ARNA Genomics

Join us in development and deployment of novel proprietary blockchain expert system ARNA

Panacea that will unite the entire modern healthcare universe in one transparent manipulation-proof data lake

Then keep joining us in launching the first ever blood test for Breast Cancer ARNA BC and validating it in ARNA Panacea

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Current version is at https://token.arnagenomics.com/

Word from CEO

Dear Early Backer!

Allow me to introduce myself. My name is Egor Melnikov: I'm the ARNA Genomics CEO. Before we proceed further, I'd like to pinpoint that ARNA will happen only because of your interest, commitment and support. I don't know you. At least, not yet. But I intend to hear from you and I'm available 24/7 through ARNA web site and Telegram channel. However, what I do know, is a fact that both you and me were born to separate women we call our mothers. I have come with an idea for ARNA Genomics back in 2002 when my close friend's mother was suddenly and violently striken by the breast cancer and there was not much left beside palliative treatment due to advanced disease stage. When in 2013 I've learned about Angelina Jolies's decision to have a preventive double mastectomy as doctors estimated her risk of breast cancer at a whopping 87% percent based on BRCA1 screening, I and my team were already on the way to the first convenient reliable blood test for Breast Cancer. Since that time I have received so much positive feedback towards my research from my peers, who have mothers, grandmothers, daughters and wives that I decided it's a high time to unveil ARNA's technology. At ARNA, we embrace new developments like CAR-T genetic-based treatments such as Kymriah from Novartis, but when I hear about a USD 475,000 price tag I think to myself once again: "there's absolutely gotta be a better way..."

I'm pleased to introduce you the ARNA Genomics Whitepaper. You will find a very detailed scientific outline below, but to save your time and to ensure we are on the same page, let me tell you this straight ahead: "We will NOT offer cancer treatment. We will NOT offer cancer cure. We will NOT offer sham alternative medicine method based on snake oil research. We WILL offer a very early stage cancers detection method that may find cancer-specific DNA long before first symptoms ever emerge. And we WILL offer a software platform on blockchain to store and validate the Evidence-Based medical data of our patients anonymously, temper- and bias-free. This platform will unite the healthcare universe and make disease treatment more efficient. Actual treatment will still be in the hands of oncologists, albeit at earlier stages, lower dosages and lower costs".

We offer a proprietary technological platform of liquid biopsy based on several scientific breakthroughs. Our findings range from unique proprietary method of DNA amplification from the whole blood we developed to defining the set of cancers DNA's, leading to confident diagnosis. ARNA platform is fundamentally powerful as it enables development of tests for different types of cancers. We will start with ARNA BC, the test for Breast Cancer, the nightmare of modern women. This is an enormous global market that keeps growing. Then we will follow with tests for cancers of lungs, liver, pancreas, colon, ovary, and prostate.

Version 3.4

ARNA is fully equipped to obtain all necessary formal approvals from FDA and other regulatory authorities, however, we recognize the most acute pain of modern healthcare that is diminishing trust between general public and the official healthcare regulation system. Even if we formally register ARNA BC, many of you, our backers, will have doubts on its efficacy and validity. Hence at the second stage of our project we bring to you and to the rest of the world ARNA Panacea, the blockchain expert system that will make possible for people to personally validate healthcare technologies. We are excited by the power and elegance of synergy between ARNA BC test and ARNA Panacea platform and explain this synergy in detail in this White Paper.

We have a world-class scientific team. With a modest budget of founder/angel investment we have completed conceptual design and initial scientific validation of our inventions. Today we aim to sell USD 40 million worth of ARNA Tokens during this Token Distribution Event. The tokens are to be exchanged for services provided by ARNA, while the proceeds of this digital crowdfunding event will be used over next 4 years to validate and deploy ARNA innovations.

Final word before you turn this page: Dear Backer, I thank you once again and hope to meet you soon personally and invite you to join us in ARNA Genomics TDE. Let's find the better way together!!!

Respectfully submitted,

Mr. Egor Melnikov

ARNA Genomics

CEO

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Executive Summary:

Cancer is a set of extremely lethal diseases, connected with genetic "damage" of cells. Cancer is a second cause of mortality worldwide, taking almost 10 million lives annually. Today there is no single diagnostic or treatment method for all types of this disease. It has been proven beyond doubt that the earlier the disease is identified, the higher are the chances to be cured. Early cancer diagnostics is one of the greatest hopes of humanity in curing the disease; however, it remains problematic as clinical symptoms do not reveal themselves neither to patient, nor to doctor until it's too late. For decades scientists attempted to develop the accurate methods of early cancer diagnostics: great advancements have been made in disease understanding, but the problem remains unsolved. The hottest current approach to early cancers diagnostics is the method called "liquid biopsy" that consists in blood test looking for the traces of the cancer cells. Such approach has already been approved by FDA, but remains challenging because of numerous technological bottlenecks.

After 10 years of scientific research ARNA Genomics founders developed proprietary technological platform of liquid biopsy based on several breakthroughs, ranging from unique proprietary method of DNA amplification from the whole blood to defining the set of cancer DNAs, detection of which leads to confident diagnosis. The platform is truly fundamental and allows developing tests for many type of cancer, starting with the most notorious killers: cancers of lung, liver, pancreas, colon, ovary, and prostate. ARNA Genomics plans to produce these tests in timely manner, however, the current focus belongs to ARNA BC, the test for Breast Cancer, the nightmare of modern women. ARNA BC demonstrates superior sensitivity and validity in the laboratory testing and appears to functionally exceed all known tests for Breast Cancer.

Immediately upon token distribution completion, ARNA Genomics is ready to initiate regulatory registration followed by commercialization of ARNA BC. Our plan is to start in the United States, apply for FDA's Investigational Device exemption to prove the test superiority, safety, sensitivity and specificity through clinical trials under FDA 510(k) process. Upon clearing regulatory market pathway for ARNA BC, we would proceed with extending the method to additional cancers types, while at the same time establishing operations in China, India, and Europe.

While ARNA Genomics is fully equipped to go through the "official" medical device registration pathway, ARNA team came to recognize one of the most painful issues of the modern healthcare, that is an unfortunate population-wide lack of trust towards evidence-based diagnostics and treatments. The most striking example is the rising of self-treatment and alternative medicine movement. Thousands of new cancer patients intentionally disregard medical advice and keep practicing clinically unproven methods. Such people firmly believe that official clinical trials and regulations are faulty and rigged by selection bias. They accuse pharmaceutical companies and regulators of hiding certain facts

from the public, while displaying the facts that are beneficial to their business only. Massive resources are spent today to prevent such manipulations: CROs and governmental agencies audit and control each and every step of the healthcare product lifecycle. Still, the bitter problem remains and more and more people loose trust into the official system.

Even after ARNA BC test is officially validated and registered as medical diagnostics, there will be people who would not appreciate its potential and disbelieve the official clinical data. ARNA team respects such skeptical people as our peers, friends, and compatriots. We will not dismiss or abandon them. Therefore, in addition to classic evidence-based medicine market pathway ARNA aims to provide people with the instruments they can use to personally validate life-saving healthcare technologies such as ARNA BC. Here comes "the" Blockchain! To serve and benefit skeptical people who would like to make personal decisions on their healthcare treatment options, ARNA group decided to create a transparent manipulation-proof, temper/bias-free system that will give all patients the opportunity to personally validate the healthcare technology. We call it ARNA Panacea. We already build it on blockchain technology that is distinguished by combination of efficiencies in trust, transparency, privacy, and data management.

It may appear surprising that such diverse technologies as ARNA BC and ARNA Panacea come together in a single project, but those who followed our logics understand the elegance of the synergy of these two innovations. ARNA BC will be supported by ARNA Panacea to reach those users who would like to rely on their own judgment, while ARNA Panacea will be supported by ARNA BC to showcase the utility and excitement of the new approach to define clinical value. This duo is destined to unite the whole society at the new level of trust to healthcare technologies showcased by saving lives with the help of the new platform of cancer diagnostics.

