Technology Overview

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I. Introduction

AniCell is a biotech company that extends the active life of animals through the development of quality biologic treatments that accelerate healing by recycling nature's blessings to create miracles. Its initial product focuses on the use of amnion derived cellular components and growth factors (MSC). This revolutionary treatment heals most debilitating injuries through accelerated and robust regeneration of tissue and bone.

II. Description of Business

AniCell Biotech is a limited liability company based in Phoenix with its roots in stem cell research and development. Its mission is to create joy by safely extending active life through the development of quality treatments that accelerate healing. The company has developed proprietary technology specifically for the equine industry. AniCell's initial focus involves the collection and processing of placenta-based biological allografts (stem cells transplants) in order to treat athletic orthopedic injuries, abrasions, lacerations, and wounds in horses marketed under the EquusCell brand. The primary products are derived from the amniotic fluid and placental sack collected non-invasively during the foals birth. This process is performed with absolutely no risks to the mare or foal and has since been evolved to support the CanisCell product line for dogs.

III. The Science

Amniotic material has been used as a regenerative medicine for wound healing and burns since the early 1900's. The beneficial use of amnion as a wound treatment has been well documented through the 1970's and recent literature has expounded on the regenerative effects of amniotic material in connective soft tissue defects or injuries in humans. These impairments often occur by damage to the extra-cellular matrix (ECM) that forms muscles, ligaments or tendons in mammals. Collagen is the most abundant structural protein in the connective tissue (ECM) and acts as a natural scaffold for cellular attachment in the body. Amnion is an abundant source of collagen, as well as the other proteins, carbohydrates, lipids, hyaluronic acid, laminin, fibronectin, pluripotent mesenchymal stem cells (MSC), epithelial stem cells and other complex growth factors that are essential for fetal growth and development.

Placental tissue is immune privileged which means they can be transplanted into another mammal without the eliciting an inflammatory immune response. Due to major histocompatibility complex (MHC), allografts would normally be recognized as a foreign antigen by the body's immune system and be attacked. The ***miracle of child birth*** is possible because amnion lacks the MHC Type 2 expressions (blood antigens) that would normally elicit an inflammatory immune response which means the body will not recognize it as a foreign tissue when implanted.

AniCell's biotechnology provides for wound healing by using the materials from the amnion and all of its natural capabilities. The pluripotency of amniotic stem cells vastly differentiate into many kinds of mature cells, including adipocytes, osteocytes, chondrocytes, myocytes, cardio myocytes, hepatocytes, neurocytes and vascular endothelial cells.[1] These MSCs mobilize base on the detection of inflammation in which the more inflammation, the better they work to repair the affected area. The amniotic material itself is a natural anti-inflammatory, anti-microbial and anti-adhesion.

Stem cell therapies are not new to equine and canine. Veterinarians have used different regenerative therapies, such as IRAP, Platelet-rich Plasma ("PRP"), bone marrow-derived stem cells and adipose tissue-derived stem cells. These have gained in popularity in the last ten years and have been highly effective due to their regenerative effects. However, these therapies are invasive to the animals requiring a painful sample extraction from either bone marrow or fat and then culturing to achieve a meaningful number of cells. This process is also complicated by needing to have a quasi-sterile environment to perform the extraction. With amniotic material, we are capable of accelerating healing joints, tendon and ligament injuries, lacerations and wounds of distal limbs, ocular surface reconstruction, and osteoarthritis without the need to harvest from the same animal we are treating.

Over the past four years, the human use of amniotic material has grown significantly for regenerative treatments. Based on this "human testing," AniCell has paved the way for "banking" amniotic equine and canine material for use in regenerative treatments in animals.

Our products are cheaper, faster, better, safer and more convenient than other existing technologies with these specific differentiators.

1. Safer because it is non-invasive - Does not require painful harvesting of bone marrow or fat or the risk of sedation or anesthetics.
2. Better because it is
    a. Amniotic Material - Our solution uses regenerative fetal material safely collected during parturition as opposed to coming from an aged adult source. Existing regenerative therapies are more inconsistent due to relying on the health and age of donor. The adult cells are also multipotent which limits the types of differentiation based on their harvested source. AMSCs are pluripotent which expands their uses.
    b. More than stem cells - Complete protein concentration not found in other therapies that help the healing process.
        i. Basic building blocks of the extracellular matrix (ECM) such as collagens, carbohydrates, lipids, hyaluronic acid, laminin, fibronectin and other complex growth factors.

