# MARKET EQUITIES RESEARCH GROUP

June 1, 2017

DIAGNOS Inc. TSX Venture ADK: C\$0.14, 12-month price target: C\$1.00/share, US Listing: DGNOF, Frankfurt: 4D4

Adoption curve expected to continue to accelerate for proprietary technology applying artificial intelligence in healthcare diabetes market.

The Company is successfully continuing its transition from R&D to commercialization of the CARA disruptive technology:

- Computer Assisted Retinal Analysis (CARA) is a web-based software application that
  integrates a proprietary image processing technology with fundus cameras which is
  revolutionizing retinal scanning for a number of serious health conditions, including
  Diabetic Retinopathy (now) and cardiac conditions (future).
- CARA has been in development since 2005 early success led to a formal team being assembled in 2009, followed by ISO certification in 2010, FDA approval in 2011 and CE (Europe) approval in 2012. Numerous studies and field trials have vetted CARA as a leading, market-ready solution, with the company now active with full commercialization efforts. The company is now active in 15 countries.



- The available market for Diabetic Retinopathy scanning is very large, with annual scanning recommended for over 400million diabetics worldwide – existing systems using manual interpretation by specialists cannot cope – CARA automates the process – at the local (doctor office) level, a systemic change.
- Longer term, even larger blue sky potential is available should DIAGNOS 'crack the code' to using its retina scanning platform to conduct early stage diagnosis for heart disease.

Background: More than 20% of health care spending in the U.S. is for people with diagnosed diabetes (Centers for Disease Control & Prevention). It is the 7<sup>th</sup> leading cause of death in the U.S. in 2013, and is the leading cause of kidney failure, lower limb amputations, and adult-onset blindness. Over the past 35 years, the U.S number diagnosed has increased by 4x to 22 million (8 million) believed undiagnosed). More than 86 million have prediabetes and 90% don't know it. Blood supply (oxygen) to the retina is critical for healthy eyes and diabetes (high sugar levels) alters this, resulting in Diabetic Retinopathy (DR) over time. Between 40%-45% of Americans diagnosed with diabetes have some stage of DR (with1/2 aware of it). It is therefore critical to have annual eye exams for diabetics to avoid progression (and ultimately blindness) as early as possible to change patient behaviors, but the high volume of patients, the need for frequent reexamination, compliance failure, and undersupply of ophthalmologists even in developed countries create barriers. Automatic, cost effective screening & evaluation of retinal images is now possible which have accuracy that equals or exceeds human grading. DIAGNOS' CARA system is leading in this area – it is proven with years of testing in over 15 countries and is now a fully commercial system. With the worldwide diabetes population at well over 400 million, the market opportunity is the billions annually.

## **Value Drivers**

- A Market Recognition. As a first mover with industry-leading accuracy, DIAGNOS Inc. has succeeded in developing partnerships with Novartis and Bayer, recognized pharma leaders in the diabetes industry. These relationships have successfully opened the doors to decision-makers in 15 countries to date.
- Leveraging the Early Business Model. As these local / national relationships develop, DIAGNOS is now implementing a phase II strategy, which is create larger scale, longer term, more lucrative contracts with national agencies. We have begun to see this with Mexico (initial testing with Novartis → initial contract → expansion of contract → next steps).
- A Timing / Disruptive & Inevitable Nature of Technology. The company has been active with market penetration strategies for several years, gaining footholds in 15 countries to date and increasing. The question is when do these tests transition to larger scale, ongoing contracts? While it is difficult to determine exactly *when*, we believe the transition to automatic scanning is inevitable disruptive technology − medical systems are not able to cope with the large and increasing number of diabetics, which need screening every year − and if not done (which it is not), the costs to treat become huge (now ~20% of health care spending). The answer is to automate, bringing routine scanning out of the exclusive realm of a short supply of ophthalmologists and into the local doctor's office, where immediate action can be taken. We believe governments / health care officials increasingly see the benefits of making this change.
- Revenue Potential. Once large scale medical systems begin to implement automatic scanning processes, it is logical that the dominos begin to fall worldwide – assuming \$10 / scan, the potential is for several hundred million scans per year, a multi-billion opportunity.



Recent Price: \$0.14 52-week Price Range: \$0.04 - \$0.20 Shares Outstanding (1): 140.6 million Fully Diluted Shares (1): 214.3 million

#### Capitalization (\$Cdn):

Market Capitalization: \$19.7 million
Net Working Capital (12/31/2016)(1): \$2.71 million
(Excl. short term Conv. Deb, Incl. recent \$2.61m issue)

#### Corporate Information:

President, CEO: Andre Larente Website: www.diagnos.ca

Several Potential Value Catalysts in 2017 / 2018 – Potential \$150M+ mkt cap, \$1+ / share.