The first working release of ARNA Panacea is planned for the middle of 2018. Approximately at the same time ARNA Genomics will be able to start the first commercial ARNA BC tests. If everything goes as planned, by the year of 2020 the world will witness rising of two new powerful tools of modern healthcare: the ARNA BC and ARNA Platform for cancer diagnostics and ARNA Panacea system for validating and unifying modern healthcare. Let us explain how exactly this will be accomplished:

- the first ARNA BC user's test results will be loaded into ARNA Panacea blockchain and stay there for some extended period of time
- in several months after the initial tests the ARNA BC results will be independently validated clinically to reveal the validity and sensitivity of the test. This follow-up data will be carefully recorded in the same ARNA Panacea blockchain
- in one year ARNA BC users will have sufficient data accumulated in ARNA Panacea to pull up Blockchain-recorded values and define the validity and sensitivity of the test themselves

We envision ARNA Panacea platform to eventually spread far beyond validating healthcare technologies and storing patient data. The system is expected to unite and serve the entire marketplace of global healthcare by providing multiple benefits to all stakeholders:

- patients will be excited by the ability to observe and validate the constantly growing set of facts on the efficacy of diverse treatments
- doctors will start using ARNA Panacea first as the storage of patient data and later as the tool to validate their own therapeutic successes
- insurance companies will follow patients and doctors to employ ARNA Panacea in patient management
- pharmaceutical companies will come to receive encrypted information about the modern state
 of the diseases and to recruit freshly diagnosed patients for all kind of research without
 revealing patient identity
- regulators will come to use ARNA Panacea data to establish safety and efficacy of healthcare technologies
- investors and scientists will join the community to exchange inventions and financing

ARNA VIP Rewards program

We are going to implement the highest level of ARNA Reward program tier, we call ARNA VIP's. To become a VIP ARNA Rewards program backer you would need to hold a balance of ARNA tokens in an amount equal or exceeding 500 000 ARNA in your wallet between TDE event and a "Trigger" event. The first such trigger event is already known: this is the FDA approval for ARNA BC test granting us ability to market ARNA BC test in USA. Please refer to Legal information section for detailed information about limitations of our responsibility to perform under such program.

Changes to ARNA Genomics upon Trigger event:

- ARNA Genomics will provide an exclusive irrevocable license of ARNA BC technology and business rights to its wholly owned subsidiary company.
- This new subsidiary company will market all ARNA BC test in USA and will eventually either acquire venture funding or going to IPO/M&A route.
- This new subsidiary company will immediately devote 10 % of its stock towards rewards pool for ARNA VIP's who will have a right to become shareholders in this new subsidiary company.

How to claim ARNA VIP reward:

- Your balance should never fall below 500 000 tokens during the period between TDE and Trigger to be eligible.
- 2. Within 10 days upon Trigger announcement by either ARNA Genomics or FDA, we would create a contact web form on the main page of arnagenomics.com and invite all interested token holders who believe they are eligible to notify us about their intention to benefit from ARNA VIP reward and provide their contact information. This form would be active for 90 days after trigger event.
- 3. We would promptly check each wallet for eligibility (it's a public information after all), calculate a total number of tokens held by eligible VIP members. A simple transparent formula would be used to calculate individual number of shares. Within 30 days we would notify them about their eligibility and number of shares they will receive.
- 4. With each interested and eligible ARNA VIP member we would sign a legal document called "futures contract" individually. Under this contract, each eligible and interested VIP member would become a shareholder of this new subsidiary company by purchasing company common stock at USD 0.00001 per share rounded to 1 U.S. cent if total purchase price is less than 1 U.S. cent. We would cover all recording, stock certificate issuance and mailing fees.
- 5. All VIP members who become stock holders in a new subsidiary company would enjoy the same rights as other common stock holders, including monetary benefits in the form of dividends or stock sales if and when this new subsidiary company decides to participate in an IPO or M&A.

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<u>IMPORTANT</u>: Below, you will find a brief outline adapted to readers without medical or biological education to keep this WhitePaper short and to the point. As a courtesy, for readers who still find this information lacking, ARNA Genomics team provides a significantly more detailed report about cancers (including breast cancer), about BC diagnostics and available technologies across the world. Please download said document at https://goo.gl/Wixo7a

ARNA Genomics today

<u>We are ARNA Genomics.</u> We are an innovative biotechnological company, launched by a team of likeminded scientists and businessmen and grown from the scientific and research laboratory into full scale venture. We develop revolutionary early detection methods for select cancers in order to launch a line of diagnostic tests for early cancer detection on the global markets.

<u>Our mission:</u> to increase the life expectancy and significantly reduce human mortality. We relentlessly pursue this goal through cutting edge screening methods, diagnosis correction, treatment monitoring, and increasing patient adherence.

<u>Our Innovation:</u> ARNA Genomics has discovered a technology enabling highly specific tests development for different cancers. Besides, the company has also developed a unique concept of blockchain-based ecosystem-grade platform intended for use as an instrument to support R&D and implementation of biotechnologies worldwide.

<u>Our Pledge:</u> ARNA Genomics have completed R&D for its first product - ARNA Breast Cancer test. The test for colon cancer test is currently in an advanced R&D stage. We devote all our resources to complete development of ARNA Panacea - a blockchain platform, that will hope will change the world by making launch of new biotech and treatment solutions against cancers much easier, cheaper and faster.

All you need to know about cancers

What is a "cancer", in general?

"Cancer" is a large group of diseases characterized by uncontrolled growth and spread of mutated cells. If their spread is not controlled, it usually results in death. Cancer is caused by both external factors (tobacco smoking, virus deceases, certain chemicals, and exposure to radiation) and internal factors (inherited and acquired mutations, hormonal changes, and immune conditions). These factors

may act together or in sequence to initiate and promote the cancer development. As little as one week and as much as ten years can pass between exposure to external factors and detectable cancer. Cancers are usually found late when first symptoms emerge and treated with varying combinations of surgery, radiation, chemotherapy, hormone therapy, biological therapy, and targeted therapy.

What is a breast cancer, in particular?

Breast cancer ("BC") is a group of diseases that affects breast tissue. Both women and men can get breast cancer, though it is much more common in women. Other than skin cancer, breast cancer is the most common cancer among women in the World with nearly 1.7 million new cases diagnosed in 2012 (second most common cancer overall). This represents about 12% of all new cancer cases and 25% of all cancers in women. Also, BC is the first most common cause of death from cancer in women, and one of the main death cause of women in many countries and the second death cause after lungs in USA, fifth in Eastern Asia.

BC knows no boundaries. It is almost equally spread between low-income countries (883 thousand cases annually), compared to in mid- and high-income countries (794 thousand cases). Incidence rate ranges from 27 cases per 100 000 people in Middle Africa to 92 cases in North America.

According to current outlooks during this decade there will be 19.7 million new cases of BC registered, including 10.6 million cases in less developed countries. During the same time this disease will take lives of more than 5.8 million women.

Can Cancer Be Prevented?

Scientific evidence suggests that about one-third of the ~600,000 cancer deaths occurring annually in the U.S. will be related to overweight or obesity, physical inactivity, and poor nutrition. Of these, a vast majority of cancers are caused by cigarette smoking and heavy use of alcohol and they could be prevented completely. Certain cancers are related to infectious agents, such as hepatitis B virus (HBV), human papillomavirus (HPV), human immunodeficiency virus (HIV), Helicobacter pylori (H. pylori), and others, and could be prevented through behavioral changes, vaccines, or antibiotics. In addition, many of the more than 2 million skin cancers that are diagnosed annually in the U.S. could be prevented by protecting skin from intense sun exposure and avoiding indoor tanning. Regular screening examinations by a health care professional can result in the detection and removal of precancerous growths, as well as the diagnosis of cancers at an early stage, when they are most treatable. Cancers that can be prevented or detected earlier by screening account for at least half of all new cancer cases.

Who Is at Risk of Developing Cancer?

Anyone can develop cancer. The risk of being diagnosed with cancer increases with age with most cases occur in persons 55 years of age and older. In the U.S., men have slightly less than a 1 in 2 lifetime risk of developing cancer; for women, the risk is 1 in 3. Additionally, male smokers are about 23 times more likely to develop lung cancer than nonsmokers and, for example, women who have a close relative (mother, sister, or daughter) with a history of breast cancer have about twice the risk of developing breast cancer. All cancers involve the malfunction of genes that control cell growth and division. However, most cancers do not result from inherited genes but from damage to genes occurring during one's lifetime. While most cancers grow from a single mutated "progenitor" cell, cancers found in advanced stages rapidly mutate and each node is made of multiple cell lines with different mutations enabling chemo resistance and recurrence. The earliest possible screening is vital to treatment success.

How Many People Alive Today Have Ever Had Cancer?

The National Cancer Institute estimates that nearly 12 million Americans with a history of cancer are alive at any given moment. Some of these individuals were cancer free, while others still had evidence of cancer and may have been undergoing treatment.

How Many New Cases Are Expected to Occur in 2017 in the US?

About 1.7m new cancer cases are expected to be diagnosed in 2017. This estimate does not include carcinoma in situ (noninvasive cancer) of any site except urinary bladder, and does not include basal and squamous cell skin cancers, which are not required to be reported to cancer registries. However, Basal cell carcinoma (BCC) is the most common form of skin cancer. Additional 2.8 million cases are diagnosed annually in the US and while BCCs are rarely fatal, they can be highly disfiguring if allowed to grow. Squamous cell carcinoma (SCC) is the second most common form of skin cancer with an estimated 700,000 cases diagnosed each year in the US, resulting in approximately 2,500 deaths.

How Many People Are Expected to Die of Cancer This Year in the US?

About 600,000 Americans are expected to die of cancer, more than 1,500 people a day. Cancer is the second most common cause of death in the US, exceeded only by heart disease, accounting for nearly 1 of every 4 deaths.