[1] ScienceDirect 2009; Progress in studies on characteristics of human amnion mesenchymal cells; Jingwei Hu [a,b,c,] Zhe Cai [c]; Zhongshu Zhou [b]; [a] Graduate School of Beijing Union Medical College, Beijing 100730, China; [b] Pediatrics Department of China–Japan Friendship Hospital, Beijing 100029, China; [c] Institute of Clinical Medical Science, China–Japan Friendship Hospital, Beijing 100029, China; Received 22 September 2008; received in revised form 3 November 2008; accepted 26 December 2008

3. Faster because amnion is immune privileged - It is the Miracle of Child Birth. Amnion lacks the MHC type II expressions (blood antigens) that would normally elicit an inflammatory immune response which means the body will not recognize it as a foreign tissue and we can treat same day or next day.
4. Lower Cost because it does not require shipping of the collection kit for a fat or bone marrow sample, the time to culture it for a month or the need for multiple applications.
5. Finally, it is more convenient because it does not require substantial investment in training or collection equipment and treatments can be performed in the field.
6. Above all, we can treat immediately during the acute inflammatory phase when the most inflammation exists, which is where MSC's are most effective and avoid the growth of granulation and fibrous tissue (scar tissue & proud flesh) by supplying all the necessary scaffolding material for fibroblasts to repair the ECM properly.

At the end of the day, we are in the recycling business. We are simply reusing nature's blessings, which would otherwise end up on the ground, to restore the Active Life of Horses and Dogs, "one *Miracle* at a time."

IV. The Outcome

Recent scientific studies done in horses proved our application in comparing existing therapies using bone marrow extracted stem cells to cryogenically frozen amniotic stem cells. This immune privileged amniotic therapy enabled the treated horses to resume activities in **half** the time of the bone marrow therapy and the rate of re-injury was **5 times less**.[2] *To date, there are no other commercial options available for veterinary's patients.*

In over 60,000 human cases, no adverse side effects in any transplant hosts has been reported because of the utilization of such membranes and fluids, known as a transplant allograft. Multiple studies have demonstrated the amplification and acceleration of wound, bone, joint, and tendon healing resulting from allograft applications.

Tendon injuries are a major cause of orthopedic injuries and often compromise the return to the same performance level. In addition to tendon pathologies, treating ophthalmological injuries, articular joint issues and other chondral and fascial pathologies such as laminitis are real challenges to horse owners and their vets. In addition, for Dogs, surgical wound treatments as well as breed specific genetic challenges such as hip dysplasia typically involve complex surgeries and treatments. Different regenerative therapies, such as Interleukin-1 Receptor Antagonist Protein (IRAP®) Therapy, Platelet-rich Plasma ("PRP"), bone marrow- derived stem cells (BM-MSC) and adipose tissue-derived stem cells (AMSC) have gained in popularity.

[2] *Cytotherapy, 2013; International Society for Cellular Therapy. Investigating the efficacy of amnion-derived compared with bone marrow derived mesenchymal stromal cells in equine tendon and ligament injuries ANNA LANGE-CONSIGLIO1, STEFANO TASSAN2, BRUNA CORRADETTI3, AURORA MEUCCI1, ROBERTA PEREGO1, DAVIDE BIZZARO3 & FAUSTO CREMONESI1 1Università degli Studi di Milano, Large Animal Hospital, Reproduction Unit, Lodi, Italy, 2Private practice, Vermezzo, Milano, Italy, and 3Università Politecnica delle Marche, Department of Life and Environmental Sciences, Ancona, Italy

However, because these therapies are derived from the animal's own body, treatment is not always feasible under field circumstances, sample sterility depends on the practitioner, donor influences are difficult to control and the isolation protocol of some therapies (BM-MSC & AMSC) takes approximately one month. See below:

	Umbilical Cord Blood (obsolete)	PRP	IRAP	Adipose MSC	Bone Marrow MSC	EquusCell AniMotion
Immune Privileged	No	No	No	No	No	Yes (No MHC-II Ag)
Market Efficacy	Best	Fair	Good	Good	Better	Best
Processing	Once in lifetime event. Liquid nitrogen storage	24 hour incubation	24 hour incubation	2-3 week process in Lab	2-3 week process in Lab	Available off-the-shelf
Potency	Most Potent	Dependent on Age	Dependent on Age	Adequate Fat Problematic	Best if collected 18 months or younger	Most Potent
Primary Benefit	Pluripotent cellular components	Multipotent cellular componets	Swelling Inhibitor	Multipotent cellular componets	Multipotent cellular componets	Pluripotent cells + amniotic growth factors
Treatments Required	1-2	3-5	3-5	1-2	1-2	1
Horse Owner Price *(Product Price)*	$2500 one-time fee + $250-$500 Annual Fee	$600-$1000	$1,000	$3500-$5000	$3500-$5000	$2,800
Veterinarian Cost *(Product Cost)*	$1500	$300	$250-$450	$1500+$400 shipping	$1500+$400 shipping	**$1200-1500 inc. shipping**

V. The Product Line

AniCell has developed a revolutionary, proprietary patent-pending collection and processing techniques to commercialize a complete canine and equine line of minimally-manipulated and media-conditioned amniotic allografts for veterinary applications. These products are marketed under the CanisCell and EquusCell product line and innovations include the ability to cryopreserve and "bank" placental tissues and prepare the allograft so that it can be used in an implantable form.