- ▲ Large, worldwide market
- A Proven technology, endorsed by major pharma
- First mover advantage, well positioned in 15 counties (and quickly growing)

[See P.13 for Revenue Potential, Summary & Conclusion]

#### DIABETES AND DIABETIC RETINOPATHY

## **KEY HIGHLIGHTS**

- Early development of CARA technology since 2005 results in first mover advantage by DIAGNOS Inc.
- Key regulatory approvals as a medical device have been gained in the U.S. (FDA), Europe (Conformité Européenne CE), Canada (Health Canada), Mexico, and others.
- Testing over several years has been successful, attracting leading pharma companies in the diabetic sphere (*Novartis*, *Bayer*), with additional leading pharma at the proposal stage.
- Technology is disruptive and easily scalable.
- Leveraging early testing successes with phase II business model of turnkey provision of all hardware / software & training in local clinics / hospitals – low cost software as a service (SAS) revenue model – immediate results provided to doctor / patient.
- Blue sky potential with cardo / other applications from use of CARA scanning platform.

# THE CARA-AI PLATFORM

<u>Computer Assisted Retinal Analysis</u> (CARA-AI) is a tele-ophthalmology platform that integrates with existing equipment (hardware and software) and processes at the point of care (POC) and comprises:

- Image upload,
- Image enhancement,
- Automated pre- screening,
- Automatic detection of pathology in retinal photographs / lesion classification / pre-triaging in order of severity (for DR, DME, and others), and
- Referral interface to a specialist.

CARA's Artificial Intelligence image enhancement algorithms make standard retinal images sharper, clearer, and easier to read. It is a platform which:

- Is compatible with all fundus camera brands and all recognized image formats,
- Operates in real time,
- Can be used with any number of imaging fields,
- Is compatible with both mydriatic and non-mydriatic technologies,
- Is at least as reliable and accurate as human graders of retinal images,
- Has an easy to use, secure web interface,
- Is scalable,
- Is constantly updated,
- Is EMR compatible ("electronic medical records"),
- Is customizable to customer needs,
- Recognizes both normal retinal landmarks (optic nerve, vascular system, macula, fovea), as well as pathological changes (exudates, haemorrhages,

micro-aneurisms, neovascularisation) – allowing definition throughout the spectrum of retina conditions (healthy  $\rightarrow$  critical).

**Development Timeline** 

**2005**. Initial CARA product launch as ongoing R&D effort.

<u>2009</u>. CARA beta version released & formal management team assembled to execute go forward strategy. ISO 13485 certification received. Health Canada registration received.

**2010**. Many local and international field trials carried out to test CARA product, service, and target market.

2011. US FDA registration received

2012. CE Mark EU registration received

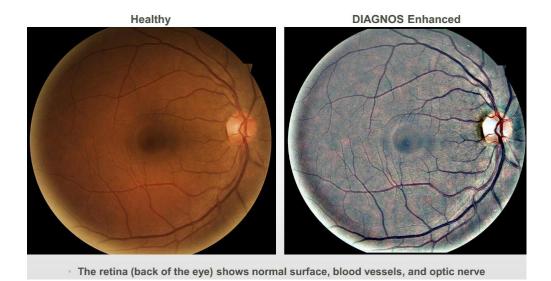
**2013**. Initial Agreement signed with *Novartis* (initial deployment in Mexico), continuing testing & market development in several countries

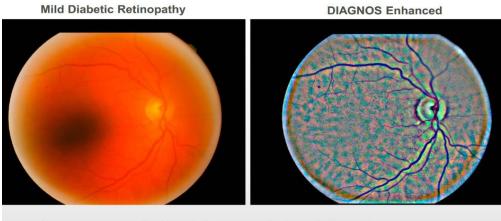
<u>2014-15</u>. Continued market development in more countries (incl. expansion of Novartis partnership), expanding applications for CARA (i.e. age related macular degeneration (AMD), adapting new approaches and technologies to improve performance and reduce costs.

**2016-17**. New additional partnership with <u>Bayer</u> (entry into Colombia, recently Canada), larger-scale contract with Mexico, Several additional countries entered. Sales of natural resources AI technology to focus exclusively on CARA.

Because it is highly accurate, scalable, and has low initial and ongoing costs, CARA is capable of being placed not only in larger centers but also in smaller, less urban locations, offering doctors and patients immediate feedback, freeing up valuable retina specialist time. It offers health care systems a real alternative to the growing problems facing health care systems worldwide pertaining to diabetes and also for other serious conditions capable of being diagnosed utilizing retinal scanning.

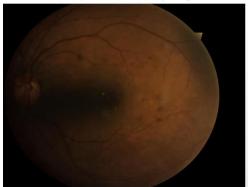
The company is now leveraging its past development efforts and testing successes to move beyond cost-covering testing to longer term, ongoing commercial arrangements.