What Percentage of People Survive Cancer in the US?

The 5-year relative survival rate for all cancers diagnosed between 2001 and 2007 is 67%, up from 49% in 1975-1977. The improvement in survival reflects both progress in diagnosing certain cancers at an earlier stage and improvements in treatment. Survival statistics vary greatly by cancer type and stage at diagnosis.

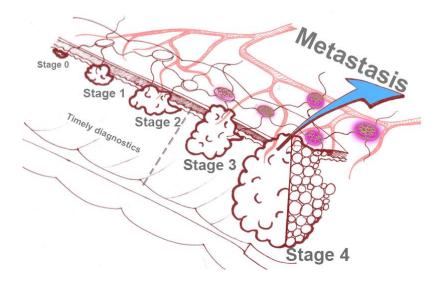
What Are the Costs of Cancer?

The Cancer diagnostics and treatment industry is huge. The National Institutes of Health (NIH) estimates that the overall costs of cancer are about USD 230 billion, or about USD 45,000 per case: About USD 107 billion for direct medical costs (total of all health expenditures) and USD 123.0 billion for indirect mortality costs (cost of lost productivity due to premature death). Lack of health insurance, high cost and other barriers prevent many Americans from receiving optimal health care. Uninsured patients and those from ethnic minorities are substantially more likely to be diagnosed with cancer at a later stage, when treatment is usually more extensive and more costly.

Existing problem #1: Mortality due to first diagnosis in an advanced late stage

Cancer is one of the leading mortality causes all over the world. More than 50% of all cancer cases are diagnosed at the stages III to IV (implicating presence of malignant metastases), which leads to significant decrease of survival rate.

Today **there are no test systems** on the market, allowing to detect BC's and other oncological diseases at very early stages when there are still no symptoms and with 90%+ accuracy.

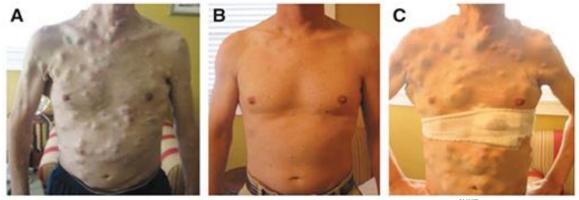


Picture 1. Stages of cancer tumors development

Disadvantages of current diagnostic methods:

- Lack of efficiency in existing biomarkers
- Morbidity and invasiveness (biopsy, colonoscopy, mammography)
- High cost and long of waiting times (PET-scanning, MRT)

Once cancer is diagnosed, it must be treated. Conventional chemotherapy is highly toxic, usually non-specific. Gene, immune, and other novel methods are time consuming, tremendously expensive and non-scalable. All of them result in relapses and chemo-resistance in vast majority of cases. Individual fractions of surviving cells in an otherwise sensitive tumor can either be intrinsically resistant or gradually acquire resistance and this significantly impairs the cure of cancer patients.



A) A metastatic patient prior to gene therapy. B) Same patient after 15 weeks of therapy with the BRAFV600E-inhibitor PLX4032. C) Same patient 23 weeks after therapy [Wagle, N., et al., Dissecting therapeutic resistance to RAF inhibition in melanoma by tumor genomic profiling. J Clin Oncol, 2011. 29(22): p. 3085-96.]

Picture 2. Dynamics of metastases before, during and after therapy.

Above illustration might be overwhelming and please accept our apologies for graphic content. Yet it does illustrate, that the only viable way to ensure survivability is a wide adoption of the earliest diagnostics possible.

Existing Problem #2: Lack of public trust into Evidence-Based healthcare

Public opinion about present state of business in pharmaceutical and biotechnological industry is truly depressing. R&D is undoubtedly very expensive, thus new treatments become more and more expensive too. Big pharma is perceived as greedy and unrelenting. Adding insult to injury, when Turing Pharmaceuticals has obtained the manufacturing license for the antiparasitic drug Daraprim and raised its price by a factor of 56 (from USD 13.5 to 750 per pill) in 2015, its CEO became known as "the most hated man in America" and "Pharma Bro". All this leads to a low trust between public and "official" system of healthcare. It is widely believed that official healthcare is plagued by selection bias: pharmaceutical companies and regulators are suspected of hiding certain facts from the public, while displaying the facts that are beneficial to them. Massive resources are wasted today to prevent such manipulations: CROs and governmental agencies audit and control each and every step of the healthcare product lifecycle. Still, the bitter problem remains and more and more people loose trust into the official system.

From the moment of product development completion (Research and Development), the next very important stage comes in its lifecycle – Product Testing. The world "testing" among experts means:

- **independent** with engagement of neutral third party a qualified special organization CRO and one or more medical organizations, with approval of trial's parameter by the regulator and ethics committee, and
- evidence-based as an example of diagnostic test: the conditions are created, under which
 the researcher should make a conclusion, whether the patient is ill or healthy, on the basis of
 analysis, for example, of blood plasma, not knowing which sample he is testing blood of
 patient with the diagnosis or blood of a healthy volunteer; there are several types of "blinding
 protocols".

Market size estimation for cancer and breast cancer screening

Screening – is a set of arrangements in healthcare conducted in order to detect and forestall development of various diseases.

According to recommendations of the Center for Disease Control (CDC) USA, women at the age of 40 to 74 years should undergo examination for breast cancer annually. (https://goo.gl/dahkFV)

Today the main diagnostics method for BC is mammography with following biopsy. DNA-tests for BC do not exist, there are only tests based on DNA for colon cancer: ColoGuards and Epi proColon, which have obtained FDA market approval recently.

According to prudent estimate, we observe the following percentage of women ranged by revenue levels, who undergo annual examination for breast cancer of the age group 40 to 74 years (https://esa.un.org/unpd/wpp/):

- High income countries 231 mln women
- Middle income countries 857 mln women
- Low income countries 56 mln women

We assume, that percent of women, who will follow recommendations about annual check-ups will be distributed as follows depending on income level of countries (conservative / realistic estimation):

- High income countries 25% / 50%
- Middle income countries 7% / 35%
- Low income countries 1% / 10%,

This gives us a conservative estimation of required annual tests at around 118 million, realistic – 306 million.

According to Globoscan (https://goo.gl/cpUR6d), there are 6.2 mln women with a five-year survival rate. Every year 1.7 mln women get cancer and must be screened at least twice. Those in remission should pass the test 4 times a year, respectively 40% in the developed countries and 10% in the developing countries. Therefore, it is 8 mln tests annually in addition to above number.

- The market of in-vitro diagnostics is estimated at (All prices in USD) 56.6 bln with CAGR 2,60% by 2019.
- The market of **blood oncodiagnostics** is expected to grow to 11.6 bln by 2019 with CAGR 3,70%.
- The market of Molecular Diagnostics (DNA diagnostics) was about 4.2 bln in 2011 and expected to grow to 10 bln by 2019. In case of creation of new breakthrough technology of DNA analysis, the segment of molecular diagnostics is capable to explosive growth.
- The segment of Molecular diagnostics is the biggest and a fast-growing market of in-vitro diagnostics with CAGR of 33%.
- Also there is a developing and high-growing market of DNA diagnostics of people origins, healthy lifestyle, food compatibility – that has nothing to do with evidence-based medicine.
 And, yet, it is expected to grow to USD 10 billion by 2022.

• It should be noted as well, that market growth rate of in-vitro diagnostics is 25% in China and 15% in India.

We can make estimations on geographical distribution of BC diagnostics market based either on assumptions of number of women in one or another region in required age group or based on available statistics of market of mammography, which is a "golden standard" today for BC diagnostics:

- USA: The amount of the market for a total of about 30 mln tests annually with the number of women at the age of 40 to 74 years equal to 68 mln. Mammography market size in US in 2010 has been around USD 7,8 billion with the average mammogram price for a patient at USD 260 (https://goo.gl/VjdG9U)
- Russia: Market size is about 10 mln tests annually with the number of women at the age of 40 to 74 years equal to 32 mln. The average cost of mammography for one patient is USD 90.
- India: There are 36 mln tests annually. The number of women at the age of 40 to 74 years equals to 186 mln. 74% of breast cancer diagnosed on 3 and 4 stages. The mammography is expensive and hardly presented in India in regions due to the lack of qualified specialists.
- **Europe**: Market volume is about 50 mln tests annually with the number of women at the age of 40 to 74 years equal to 125 mln. Europe has a very high adoption of screening programs up to 95% of population and almost 125 mln women undergo programs of cancer detection at early stages regularly. The average cost of mammography for one patient is about 125 Euro.
- China: Market size is around 30 mln tests annually with the number of women at the age of 40 to 74 years equal to 300 mln. The cost of mammography for one patient is about USD 60. It is the most fast-growing market for diagnostics of cancer diseases using molecular diagnostic methods.