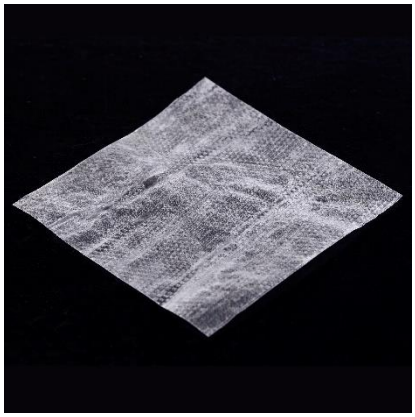
Currently, the company's product line consists of the following:

Product	***Description***	***Use***	***Amount***	***Product No.***
AniMotion	Cellular implantable allograph w/ concentrated growth factors	Ligaments, Tendons and chronic connective tissue lesions.	1mL	EQAM-1ML
AniMatrX	Acellular allograft w/ concentrated growth factors	Implantable treatment of high motion joints, less severe tendon & ligament problems	1mL	EQAX-1ML
AniOcular	Sterile 15mm round eye implant	Small sterile graft for use on ulcers and other eye issues	15mm	EQAO-15MM
AniOcular	Sterile 22mm round eye implant	Large sterile graft for use on ulcers and other eye issues	22mm	EQAO-22MM
AniOcular Plus	AniOcular Drops	Liquid eye treatment	2mL	EQAO+2ML
StemWrap	EquusCell StemWrap sterile 5X5cm biological bandage	Superficial treatment of lacerations or wounds. Also used in surgical applications	25cm^2	EQSW-5x5CM
StemWrap	EquusCell StemWrap sterile 10X10cm biological bandage	Superficial treatment of lacerations or wounds. Also used in surgical applications	100cm^2	EQSW-10x10CM
StemWrap Plus	Acellular Superficial Implantable Allograft Treatment w/ concentrated growth factors	Superficial treatment of lacerations or wounds. Also used in surgical applications.	2mL	EQSW+2ML
BioScaff CS	Sterile 2x20cm surgical bioscaffold strips	Surgical treatment designed for colic incisions	40cm^2	EQBSCS-2x20CM
BioScaff RS	Sterile 2x10cm surgical bioscaffold strips	Surgical treatment designed for colon resections	20cm2	EQBSRS-2x10CM
BioScaff UH	Sterile 2x6cm surgical bioscaffold strips	Surgical treatment designed for umbilical hernia surgeries	12cm^2	EQBSUH-2x6CM

AniMotion is an implantable, cellular fluid-based allograft that contains all of the growth factors and benefits of amniotic material. The product is designed for use where there is connective tissue damage to ligaments, tendons and muscular treatments. **AniMotion** is a veterinary administered product that is implantable at the affected point of inflammation for treatment. This product has significant potential to lessen and/or eliminate the effects of laminitis, navicular, treatment of tendonitis, sport-induced superficial digital flexor tendon (SDFT) and suspensory ligament (SL) lesions.

AniMatrX is an acellular allograft that contains concentrated growth factors for use in joints and to address areas of chronic inflammation. It can also be used in conjunction with **StemWrap** to treat severe wounds or to lessen the effects of unwanted scaring of surface wounds.

AniOcular is an amniotic eye implant used to treat eye lesions and ulcers. This product is applied to the lesion and held in place due to hydrostatic tension. In chronic cases, the addition of **AniOcular Drops** may be added to provide a more persistent week long regiment to further accelerate the treatment.



StemWrap is a surface-applied wound treatment product used for accelerated healing of open lacerations. This sterile product can be applied to "clean" sutured wounds or to "dirty" open wounds in conjunction with a dressing. Due to its natural anti-inflammatory, anti-microbial and anti-adhesion properties, this product reduces the number of dressing changes needed. The amniotic material is placed on the wound and it contains many of the concentrated proteins and collagens needed to accelerate growth and healing. **StemWrap** is available various sizes for treatment.

VI. Summary

We are extremely excited about this opportunity and its benefit to the market place. By being first to market with this technology in a space that is primed for a product that works better, is more convenient to use and less expensive, we believe that this technology will grow quickly. This, coupled with our commitment as a company to creating solutions, not treating symptoms, in a safe, ethical and healthy way will forever ensure an ever-expanding ACTIVE life for all animals!