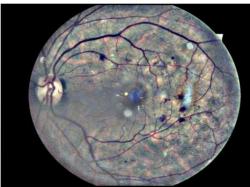


- The retina shows early signs of disease (usually affects both eyes)
- Retinopathy may indicate that damage has started to occur in other organs
- During early stages doctors may adjust medication and recommend lifestyle changes

## Severe Diabetic Retinopathy







- Severe Diabetic Retinopathy may lead to blindness and may or may not have symptoms
- It is very important to see a retina specialist as soon as possible to discuss treatment options
- The earlier the treatment is started, the better the outcome

## THE IMPACT OF DIABETES & NEED FOR NEW SYSTEMS

People with diabetes either don't make enough insulin (type 1 diabetes) or can't use insulin properly (type 2 diabetes). Insulin allows blood sugar (glucose) to enter cells, where it can be used for energy. When the body doesn't have enough insulin or can't use it effectively, blood sugar builds up in the blood. High blood sugar levels can lead to heart disease, stroke, blindness, kidney failure, and amputation of toes, feet, or legs.

Factors including rising obesity and an aging population are leading to rising rates of diabetes and the

including those related to eyesight.

incidence of diabetic-related disorders,

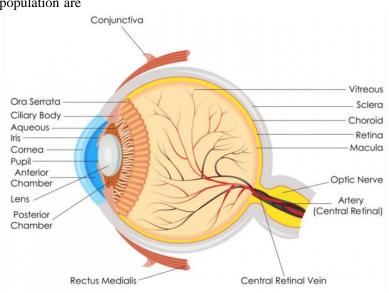
 According to the <u>World Health</u> <u>Organization</u>, the number of people with diabetes worldwide has risen from 108 million in 1980 to 422 million in 2014.

Over the past 35 years, the number of Americans diagnosed with diabetes increased fourfold, from 5.5 million in 1980 to 22.0 million in 2014. In 2014. Approximately 8 million Americans with diabetes were undiagnosed, making the total incidence of the disease in the US

more than 29 million, or 9.3% of the population.

# **Diabetes & Eyesight**

In the eye, the blood supply towards all layers of retina is done through micro blood vessels which are susceptible to unrestrained blood sugar level. When a large amount of glucose or fructose gathers in blood, the vessels start crumbling because of insufficient distribution of oxygen to cells. Any blockage in these vessels leads to a severe eye injury.



- More than a third of American adults—around 86 million have prediabetes, and 90% of them don't know it.
   With prediabetes, blood sugar levels are higher than normal, but not high enough yet to be diagnosed as diabetes.
- According to the <u>Centers for Disease Control and</u> Prevention,
  - Diabetes was the seventh leading cause of death in the United States in 2013 (and may be underreported).
  - Diabetes is the leading cause of kidney failure, lower-limb amputations, and adult-onset blindness.
  - More than <u>20%</u> of health care spending is for people with diagnosed diabetes.
  - O Up to 25% of US adults who have diabetes don't know that they have it or that they could be developing serious complications.

#### Diabetic Retinopathy (DR)

Diabetic retinopathy is characterized through several lesions which are all caused by disorders in the retinal blood supply (bleedings, precipitations of albumen from the bloodstream, oedema, and several abnormalities in the blood vessels).

The changes start in the retinal periphery and may develop into two eyesight-threatening forms; diabetic maculopathy (DKma) where the changes spread to the central parts of the retina and damage the central eyesight; and proliferative diabetic retinopathy (PDR) where the new blood vessels sprout up to replace the closed blood vessels in the eye periphery. However, the structure of blood vessels is abnormal, and thus, they cause bleedings in the vitreous body or detachment of the retina causing a severe impact on the eyesight.

- Diabetes complications and related conditions include the following:
  - Heart disease and stroke: People with diabetes are twice as likely to have heart disease or a stroke as people without diabetes—and at an earlier age.
  - Blindness and other eye problems: Diabetic retinopathy (damage to blood vessels in the retina), cataracts (clouding of the lens), and glaucoma (increase in fluid pressure in the eye) can all result in vision loss.
  - <u>Kidney disease</u>: High blood sugar levels can damage the kidneys long before a person has symptoms. Kidney damage can cause chronic kidney disease, which can lead to kidney failure.
  - Amputations: Diabetes damages blood vessels and nerves, particu-larly in the feet, and can lead to serious, hard-to-treat infections. Amputation is sometimes necessary to stop the spread of infection.

<u>Diabetic Retinopathy</u> ("**DR**") is an eye disease associated with long-standing diabetes. All diabetic patients are at risk of developing DR, which usually has no early warning signs. Between 40% - 45% of Americans diagnosed with diabetes have some stage of diabetic retinopathy, although *only about half are aware of it*. Women who develop or have diabetes during pregnancy may have rapid onset or worsening of diabetic retinopathy. Worldwide, DR is estimated to affect over 93 million people.