Future drivers of the molecular diagnostic market growth:

- Launch of state-sponsored screening program for the main types of cancer in connection with appearance of accurate, reliable, inexpensive, simple, convenient and quick diagnostic methods on the market.
- Growth of implementation of early diagnostic concepts among subject matter specialists and population.
- Extension of screening programs for wider patient groups, excluded from screening programs.
- Increase of the number of cancer types in one test (more complicated and sensitive tests).
- Increase of accessibility of diagnostic laboratories for population and specialists, increase of marketing activities on improvement of early diagnostic concept.

ARNA's 2-step approach to problem solving

STEP 1: Cancer diagnostics at pre-clinical, early stage

The leading experts expressly recognize that one of the key solutions to increase the survival rate of patients is the earliest possible diagnostics of oncological disease.

Introduction in medical practice of the diagnostic test capable to detect presence or absence of any forms of Breast Cancer at the earliest stages with an accuracy of more than 90% will allow to lower considerably the mortality from this disease, mainly in developing countries, to simplify passing the annual screening in the developed countries that as a result will make the test the "golden standard" in diagnostics of this disease.

Our technological approach to this problem which humanity was trying to find for decades, is currently protected as intellectual property (IP), with some of the IP is decidedly kept in a know-how regimen to prevent early copy-cuts, others we can and will patent (patent in Russia and international PCT application that will be extended to national phase patents in multiple countries by the end of 2019).

Below, we provide a partial disclosure of ARNA's principal technological and competitive advantages, enabling ARNA BC test accuracy not seen in any available product on the market today.

Tumor cells not only grow, but also decay. It is commonly accepted that by means of analysis of concentration of DNA fragments by different methods in blood and other human body liquids there is a possibility to diagnose oncological process in human body, including very early stages of tumor development.

A unique DNA amplification method created by us and technology of biomarker genes selection across whole human genome allow solving the problem of **accurate and early** diagnostic of oncological diseases and has no analogues in the world – all the companies follow DNA sequencing and methylation, **extracting** DNA from blood plasma beforehand (if they are working with plasma). In our opinion, it is extraction of **DNA which introduces a key error,** not allowing to ensure high accuracy values.

STEP 2: Returning Public trust through blockchain-based marketplace solution

Even after ARNA BC test is officially proven and registered, many people in the market will not appreciate its potential. To serve and benefit these people ARNA group decided to create transparent manipulation-proof system that will give people the opportunity to personally validate the technology. Such system is called ARNA Panacea and enabled by blockchain technology that is distinguished by combination of efficiencies in trust, transparency, privacy, and data management.

Each biotech-startup passes through a large number of rounds of examinations of individual experts. It is extremely difficult to find the "appropriate" experts who will want to listen to you and at the same time will be able to give the information in reply necessary to take further steps. At the same time it is even more difficult to keep confidential the technology itself. The blockchain allows to significantly simplify the access to examination and analysis of the results of technology without a need in obligatory disclosure of all "know-how".

Having realized how global the formulated task is, ARNA Genomics team also understood that similar solutions should come to minds of both strong market players, such as large pharmaceutical companies, and to any professionals who have faced this problem. However, for obvious reasons, big and rich market players are just not interested in changing anything.

At first we formulated the need of blockchain analogue of laboratory notebooks of scientists which they maintain in their daily, creative science activities, from which sometimes revolutionary products are born changing the quality of people's life. Later we realized that such notebook is needed at every stage of drug development process and the most demanded notebook will actually record not development, but usage of the product. If daily information of the product use is stored in tamper-proof blockchain, users will be much more comfortable to make their healthcare decisions.

The beauty of our situation is that ARNA is actually the first and the most grateful customer of this approach: we will put all the results of our ARNA-BC product testing in the blockchain ecosystem and then call users to validate them. Furthermore, in the nearest future, during independent and blinded studies of ARNA-BC, we will use the system on the basis of the blockchain for publication of all the results of the studies conducted by the project.

In future, we are planning to develop and use this system for all our products at the stage of development, trials and their further use. We are planning to produce from 2 to 5 new products annually, created on the basis of the developed technologies: our second product will be ARNA- Colon - test for colon cancer, as it has practically been completed, then we will make tests for lungs, liver, esophagus, pancreatic gland and ovarium – and this is only the beginning.

Having started our own development of blockchain solution, we have again reviewed the scope of the whole problem – to develop new standards of communication for all roles in the process, which are about 10, to make analogues of real time processes in blockchain, which allows:

- to accelerate and to reduce the price of all processes;
- to redistribute rewards for every participant of the process, based on the present market mechanisms, which creates a correct incentive system;
- to make available and transparent as much as possible communication of all participants of the process from creation of biotechnological solution and its examination to commercialization, acceleration of market entry and availability to end consumers

We suppose that the set of these factors will impact the survival rate and human life expectancy.

Our solution of this problem is creation of an integrated ecosystem based on blockchain for conduction of all the stages, accompanying biotechnological products - from development to statistics and data collection - **ARNA Panacea**.

Core Product - ARNA BC

Introduction

ARNA Genomics has developed and validated in lab setting the efficiency of its product we call the "ARNA BC" – breast cancer test, based on the analysis of free-circulating DNA in human blood plasma.

ARNA BC studies we've completed to date, clearly show that this test is capable to diagnose breast cancer at all stages, including the earliest ones through specific blood plasma analysis. Lab sensitivity and specificity of ARNA BC are both close to 95% rate. What this means is that ARNA BC currently doesn't even have any close competition in terms of its efficiency among any other available or indevelopment tests. And far surpassing traditional methods of BC diagnostics such as mammography and MRI (as screening methods) followed by biopsy: Trifecta known as a "golden standard" of BC diagnostics.

How test "accuracy" is determined?

In general, test accuracy is determined by a number of parameters, characterizing it separately. To calculate these parameters all the study results are entered in the following table:

	True pation	Total	
Test results	Sick	Healthy	i Otal
Positive	а	b	a + b
Negative	С	d	c + d
Total	a + c	b + d	a+b+c+d

- a. Sick patients identified using test (true positive)
- b. Healthy subjects with positive test result (false positive)
- c. Sick patients not identified using the test (false negative)

d. Healthy subjects with negative test result (true-negative)

On the basis of the specified measurements, the following parameters are calculated:

- Accuracy is a ratio of correct test results (i.e. total amount of true-positive and true-negative results) among all the patients examined. It is calculated as (a + d) / (a + b + c + d).
- **Sensitivity** (true positive ratio) reflects a ratio of positive results, which are correctly identified as such, that is sensitivity of diagnostic test shows a probability, that the patient will be classified exactly as a patient. It is calculated as a / (a+c).
- **Specificity** (true negative ratio) reflects a ratio of negative results, which are correctly identified as such (i.e. a probability, that healthy subjects will be classified exactly as healthy). It is calculated as d / (b+d).
- Likelihood ratio for positive and negative result a probability, that this result of diagnostic test will be expected in the patient with the disease in comparison with a probability, that the same result will be expected in the patient without the disease. It shows, what fold higher (lower) is a probability to get this test result in patients, rather than in healthy people. It is calculated as Sensitivity / (1 Specificity) for positive ratio, and as (1 Sensitivity) / Specificity for negative.
- Positive predictive value is a disease probability in case of positive (abnormal) result of diagnostic testing (test). It is calculated as a / (a+b).
- **Negative predictive value** is a probability of disease absence in case of negative (normal) result of diagnostic testing (test). It is calculated as d / (c+d).

Results of laboratory trials of ARNA BC

Results of our laboratory trials of ARNA BC are provided below:

ARNA BC	Sick	Healthy	Total
Positive	153	3	156
Negative	6	57	63
Total	159	60	219

ARNA BC test parameters	Value
Accuracy	95,89%
Sensitivity	96,23%
Specificity	95,00%
Likelihood ratio for positive result	19,25
Likelihood ratio for negative result	0,04
Positive predictive value	98,08%
Negative predictive value	90,48%

Sensitivity and specificity of the tests that exist on the market today and other methods of breast cancer diagnostics (mammography, MRI, examination, ultrasound, etc.) do not exceed 70-80%.

Biopsy specificity can barely exceed 90%. In other words, in every 3rd – 5th case - they result in error, with great probability - fatal.

http://www.scielo.br/scielo.php?script=sci_arttext&pid=S0104-42302015000600543

Our test on the basis of the specified data may show erroneous result 1 time out of 19, which makes this product truly unique!

However as promising as ARNA BC results are, we must still disclose, that our lab setting results still need to be independently validated.

