 A	Q3 A	Q4 E	2019 E	2020 E	2021 E
Total Revenues	**$16.6**	**$8.1**	**$10.7**	**$11.3**	**$12.0**	**$42.0**	**$66.7**	**$97.2**
Revenue Growth	543.0%	296.2%	216.3%	166.9%	66.7%	152.9%	58.6%	45.7%
Cost of Goods Sold	$4.0	$2.9	$3.1	$4.8	$4.2	$14.9	$23.3	$33.0
Gross Margin	76.1%	64.4%	71.4%	57.7%	65.0%	64.6%	65.0%	66.0%
Gross Profit	**$12.7**	**$5.2**	**$7.6**	**$6.5**	**$7.8**	**$27.1**	**$43.4**	**$64.1**
Sales & Marketing	$12.7	$2.4	$3.4	$2.9	$3.3	$12.0	$13.2	$14.0
General & Administrative	$5.8	$2.6	$2.5	$4.8	$2.8	$12.7	$11.0	$11.5
Research & Development	$1.9	$0.6	$1.8	$1.5	$1.0	$4.8	$3.2	$3.5
Amortization & Depreciation	$4.6	$1.7	$2.0	$2.4	$1.7	$7.7	$6.8	$6.8
Operating Income	($12.3)	($2.1)	($2.1)	($5.0)	($1.0)	($10.2)	$9.2	$28.3
Operating Margin	*-74.1%*	*-25.6%*	*-19.4%*	*-44.6%*	*-8.3%*	*-24.2%*	*13.8%*	*29.2%*
Interest Income (Expense)	$0.2	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Total Other Income	($0.9)	$0.0	($0.6)	$0.1	$0.0	($0.5)	$0.0	$0.0
Non-controlling Interest	($0.1)	($0.3)	$0.0	$0.0	$0.0	($0.3)	$0.0	$0.0
Pre-Tax Income	($13.1)	($2.4)	($2.7)	($4.9)	($1.0)	($11.0)	$9.2	$28.3
Taxes & Other	$0.0	$0.0	$0.0	($1.2)	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($13.1)	($2.4)	($2.7)	($3.7)	($1.0)	($11.0)	$9.2	$28.3
Reported EPS	**($0.06)**	**($0.01)**	**($0.01)**	**($0.01)**	**($0.00)**	**($0.04)**	**$0.03**	**$0.09**
YOY Growth	-					-	-	*205.6%*
Shares Outstanding	217.7	223.3	230.1	272.0	300.0	256.3	310.0	313.0

Source: Company Filing // Zacks Investment Research, Inc. Estir

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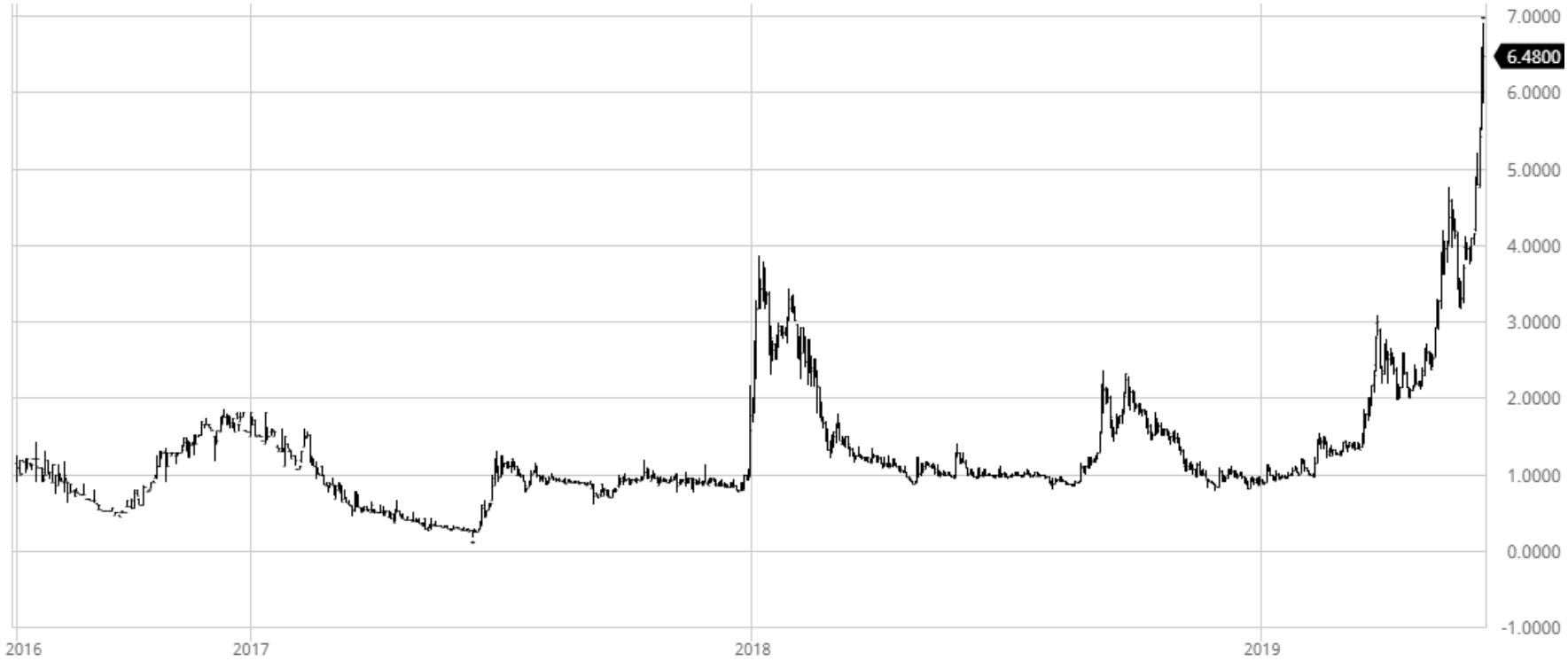
HISTORICAL STOCK PRICE

Predictive Technology Group, Inc. – Share Price Chart[14]



[14] Share price chart courtesy of barchart.com

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