# The Progression of DR

Chronic high blood sugar levels from diabetes is associated with damage to the tiny blood vessels in the retina. The retina detects light and converts it to signals sent through the optic nerve to the brain. DR can cause blood vessels in the retina to leak fluid or hemorrhage, distorting vision. DR is progressive, undergoing several distinct phases:

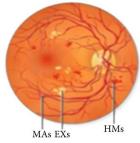
- Mild. Small areas of balloon-like swelling in the retina's tiny blood vessels, called microaneurysms (MAs) may leak fluid into the retina.
- 2. Moderate. Blood vessels that nourish the retina may swell and distort, and may lose their ability to transport blood. Both conditions cause characteristic changes to the appearance of the retina.
- Severe nonproliferative retinopathy. Many more blood vessels are blocked, depriving blood supply to areas of the retina. These areas secrete growth factors that signal the retina to grow new blood vessels.
- 4. Proliferative diabetic retinopathy ("PDR"). Growth factors secreted by the retina trigger the proliferation of new blood vessels, which grow along the inside surface of the retina and into the vitreous gel, the fluid that fills the eye. The new blood vessels are fragile, which makes them more likely to leak and bleed. Accompanying scar tissue can contract and cause retinal detachment. Retinal detachment can lead to permanent vision loss.

Microaneurysms are an earlier sign of DR. This disease brings changes in the size of blood vessels (swelling). The indications of DR include microaneurysms (MAs), exudates (EXs), and hemorrhages (HMs) as well as the abnormal growth of blood vessels.

<u>Diabetic Macular Edema</u> ("**DME**") is the build-up of fluid (edema) in a region of the retina called the macula. The macula is important for the sharp, straight-ahead vision that is used for reading, recognizing faces, and driving. DME is the most common cause of vision loss among people with diabetic retinopathy. About half of all people with diabetic retinopathy will develop DME. Although it is more likely to occur as diabetic retinopathy worsens, DME can happen at any stage of the disease.

Duration of diabetes is a major risk factor associated with the development of diabetic retinopathy.

- After 5 years, approximately 25% of Type 1 patients will have retinopathy. After 10 years, almost 60% have retinopathy, and after 15 years, 80% have retinopathy.
- Of Type 2 patients over the age of 30 who have a known duration of diabetes of less than 5 years, 40% of those patients taking insulin and 24% of those not taking insulin have retinopathy. These rates increase to 84% and 53%, respectively, when the duration of diabetes has been documented for up to 19 years.
- Proliferative diabetic retinopathy develops in 2% of Type 2 patients who have diabetes for less than 5 years and in 25% of patients who have diabetes for 25 years or more.





(a)

Abnormal growth of vessels

**b**)

The disease often progresses unnoticed until it affects vision. Bleeding from abnormal retinal blood vessels can cause the appearance of "floating" spots. These spots sometimes clear on their own. But without prompt treatment, bleeding often recurs, increasing the risk of permanent vision loss. If DME occurs, it can cause blurred vision.

Glycemic control is the key modifiable risk factor associated with the development of diabetic retinopathy. There is general agreement that duration of diabetes and severity of hyperglycemia are the major risk factors for developing retinopathy. Once retinopathy is present, duration of diabetes appears to be a less important factor than glycemic control in forecasting progression from earlier to later stages of retinopathy. Diabetic retinopathy progresses in an orderly fashion from mild to more severe stages when there is not appropriate intervention. Progression to vision impairment can be slowed or averted if DR is detected in time. Detection is now done through a comprehensive eye exam that looks for early signs of the disease. Several decades of clinical research have provided excellent data on the natural course of the disease and on treatment strategies that are 90% effective in preventing the occurrence of severe vision loss. Thus, it is obvious that detection and treatment at the earliest time is needed.

# However,

- Detecting DR is a time-consuming, manual process that requires a trained clinician to examine and evaluate digital color fundus photographs of the retina.
- While this approach is effective, *its resource demands are high*. The expertise and equipment required are often lacking in areas where the rate of diabetes in local populations is high and DR detection is needed.
- As the number of individuals with diabetes continues to grow, the infrastructure needed to prevent blindness due to DR has become even more insufficient.
- By the time human readers submit their reviews, often a day or two later, the delayed results lead to lost follow up, miscommunication, and delayed treatment.
- A significant disadvantage of the manual process is that it is sensitive to the screener's experience and fatigue human (manual) screening has been shown to have an estimated <u>error component of 20% 30%</u>.

• Finally, given that there are reportedly only <u>1,800 retina specialists</u> in the U.S. for the over 20 million diagnosed diabetics, the problems become compounded. Currently, national retinal screening rates are *less than 40%*.

The delivery of diabetic screening will become more problematic as the number of people with DR is expected to increase threefold in the United States by 2050 and to double in the developing world by 2030, particularly in Asia, the Middle East, and Latin America. Screening simply has not – and cannot – keep pace with the proliferation of diabetes.