Barriers to Entry: Regulator Approval

The principle hurdle that ARNA BC must overcome is the Food and Drug Administration (FDA) approval. When one hears a word "medical device", one can imagine a prosthetic arm or X-Ray apparatus, yet the definition is a lot broader. While ARNA BC is a screening test and ARNA Panacea is an IT Expert system, FDA still classifies them as medical devices, albeit in different categories. The path to a marketed medical device usually involves a long, formal and rarely straightforward journey through basic research, discovery of the biology effects, preclinical development tests, increasingly complicated clinical trials with humans, and the actual regulatory approval by the FDA. Complexity of regulatory path depends on a class of medical device, with 3rd class being the least simple, and if such medical device could show similarities with existing FDA approved technologies. Luckily for ARNA BC, predicate devices already exist and we identified them. The example of predicate devices for ARNA

BC is Cologuard (https://www.cologuardtest.com/) an FDA approved screening method for Colon Cancers. For ARNA Panacea the predicate device is an expert system developed by 23AndMe (https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm551185.htm). We believe we would not have to prove a complex "de-novo" classification and will be allowed to proceed with a simpler, faster and cheaper pathway known as 510(k) process. However, we must note, that even though Arna Genomics will follow existing approved technologies, these medical devices are not entirely similar to ARNA BC and Panacea and therefore do not correspond to competing technologies, only to substitutes.

FDA Approval Path

We know and inform you, our backers, that the actual path from lab-validated prototype to marketed product can be quite variable and quite different. Therefore, this pathway may change depending on a magnitude of factors. However, we must note that we would do everything within our means to facilitate the successful outcome. After much research and consultations we believe that the following regulatory approval path is realistic and we offer a simplified and condensed plan below.

Classification: Class II, product code: In Vitro Companion Diagnostic Devices.

Advisory committee: Center for Biologics Evaluation and Research (CBER)

Submission process: 510(k) with (most likely) or without (least likely) clinical trials

Clinical trial protocol: Investigational Review Board (IRB) protocol submission, Investigational Device Exemption to start trials with U.S. based clinics,

Potential partners for trials: John Hopkins Institute (Baltimore, MD); Hershey's Cancer Institute (Hershey, PA).

FDA Action Plan Checklist

With high confidence we anticipate the need for the following action points in order to obtain FDA approval for ARNA BC with respect to breast cancer:

Translation from Russian of the available clinical data

Lab test results of ARNA BC

Patient's complete information

Design outline for a commercial version of ARNA BC device with integrated blood collection kit and FDA approved PCR kits*

Safety features

Standardization of PCR procedure

Animal studies design

Reporting, Labeling, Management certification and other FDA controls compliance

ARNA BC operations during and upon FDA approval

Immediately after completion of clinical trial and obtaining of market approval we plan to open additional laboratory blocks to increase our own laboratory capacity of samples from clinics and networked diagnostic centers.

After that we will organize centers for blood samples processing for ARNA BC and other future tests as soon as they get to the market in several cities in USA and Russia. Own funds and revenues of the project will be used to perform this step.

Offices

1. U.S. office

Based on TDE token performance, within months upon TDE completion we intend to establish and maintain ARNA Headquarters, R&D facility, manufacturing unit and a warehouse in the U.S. somewhere in close proximity to FDA and National Cancer Institute.

For a growth stage, we estimate a need for a relatively small facility housing office space and manufacturing/assembly. ARNA Genomics believes that to avoid unnecessary facility certification it will purchase existing licensed laboratory, certified to collect blood for PCR further testing.

We believe we would also need a partnership agreement with an appropriate cell culture laboratory and, separately, animal studies laboratory.

Upon human trials design approval we will partner with existing clinical research facility to refine ARNA BC and perform clinical trials.

2. Russian office

ARNA Genetics have already established a Russian R&D subsidiary called BIOMARKER-RU, LLC a developer of current ARNA BC lab prototypes and Intellectual Property owner. We will further establish a presence at Skolkovo Bio-Cluster to benefit from tax breaks and Skolkovo 3-year grant program.

Russian office will receive the Russian medical certification prior at the same time with FDA approval to get a legal ground to apply for Indian medical device certification. Russian office will commence first sales, pending medical certification with Russian Ministry of Health.

3. Indian and Chinese offices

We intend to base two ARNA Genetics corporate Asian headquarters in India and China, given the acquisition of sufficient capital upon TDE conclusion and/or separate venture capital funding round.

We envision the establishment of a production/assembly operation in India, benefitting from existing local Pharma-centered infrastructure. We may engage a local CRO/service provider to handle the acquisition of a local medical certification. If economy of scale assumptions prove to be correct, we will employ Chinese office to produce PCR components necessary for the first production run of approximately 2,000 ARNA BC tests. These components will be ordered separately from several contractors (so no single contractor knows specifics of the whole product) and shipped to our warehouses in India and China for assembly and placement of the finished ARNA BC tests with selected Indian Value Added Resellers for testing in the marketplace. Also, we may identify appropriate suppliers to produce the crates and packaging during the first six months to have ARNA BC tests shipped to USA in climate-controlled conditions.

Finally, given the social value of ARNA products, we are interested in working closely with Chinese and Indian economic development organizations and centers of excellence.

Project funding

1. SBIR and R&D Grants

We plan on attracting NIH/SBIR Phase I-III funding to support R&D efforts to extend the ARNA BC technology beyond breast cancer. We plan on preparing and submitting new proposals covering additional ARNA platform applications. Exact succession and market viability would be further assessed.

2. Venture Capital

We would carefully consider all incoming funding proposals and M&A solicitations, but given such a strong interest from potential backers on presale at this moment we do not plan any dilution events associated with venture funding. We may return to this question in several years when ARNA Genomics is ready to grow internationally and offer ARNA BC test across the world.

Patent protection of ARNA BC

All ARNA Genomics intellectual property assets are currently protected and owned by BIOMARKER-RU LLC patents (PCT application can be find below). It's worth noting, that key part of the ARNA test technology is protected by a "Coca-Cola-type" strict "know how" regimen to avoid early copycats.

We intend to follow a robust strategy of intellectual property protection from, which will be detailed and brought to execution with engagement of TOP 10 legal counsel in IP protection after completion of TDE.



Picture 3. PCT application

ARNA Panacea development

Introduction

ARNA Genomics will provide to all market players working with cancer a fundamentally new way to access and interact with the clinical trials data collection and storage environment. Using ARNA tokens the holders would be able to pay for other system members services (e.g. cancer check-ups, tests, etc.), get access to the medical trial data storage system for professional medical use, pay for other system users services or start fundraising to perform a new study.

In cooperation with FDA regulator (U.S. Food and Drug Administration), ARNA Genomics will test the corresponding Data Storage System to collect evidential base to be used by the regulator for further product licensing opportunities (Breast cancer detection ARNA BC) for the US mass market.

ARNA Genomics will be using the existing methodology and "best practices" available for the successful development and implementation of this solution for all members of the ARNA Panacea ecosystem:

- Discuss and Discover: the first phase of the project would include discussion and evaluation
 of the key market players requirements in terms of their adaptability towards the Blockchain
 technology, as well as all of the technical requirements.
- Design & Prototype: this phase deals with the Blockchain node prototype development in affiliation with our trusted partners in order to evaluate and perform comprehensive functionality testing of the ARNA Panacea ecosystem.
- **Development**: the basic system model development will be completed during this phase.
- **Deployment**: this phase involves the deployment of the ARNA Panacea ecosystem as well as the involvement of new partners and market players.
- Application Support: ARNA Genomics will continue to support the system and its members for an indefinite period of time.

Background for development

For a better understanding of the practical benefits of creating and implementing the ARNA Panacea system we will provide a simple example – a typical clinical proof cycle of diagnostic method efficiency (it may vary from one country to another but the general methodology remains similar):

1. The Researcher develops a technology/method.

- 2. The Researcher calls on an independent clinical research organization (Clinical Research Organization CRO).
- The clinical or clinic-laboratorial study design is developed in cooperation with the CRO, the main goal of the trial is to validate the Researcher's statement concerning the final results of the test.
- 4. The study design developed is reviewed and approved by the State regulator, the Ethics Committee and other regulatory authorities.
- 5. CRO collects biological samples from patients and documents them, with that they are "blinded" (adopted term meaning the acquired samples are coded before transferring them on to the Researcher so that no additional patient information is passed with a sample, such as the patients diagnosis, personal details, etc.)
- 6. The blinded samples acquired are passed to the Researcher, who performs the testing using his own method and reports the results for each blinded sample to the CRO.
- 7. CRO performs the "unblinding" procedure, i.e. matches the available patient and sample information with the results acquired by the Researcher, upon which it issues the expert report concerning the method efficacy.
- 8. Based on the results acquired, if they are satisfactory, the Researcher publishes research papers briefly describing the method and focusing more on the obtained results.
- 9. The Researcher reports the obtained results to the State regulator to receive the authorization for the commercial use of the technology (test method).

The path described above is approximate and can vary considerably from country to country, but the cooperation of the three parties (the State regulator, CRO and the Researcher) is mandatory.

This process can take a considerable amount of time (months, sometimes even years!), it requires a significant amount of funding and is absolutely nontransparent to either the market **or** the other **Researchers**. To put it simply, no one can see the progress of the study – everyone only gets to see the final result.

Many Researchers around the world often struggle to address similar problems and challenges, combining their efforts to develop new methods for DNA analysis to detect cancer and other diseases will obviously allow to speed this process up significantly and make it as transparent as possible.

Moreover, the documentation of the results in the research process is greatly influenced by the human factor – both the Researcher and the CRO can deliberately or unintentionally distort the results of research, which can lead to a potentially important and universally necessary technology being found

ineffective. Using conventional means of data recording (a paper notebook, an Excel spreadsheet, and other more sophisticated but essentially similar methods) provides no future guarantee that the results of the research haven't been distorted, corrected, adjusted, etc.

For example, the sample blinding protocol, as described above, is retained by the CRO and the Researcher does not know it's contents. The blinding protocol is the key, on the basis of which the results obtained from the Researcher are compared with the initial patient data.

It is evident that in the process of creating a blinding protocol or performing the unblinding procedure, the CRO (whether deliberately or not) can make an error as a result of which the entire outcome of the research will be distorted.

The use of the Blockchain technology allows to eliminate the risk described above completely: the blinding protocol including the patient data, is created in an open, but encrypted form, unavailable to the Researcher; data acquired from the Researcher also enters the block and the unblinding procedure is performed without the human factor involved, and with no possibility of results distortion or alteration on either side.

ARNA Panacea application for ARNA BC

ARNA BC is going to be the first diagnostic test in the history of medicine, the clinical research data of which will be entered into the Blockchain to subsequently prove the effectiveness of our test to bring the product to the mass consumption market.

We also plan to publish all of our further research, including the R&D stage, in the blockchain, as well as to engage various scientific research companies working with the human genome in every possible way, including for the cancer detection purposes.

ARNA Panacea Technical implementation

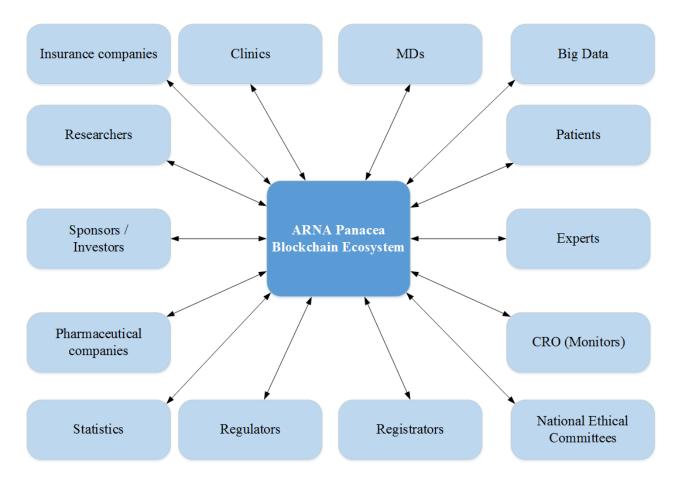
Description

The ARNA Panacea platform is designed to collect, store and analyze the information on available and new methods of cancer detection and treatment worldwide.

The data is stored in the blockchain and is available to all system users who have access to ARNA Panacea. The user can get access to different levels and various types of data, depending on (a) the user's role in the system; (b) his direct relation to the data.

We will use the platform to collect and store evidentiary information from clinical trials of our product – ARNA BC – from the launch of the development stage.

User roles in ARNA Panacea



Picture 4. Roles of users in ARNA Panacea.

The list of primary ARNA Panacea user roles

Researcher

When developing or modifying a biotechnological product, the Researcher maintains the "researcher's journal", encrypted with his personal key. At the discretion of the Researcher, the data can be disclosed in whole or in part to either another Researcher (co-researcher) or any other member of ARNA Panacea.

• Investor / Charity giver

Makes a decision to finance any of the developments presented by the Researcher (before or after the expert report). On the basis of smart contracts, the raised money guarantee the Sponsor's rate of return defined by the smart contract in case of successful introduction of

technology to the market. The proceeds provided by the Sponsor to the Researcher are used to pay for other ecosystem members' services.

Also is able to makes charity contributions in ARNA tokens that can be utilized based on the results of a vote taken by the ARNA Foundation members (a crypto-currency charitable foundation, the creation of which will be announced separately beyond the framework of the current TDE).

Patient

Has full access to personal data encrypted with a personal key, which includes the access via a mobile application. Can purchase ARNA tokens and use them to pay for the testing services (or other services offered to private individuals by the ecosystem members). Receives offers from Pharmaceutical companies, Researchers, Health Clinics and Doctors to participate in research based on a smart contract that stipulates compensation payment to the Patient.

FDA and regulatory agencies in other countries of interest

Approves applications for clinical trials, monitors results during the research process and conducts post-monitoring, as well as performs other supervisory and regulatory functions regarding new technologies.

Record keeper

Issues, extends or terminates a license to use the technology (drug or medical device) in certain jurisdiction.

• CRO (Monitor)

The research organization contractor coordinates clinical trials, approves research protocols in the ARNA Panacea system and monitors data collection and analysis procedures in individual clinical trials.

Insurance company

The insurance company pays for the patient testing both on the basis of insurance contracts on doctor's orders, and before the conclusion of an insurance contract to reduce the likelihood of the policy owner having and/or being predisposed to the said disease. We are also currently considering the possibility of cooperation with insurance start-ups in the Blockchain.

Pharmaceutical company

Has access to data from clinical trials performed, as well as to patient data apart from the personal information. Has an opportunity to select patients of interest without disclosing their personal information and offer participation in research in exchange for a compensation - this information is received by all patients selected by the Pharmaceutical Company personally.

Each Patient decides whether to participate in the study or not and chooses the level of private information disclosure.

Health clinic

Interacts with the system by entering data from patients undergoing clinical trials. Prepares sample blinding protocols. Historical data analysis module forms a confirmed rating of the clinic for certain diseases and the effectiveness of their treatment.

Doctor

Enters patient data and other information (in this case it's the Health clinic sub-role). The historical data analysis module also lays down the Doctor's rating based on the results of the accumulated statistics review.

Expert

Conducts the evaluation of the results submitted by the Researcher for further report to the Regulator.

Software developer (near-clinical mobile applications)

Has an opportunity to enter and request data from the system using an open API.

Big Data

Has access to the accumulated information file via the open API interface with the functionality necessary to analyze the available data.

Statisticians

Develop biostatistical research models used in clinical trials and to verify obtained results.

Each user can combine roles in one or several various projects, but the keys for data entry will be different, so the information on the roles the user has in each project will be displayed in the blockchain.

Technical solution

This part of the whitepaper describes the model of blockchain integration into ARNA Panacea system.

ARNA Panacea is intended to bring the highest level of security and privacy on each step of pre-clinical drugs research. The main requirements of any secure system are the following:

- confidentiality
- integrity
- availability
- accountability
- information/identity assurance

In order to satisfy the above stated design requirements, the final solution will be implemented as a system of several independent modules. Each module ensures that only authorized entities may interact in an approved manner, and provides a mechanism to increase security while maintaining availability. Detailed description of the system is presented below.

The core module of the system is Private Permissioned Blockchain (PPB) network. The nodes of the network are only authorized to interact with each other inside the network. Interaction with the network itself is constrained by authorized interconnections with:

- Key Generation Service(KGS),
- the HIPAA compliant data storage service(HIPAA-DSS),
- Remote Procedure Call (RPC) service.

The KGS is the resource that generates private/public key pairs to be used inside the blockchain network. The RPC service acts as a public facing service for requests from third-parties, and as an interface to the core PPB.

The HIPAA compliant storage service hosts the electronic private health information (ePHI). More about HIPAA could be found by the link.

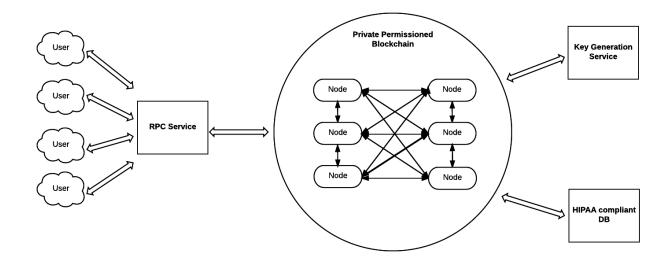
For every registered user, there's only one contract in the blockchain which the user is authorized to directly connect to. This contract contains the permissions which regulates data access rights.

All interactions with ARNA Panacea from the third-parties are only established by submitting transactions. The transactions are signed by a public key of a user. All transactions are received by the RPC service, which authorizes the appropriate user by matching the signature to a public key stored in the system.

The RPC service includes a load-balancer, which forwards the requests to a node in the blockchain network. The node then submits the transaction to the appropriate user's smart contract. Received request is executed and if it is permissioned, the transaction is stored in the next block.

If the contract execution result is successful, the initial request to the HIPAA-DSS is triggered. Then the retrieved data is encrypted and returned to the RPC service, and further to the requesting party.