Studies show that controlling diabetes slows the onset and worsening of diabetic retinopathy (i.e. keeping blood glucose level as close to normal as possible), *as well as kidney and nerve diseases*. So, in a more general sense, patient awareness

# The Importance of Early Screening

- Early detection and treatment can reduce the risk of severe vision loss by 90%
- People who are screened tend to take better care of their diabetes
- The patient may experience no symptoms until the condition becomes severe
- People who are unscreened are more likely to present in the ER, become blind, and have other complications

of their condition is critical not only to prevent the progression of DR and DME, it can be a useful tool in preventing the potential onset of other critical disease related to kidneys, etc.

Vision lost to diabetic retinopathy is sometimes irreversible. However, early detection and treatment can *reduce the risk of blindness by 95%*. Because diabetic retinopathy often lacks early symptoms, people with diabetes should get a comprehensive dilated eye exam at least once a year. People with diabetic retinopathy may need eye exams more frequently. Women with diabetes who become pregnant should have a comprehensive dilated eye exam as soon as possible. Additional exams during pregnancy may be needed.

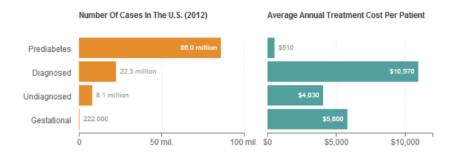
Treatment for diabetic retinopathy is often delayed until it starts to progress to PDR, or when DME occurs. Comprehensive dilated eye exams are needed more frequently as diabetic retinopathy becomes more severe. People with severe nonproliferative diabetic retinopathy have a high risk of developing PDR and may need a comprehensive dilated eye exam as often as every 2 to 4 months.

DME can be treated with several therapies that may be used alone or in combination.

- <u>Anti-VEGF Injection Therapy</u>. Anti-VEGF drugs are injected into the vitreous gel to block a protein called vascular endothelial growth factor (VEGF), which can stimulate abnormal blood vessels to grow and leak fluid.
- <u>Focal/grid macular laser surgery</u>. In focal/grid macular laser surgery, a few to hundreds of small laser burns are made to leaking blood vessels in areas of edema near the center of the macula. Laser burns for DME slow the leakage of fluid, reducing swelling in the retina.
- <u>Corticosteroids</u>. Corticosteroids, either injected or implanted into the eye, may be used alone or in combination with other drugs or laser surgery to treat DME. They are biodegradable and release a sustained dose of corticosteroids to suppress DME. Corticosteroid use in the eye increases the risk of cataract and glaucoma.

For decades, proliferative DR has been treated with scatter laser surgery, sometimes called panretinal laser surgery or panretinal photocoagulation. Treatment involves making 1,000 to 2,000 tiny laser burns in areas of the retina away from the macula. These laser burns are intended to cause abnormal blood vessels to shrink. Although treatment can be completed in one session, two or more sessions are sometimes required. While it can preserve central vision, scatter laser surgery may cause some loss of side (peripheral), color, and night vision. Scatter laser surgery works best before new, fragile blood vessels have started to bleed.

As indicated in the chart below, it is very costly to treat patients:



#### AUTOMATIC DETECTION – THE SOLUTION

DIAGNOS Inc. has shown that inexpensive digital fundus camera technology, combined with automatic detection technology, can effectively and reliably replace the Tier 1 screening now being done by retina specialists (opthamalogists).

Color fundus photography is the most frequently used imaging modality because it is noninvasive, well accepted by patients and above all, because it allows documentation and automated analysis of the ophthalmoscopic examination. This camera takes images of the internal surface of retina, posterior pole, macula, optic disc, and blood vessels. These digital images can then be processed by various algorithms for computerized screening and analysis.

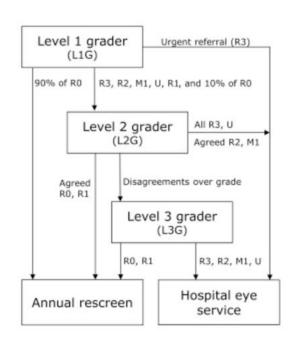
Whereas now patients must be screened manually by an ophthalmologist, the CARA system can be placed in a variety of settings, and can effectively replace a Tier 1 screener. What this enables is that in terms of early stage screening, this can be done at local clinics and together with the patient's regular doctor – patients do not have to visit the retina specialist for an eye exam, and then have follow up at the doctor's office – it can all be done in one convenient trip to the regular doctor. It represents a vast improvement in the system and makes annual scanning much easier, available, and less costly. Internationally, where patients have to cover the costs themselves, this method is far less costly.

There are many benefits for this system:

- Lower cost.
- More accessible cameras can be placed in any number of locations, including regional and local
- settings and operated by trained local staff testing can be accessible to virtually everyone.
- Eliminates multiple visits.
- Immediate viewing 24/7 by doctor / patient.
- Patient education annual retinal scanning can be used as an opportunity to educate only 6.8% of people diagnosed with diabetes in 2011 and 2012 were given diabetes self-management training – so bringing scanning into the doctor's office, with immediate feedback can change this.
- Disease progression can be monitored by reviewing sequential images over time.
- Detection and correction of any error in the photographic process can be done immediately, with images retaken.
- It allows retina specialists to focus on cases which truly need their attention.

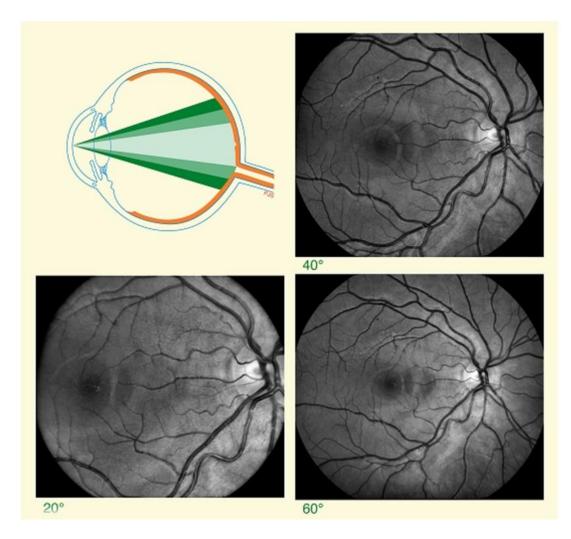
In essence, the use of a CARA system serves to effectively streamline routine retinal scanning. It frees up retina specialist time, and education and coaching for diabetics can be accomplished at the patient's regular doctor's office, increasing compliance – which is what is required system-wide. Advanced cases can simply be referred to the specialist, as is the case with other medical conditions.

# Clinical practice



- D- = disease absent classification by automated system
- D+ = disease present classification by automated system
- TF = technical failure
- RO No retinopathy; MO no maculopathy; R1 background retinopathy;
- U ungradable images; M1 maculopathy; R2 pre-proliferative retinopathy; R3 proliferative retinopathy (R3) 17

A fundus camera is a specialized low power microscope with an attached camera. Its optical design is based on the indirect ophthalmoscope. Fundus cameras are described by the angle of view - the optical angle of acceptance of the lens. An angle of 30°, considered the normal angle of view, creates a film image 2.5 times larger than life. Wide angle fundus cameras capture images between 45° and 140° and provide proportionately less retinal magnification. A narrow angle fundus camera has an angle of view of 20° or less.



The deep learning of DIAGNOS' artificial intelligence positions its unique and proprietary CARA system without comparable in the marketplace; the AI continually refines its datasets to minimize misclassifications (e.g. false negatives or false positives) of lesions. The technology is now to the point DIAGNOS' AI, as first-mover and leader, effectively has no competition even close to being on par with it in this sector.

#### **DIAGNOS BUSINESS PLAN FOR CARA**

As noted, DIAGNOS Inc. has been advancing the CARA system since 2005, and has had a dedicated management team to bring the system to market since 2009.

The commercialization of CARA has been a multi-phase effort.

<u>Phase I.</u> This has involved forming relationships with large pharma which has contacts internationally. Shown below are the leading diabetes companies worldwide. To date, DIAGNOS Inc. has partnered with two of these, Novartis and Bayer. Together with these large companies, a pilot test will be conducted by DIAGNOS Inc. in the relevant country, funded by the pharma. What will happen is that the CARA screening will identify those with advanced cases – those that need treatments (such as those mentioned earlier in this report). Those with less advanced cases can work with their regular doctor for appropriate education and follow up. *The pharma companies actually have found this to be a profitable exercise with high ROI and have continued with this process*.

Top 10 Diabetes C	ompanies Worldwide 2013
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ф	<del>-</del>	Sales (\$MN)∳	Share <b></b> ‡	Growth 2012-2013
	Global Diabetes Market	54,015	100.00%	10.20%
1	Novo Nordisk	12,031	22.30%	15.80%
2	Sanofi	9,107	16.90%	21.90%
3	Merck & Co	6,430	11.90%	13.40%
4	Lilly	5,197	9.60%	15.00%
5	Johnson & Johnson	2,339	4.30%	7.30%
6	Bristol-Myers Sqibb	1,952	3.60%	14.80%
7	Roche	1,946	3.60%	1.90%
8	Bayer	1,461	2.70%	-0.50%
9	Abbott	1,373	2.50%	11.10%
10	Novartis	1,367	2.50%	28.90%
	Top 10	43,204	80.00%	14.90%
Source	IMS Health MIDAS Mar 2014			

The benefit to DIAGNOS Inc. is that they obtain a foothold in the relevant country. Valuable contacts are made within the health care system and with the various related government and non-governmental agencies. To date, DIAGNOS Inc. has worked with Novartis in countries including;

- Saudi Arabia,
- Japan,
- Spain,
- Egypt,
- Oatar,
- Kuwait, and
- Malaysia.