Any request to publish data from the system is signed by a public key of the HIPAA-DSS. The mechanism has all the same steps while the data bubbles up to the RPC service.



Picture 5. ARNA Panacea blockchain integration scheme

Example of clinical trial process using ARNA Panacea

The primary data collection process for a medical device like ARNA BC is described below:

- 1. Researcher conducts scientific development of the medical device. The data obtained during the research process is entered into the system on his behalf. The data can be of any format, organized either as measurement and experiment results, or as general laboratory notebook entries, notes, ideas, etc. Researcher encrypts all his data with a personal private-public key pair, so only this Researcher has access to this data. The Researcher has an option to provide other ARNA Panacea members access to his research data in full or partially, as well as for new data contribution on this development (collaborative work). The data is entered for a small fee (or free of charge) to encourage participants to actively use the system.
- Having completed the development of the method, the Researcher publishes the results and invites Investors to fund the clinical trial of the new technology. Investors provide Researcher with funding in ARNA tokens.
- The Researcher invites opinion leaders (Experts), and with that draws up an application to the Regulator to obtain a clinical trial permission. All materials are enclosed with the application, including encrypted materials accessible only to the Regulator that can be enclosed separately.
- 4. The Regulator makes a decision to either approve or deny the application, the result is also entered into the system.
- 5. If the design of clinical trials gets approved, the Researcher invites the CRO to design the study via the system. This trials design is stored in the system in encrypted form (available only to certain categories, as indicated below)

- 6. The Health clinics registered in the system have access to the study design and, if interested, can begin to select patients and acquire bio-samples for research in accordance with the design. The study can be conducted both at the premises of the health clinics themselves, and in the laboratory (-ies) of the Researcher.
- Health clinics keep a record of all patients, collecting their personal information and entering it
 into the system. The access to this data should be restricted and only available at the Health
 clinic.
- 8. Health clinics enter data on the biological samples collected for each patient. This data is also initially restricted to anyone except for the Health clinic and the CRO.
- 9. On cooperation with the CRO, the Health clinic performs the sample blinding procedure, the "key" to which is kept in encrypted format and can not be changed.
- 10. The Health clinic sends samples to the Researcher in the real world and opens access so that the information on the results of sample analysis can be entered into the system in a blinded format (X1, X2, etc.
- 11. Using the developed method and the study design, the Researcher conducts the analysis of the samples and fills the results into this form.
- 12. The design should include periodic unblinding (for example, for every 5-10-100 samples or by other criterion). Once the criterion is reached, the Researcher, as well as all system members can see information on patient X (personal data should be restricted), including age, sex, weight, etc., diagnosis, disease stage, sampling date, date of the analysis and the result of the analysis.
- 13. After the design implementation is complete, the system generates the final statistical report on the results obtained (all intermediate biostatistical parameters of the ongoing study are displayed in the process).
- 14. The Monitor (CRO) can also request additional samples for a sub-study in blinded format to confirm the validity of the results. The blinding is then carried out directly by the Monitor without the Health clinic's involvement.
- 15. The results of the study are sent to the Regulator, who decides whether to grant the test a marketing authorization or to conduct additional research with an altered design.
- 16. In the future all analysis results obtained using each product approved for the market will also be entered into the system.
- 17. Patients receive full private access (using private key) to the results of their personal samples analysis, and may also consent to disclose their personal information and/or participation in groups of volunteers for the research conducted by Pharmaceutical companies.
- 18. Over time, the platform will accumulate research information and participants data, which would allow to maintain the following statistics:

- a. Method/drug efficacy in terms of region, health clinic and doctor.
- b. Indicators of diagnostics and cancer treatment effectiveness of individual health clinics and doctors (success rate).
- c. Researchers success rate (in many cases they can take on the role of Experts in third parties developments).
- d. The shared storage of Big data on various diagnostic techniques and cancer treatment studies will allow to conduct multifactorial statistical analysis and receive statistical information on this disease and its dynamics in real time.
- e. In perspective, there might be an opportunity to use Artificial Intelligence technologies to search for "patterns" in a vast information scope, which would allow us to develop new diagnostic and treatment techniques and hasten humanity's complete victory over this disease.

The aim of data recording/storage

We believe that the market for in vitro diagnostics (IVD) of early stages of cancer is currently in its very infancy, the explosive growth of this market is inevitable in around 3-5 years from now. The **ARNA Panacea** solution will provide access to a huge data cluster for various market players from around the world.

Each patient's information will be stored in encrypted format, but the system software will allow the participant to disclose his personal information to any of the ecosystem members in exchange for a reward to patient for each request. Since this is recorded in BlockChain patient will be able to see each request occurred at any moment. Or easily "opt out" at any time making data anonymous and aggregated.

Further on we plan to cooperate with Big Data and AI (artificial intelligence) systems development teams to improve the statistical analysis capabilities for it's more efficient use with the information stored in the ecosystem. The use of such revolutionary technologies will allow to uncover patterns and trends in great scope of information, which should have a positive influence on the resolution of cancer issue worldwide.

ARNA Tokens

Goal and description

ARNA is an open source cryptographic token designed as a crypto-currency intended to be used as a payment tool for ARNA Panacea platform members' services as well as one of the payment methods for ARNA BC test after its market launch. ARNA token will become an accounting unit in all economic transactions of the ARNA Panacea Blockchain platform and will serve as a basis for interaction with other market players and clinical trials, including human DNA research.

As described below, the major portion of ARNA tokens money supply will become readily available in the near future, since part of ARNA tokens will be reserved for ARNA Genomics payment vehicle. Like other crypto-currencies, ARNA tokens are interchangeable and transferable; their placement on crypto-currency market is expected.

The use of ARNA tokens

ARNA tokens are used to pay for system interactions (data entry, obtaining access to research conducted, etc.) by all of its members. ARNA utility tokens are also used as a way for ARNA patients to pay for cancer screenings with ARNA BC tests at partner clinics and laboratories around the world paid in ARNA tokens. The results of the screening will also be provided to the Patient through the platform in the personal account section of the site or in the mobile application. Patients will be able to provide access to their personal data, including medical history and clinical data on their treatment, to participate in new research conducted by Pharmaceutical companies for an ARNA fee. Sponsors may use ARNA tokens to fund clinical trials of the latest cancer treatment technologies and techniques. The Investigator could also receive payments based on the results of a successful clinical trial of the method from the sales proceeds.

We intend to promote ARNA tokens as an actual currency of choice for Pharmaceutical companies enabling payments in ARNA tokens for their own research (when acting as the Investigator), for using research results (to the Investigator and the Health Clinics for accessing patient data), as well as for using other methods on the site.

In the process of ARNA Panacea development, additional ways of using ARNA tokens and rewarding Token holders can be established or redefined.

Choosing standards of tokens

According to the information provided by our lawyers, ARNA tokens are Utility Tokens and are not subject to SEC regulation (The United States Securities and Exchange Commission).

The issue of ARNA tokens will be implemented on the public blockchain Ethereum as standard ERC20. (https://github.com/ethereum/EIPs/issues/20)

The Ethereum blockchain is currently the standard for issuing digital assets and smart contracts. ERC20 token interface allows deploying a standard token that is compatible with the existing infrastructure of the Ethereum ecosystem, including development tools, wallets and exchangers. The ability of Ethereum to deploy Turing complete smart contracts without a guarantor intermediary supports the implementation of complex issues of crypto-currency, digital financial contracts and automated incentive structures. Ethereum with its advanced capabilities and an active ecosystem is ideal for creating ARNA tokens.

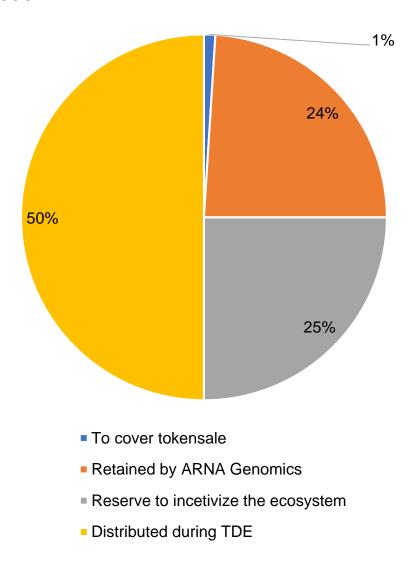
Acquisition of ARNA tokens

ARNA tokens can be purchased on the crypto-currency market from another patient/user or through transfer of own insurance company. The users of the platform will have the opportunity to purchase ARNA tokens by sending Ether (ETH) in the blockchain to the address of the created smart contract during the pre-session of ARNA tokens. The ARNA interface will integrate a third-party conversion application such as ShapeShift and Coinbase for those users who do not have ETH.