DIAGNOS Inc. works with Bayer in;

- Latin America,
- Europe, and
- Canada.

We understand that the company is at or near proposal state with two other top 10 pharma companies.

<u>Phase II – Work Directly with Government Agencies</u>. After DIAGNOS Inc. becomes known and established in a country, management and the sales team continues to work towards gaining additional follow up contracts. This has been successful in Mexico, where DIAGNOS Inc. was active early on, converting its' early efforts into an initial contract to screen 70,000 patients in June, 2016. This contract was with the <u>Mexican Social Security Institute</u> (IMSS). In January, 2017, a contract extension was announced to bring the total number of patients screened to 106,300. It has been announced that

negotiations are underway for a two-year national coverage contract – the objective is to work with ISSSTE and cover three times the volume of 2016 and to expand national coverage by supporting its MIDE flagship diabetes program.

As a hybrid to this approach, DIAGNOS Inc. will also work with local resellers and other players having expertise in the local market. This has been successful in Bangladesh, where the company has teamed up with 'Eyes for All', a health technology consultancy company with relationships in Bangladesh across non-government organizations, health care research institutes, and the public sector hospital network.

<u>Phase II – Work Directly with Private Organizations</u>. This strategy is beginning to be rolled out, principally in the United States. Here, the strategy is to work directly with the owners of clinics. Diagnos will provide a turnkey solution, including training of staff and providing the fundus camera and related systems. Diagnos bills for each scan taken. Diagnos intends to work directly with health insurance companies as a means of rationalizing systems and lowering costs of treating diabetes related illnesses through prevention and mitigation strategies, achieved through automatic scanning.

Within this framework, services can vary from image enhancement only, to turn-key solutions. Deployment can also be made on a mobile basis (i.e. vans) using the company's staff.

#### POTENTIAL APPLICABILITY OF CARA TECHNOLOGY TO HEART DISEASE

Despite the best efforts of the medical community and significant advances in diagnosis and management, *heart disease remains the number one killer in the United States*. Traditional risk factors such as hypertension, hyperlipidemia, diabetes, etc. allow physicians to treat high risk patients, but a substantial proportion of cardiovascular disease is not explained by traditional risk factors alone. Examination of the retinal vasculature has long been proposed as a noninvasive and cost-effective means of further risk-stratifying patients with coronary heart disease.

It is hypothesized that because retinal vessels are approximately the same magnitude as coronary microvasculature ( $\sim 100$ -250 $\mu$ m in diameter) they can serve as representative of processes occurring in coronary microvessels, and therefore serve as a marker for subclinical or microvascular coronary disease.

In the past two decades, an increased awareness of the contribution of coronary microvascular disease to the overall heart disease burden has heightened interest in *using the retinal microvasculature as a marker for coronary disease*. This is especially true for women, who may have a larger component of microvascular processes contributing to their coronary heart disease (note – traditional predictors of risk may not be adequate – the consistent associations in women are important because this group is more often classified low/moderate risk by traditional risk scores, and may be a good candidate for further screening).

# Potential applicability:

- Coronary arterial disease, which is the leading cause of heart attacks (coronary angiography is
  the gold standard for diagnosis, but its hazards and costs preclude use in early evaluation of atrisk patients).
- Macrovascular disease (i.e. large artery atherosclerosis)
- Subclinical / microvascular coronary disease.

For decades, the retinal vasculature has been proposed as an easily and safely measured surrogate for the coronary circulation, but there has been conflicting evidence as to its utility in this area.

However, in the last few decades, digitized retinal photography and other methods have become accepted as more standardized and objective techniques for characterizing retinal microvascular phenomena. More particularly, over the last 8-10 years, multiple large, prospective studies examining

the relationship between retinal vascular changes and clinical endpoints of coronary disease has provided strong evidence for a positive correlation between the two.

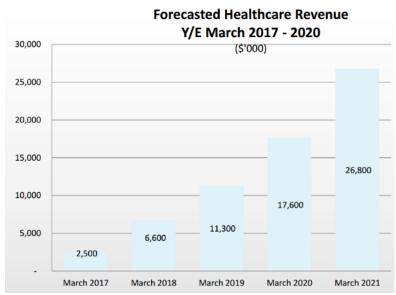
As one example of the far-reaching potential for this technology, consider the fact that based on data from the Third National Health and Nutrition Examination Survey (NHANES III), 95% of women under the age of 70 fall into the lowest category of Framingham coronary heart disease risk (meaning that their 10-year predicted risk of coronary events is less than 10%). Despite this fact, heart disease remains the leading cause of death in women in the United States, suggesting that further risk stratification in this group is necessary to enable more effective primary prevention strategies. Given that most of the larger studies examining the relationship between retinal microvascular abnormalities and coronary events show stronger associations in women, it could be proposed that clinicians should consider retinal examination by an ophthalmologist (specifically looking for signs of retinopathy or decreased arteriole to venule ratio) in women with one Framingham risk factor. A recent study of women showed that a significant proportion of women deemed "low risk" by Framingham had increased coronary artery calcium scores, which were predictive of future coronary events. The fact that retinopathy has been shown to correlate with increased coronary artery calcium scores further supports the use of retinal examination in women who are otherwise deemed "low risk."

So, where does this leave us. *It is known that abnormalities in retinal images can potentially provide useful information about clinical and sub-clinical (not severe enough to present definite or readily observable symptoms) cerebrovascular, cardiovascular, and metabolic health of the patient.* There are therefore advantages of using digital image analysis to quantify the extent of retinal pathology in vascular diseases, diabetic retinopathy (DR), age-related maculopathy and other conditions.

We are aware that DIAGNOS Inc. is actively working on this – while we do not know what the chances of success in this area are for accurately screening for heart (and other) conditions, if they can solve some of these problems, the implications of this are very far reaching and potentially extremely rewarding for shareholders.

#### **REVENUE POTENTIAL**

Shorter term, the FY forecast is predicated on DIAGNOS Inc. continued success in Mexico (i.e. 2/3 of FY 2018 revenue), combined with ongoing testing in several other countries. Beyond that, expectations are based on CARA gaining additional traction in one or more markets where management is active currently with prospects and proposals.



(Source: Company disclosures)

**NOTE:** The Company has an established history of being conservative and exceeding forecasts. Forecasts are based on known events & conservative assumptions -- any number of catalysts have the potential to dwarf the above figures, and likely will.

At this stage, however, in light of all the considerations mentioned previously, the story for DIAGNOS Inc. is not necessarily a quarter to quarter revenue story, nor is it about annual results year over year. The real story is a fundamental analysis regarding the ultimate adoption of large-scale medical systems of automated retinal screening – we believe such adoption is basically inevitable.

The question then becomes to what extent DIAGNOS Inc. will participate in this revolution. From our perspective, what we see is an early and successful advancement of CARA, ISO certifications, regulatory approvals, partnerships with major pharma companies, and a presence in an increasing number of countries. Given the worldwide nature of the problem and DIAGNOS Inc. worldwide focus, we believe that the company is well positioned going forward, and the market for CARA appears to be approaching an inflection point, perhaps in 2017 and if not over this timeframe, in 2018.

Longer term, CARA as a platform technology that has potential to revolutionize scanning and diagnosis for large scale health care issues, there is little doubt that true blue sky exists.

## **SUMMARY & CONCLUSION**

We view DIAGNOS' CARA technology as a leading edge retinal diagnostic platform. It is know that it is leading edge in its field and has been tested extensively in over 15 countries. It is endorsed by top 10 pharma companies and appears to be gaining traction.

The issue is that as a disruptive technology, it takes time for large scale medical systems to make major changes in how it approaches a large scale problem, such as diabetes. We believe that manual scanning, given the issues involved combined with the accuracy and cost of automated scanning, will ultimately become a thing of the past. We believe that DIAGNOS Inc. is very well positioned to take advantage of this. The question is not so much if, but when. Management and sales staff are dedicated to making this happen.

Our current 12-month \$1/share price target for TSX-V:ADK is based principally on DIAGNOS Inc.'s own corporate forecasts bearing out for its CARA platform alone, ignoring additional upside from the apparent likelihood and high probability of new business from big-Pharma, governments, hospitals, and clinics world-wide developing. Acceleration of the adoption curve for DIAGNOS' technology is likely to continue and will further warrant upside revaluation, above \$1/share as it materializes. As the business grows, the longer-term strategy for the Company is to eventually shift more toward standalone deployment of its technology, with others/partners carrying the operating costs, and DIAGNOS acting as a centralized world-wide cloud-based database/processing center (The Company has a secure state-of-the-art facility in Montreal where its software enhances and analyzes retinal images of patients) handling ever larger volumes of transactions, further benefiting from higher related margins and economies of scale.

Over the longer-term, there seems little doubt that as systems improve and more resources are devoted to it, retinal scanning will ultimately provide far reaching benefits for the scanning for a number of conditions, including heart disease. DIAGNOS Inc. is working on this, and if it can become a central player in this field, the financial potential for the company is enormous. Any news regarding developments of DIAGNOS' AI technology in the heart disease sector have the potential to catapult the Company share price well beyond our \$1/share 12-month target as the size of the heart disease sector is on an order of magnitude dramatically larger than diabetes and would accelerate the Company towards imminent take-over target status.

From an investment perspective, for those looking for diversification through their portfolio and exposure to disruptive types of technologies, this is what DIAGNOS Inc. represents. Certainly one well-heeled investment group, <u>Dundee Corp.</u>, now has an ownership position of over 10%.

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