The primary offer of ARNA tokens will be in the form of a pre-selling, which will offer a limited number of ARNA tokens in the amount of USD 1 000 000 (One million tokens), each with nominal value of USD 1. We provide bonuses for "early birds" according to terms published at https://token.arnagenomics.com/How to Participate in ARNA PreSale.pdf.

At the main sale event we will convert these tokens to main event tokens.

Distribution model



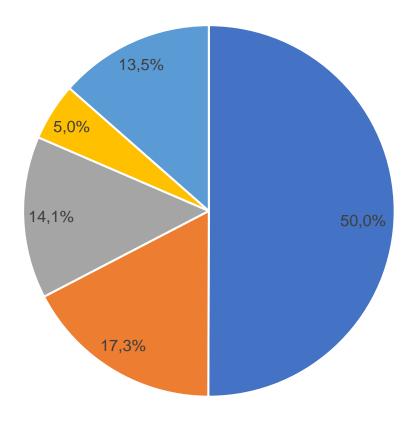
In order to finance activities in accordance with the road map, ARNA Genomics will distribute tokens in the form of a limited time or maximum sales amount of 50% of ARNA tokens from the total volume of the issued tokens - 1,000,000,000 (one billion).

The founding team of ARNA Genomics will receive 10% ARNA, half of which will be distributed immediately after TDE, another half will be "frozen" for 12 months. These tokens will serve as a long-term incentive for the founding team of ARNA Genomics.

The participants of the project team will distribute 15% of ARNA tokens in order to motivate the work team as well as our advisers. The release of tokens is planned for 3 years in equal parts every 6 months. The first distribution will be made after the completion of the sale of the tokens in order to compensate the contribution of individual participants to the project.

25% will be reserved for the purpose of entering into mutually beneficial deals with potential partners for promotion purposes, including the ARNA Panacea platform.

Distribution of TDE proceedings (Project budget)



- Regulator and launch of ARNA BC
- Development and implementation of ARNA Panacea
- R&D
- Legal support costs
- Operational expenses including marketing

According to the ARNA Genomics budget, 50% of the revenues from the implementation of ARNA tokens during the TDE will be aimed at conducting a full-fledged clinical study of the ARNA BC product under the supervision of the FDA (US Food and Drug Administration). This expense item consists of the costs for passing all phases of interaction with the FDA, the balance of funds will be spent on the deployment of a network of laboratories in key cities in terms of marketing of the USA cities. The exact allocation of funds between these directions will be determined by the results of the regulatory strategy chosen in the course of interaction with the FDA (510k, PMA or otherwise). At the same time, we plan to continue to register a medical device in Russia, since the costs in this direction are insignificant compared to the cost of the FDA, and the market is huge. In the future, it is planned to conduct research

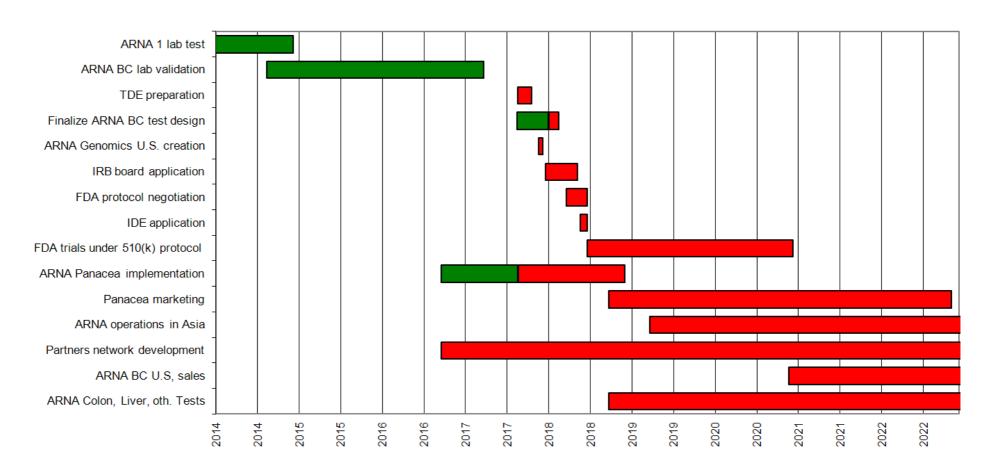
in Europe, China and India with the release of the product to the markets of these countries at the expense of funds coming from the sale of tests in the USA and Russia, or through the involvement of partners.

The cost of developing and implementing the first full-fledged ARNA Panacea release is estimated at about USD 7 million over 3 years after the TDE.

ARNA Genomics project highlights

#	Highlight	Description
1	Unique test ARNA BC for detection of breast cancer	ARNA BC currently has no analogues on the market and in R&D stage to the best of our knowledge. After completion of clinical trials in USA and Russia this test will become a "golden standard" for diagnostics of breast cancer and will quickly replace all existing today methods (mammography, biopsy, etc.)
2	Instantly available market	 BC diagnostics market already exists, it enough to provide a test more accurate in at least one parameter – and the market will rapidly turn to using new technology with almost zero marketing expenses. Market volume of US + Russia is 40 mln tests annually. Even 10% of this market size with a weighted average price of USD 90 per test already gives us USD 350 mln annual revenue. Weighted average multiplier for oncology companies EV/ Sales from 2012 to 2015 has grown from 4 to almost 10. Thus, preliminary conservative valuation of ARNA Genomics company will be in range USD 1.4-3.5 bln (not including in this valuation new cancer tests which are currently in R&D stage).
3	Private club for tokens owners – unprecedented privileges	In order to provide to our backers unprecedented privileges we would like to offer you in future ARNA VIP Reward program, which preliminary terms and conditions as outlined in ARNA VIP Rewards program section of this White Paper.
4	Platform approach to the project and its monetization	 Creation of ARNA Panacea will allow us to substantially speed up launch of our new products according to our plan. Additional monetization is expected from proceedings of new platform participants.

Roadmap



Executive Team

- Egor Melnikov, CEO. More than 10 years ago started the project with mission to save lives from cancer. Economist and manager by education, entrepreneur by experience and spirit. Made several successful startups as founder and co-founder in advertising and production business, international logistics, IT solutions for large-scale projects, was CEO of international telecom operator. ARNA Genomics – is Egor's life-time project.
- Anatoliy Melnikov is our Chief Scientific Officer and inventor of ARNA BC test with underlying technologies, co-founder. Having more than 40 years of experience in molecular biology and genetics, he is the author and co-author of more than 50 scientific articles. For 15 years he worked in the USA in oncological centers, before that in Canada, Hungary in various scientific companies, and Russia a branch of the Institute of Bioorganic Chemistry of the Russian Academy of Sciences and the Institute of Biochemistry and Physiology of Microorganisms of the Russian Academy of Sciences. He graduated from the biological faculty of the Lomonosov Moscow State University.
- George Nikitin is one of early co-founders and blockchain ecosystem ideologist is a physicist by education (MSc in plasma physics, diploma with honors, 14 published articles as co-author), worked with Deloitte, as well as in private projects of private equity companies (telecom, subsoil use and real estate). He has extensive experience in operational management of various business areas and held senior management positions in a number of private and public companies.
- Sergey Chernyshev, PhD, molecular biotechnologist, Puschino branch of the Institute
 of bioorganic chemistry, specializes in molecular biology, biotechnology, genetic
 engineering. Sphere of scientific interests: regulation of gene rexpression,
 transcription, translation, molecular mechanisms for phage lysis of bactreriums.
- Ilya Senechkin, PhD, Wageningen University, Netherlands, medical director in Sweetchild Group, Medical Advisor in MC Vitriolife, before that IVF Professional in MD Medical Group and scientific expert in Wageningen University in Netherlands.
- Magomed Chatuev is our software architect and developer. Has a big experience
 working with start-ups in the areas of e-commerce, PR & Marketing, finance,
 transportation, ERP development. Mainly focused on building SaaS, APIs & complex

- business processes automation. Had been working in international companies in Russia, Ireland, and Germany.
- Sergey Dolgachev is head of finance and risk department, co-founder. Sergey is a businessman and co-owner of several companies providing services for oil&gas industry, healthcare and biotech. Graduated the Faculty of Computational Mathematics and Cybernetics of Lomonosov Moscow State University, and MBA of Highest School of Economy, studied at Management School in Skolkovo, INSEAD and post-graduate of MGIMO. Has extensive experience in shelf oil&gas industry, where he hold top management positions in large companies. Started himself a company in that industry.

Advisory Board

- Dmitry Grigoryev has more than 20 years of experience of managing large enterprises with successful results in optimizing simultaneously costs and increase in sales in oil & gas sector. Currently Dmitry is involved in a number of high-tech projects as investor and strategic leader. Has a vast experience in successful strategies implementation, including mass and technological sectors.
- Sergey Borovskiy worked and lived in China since 1991. He has more than 20 years
 of experience in international management in China and Hong Kong. He held the
 positions of Chairman of the Board of Directors in various companies in China involved
 in international trade, investment and production. Since 2017, he was the General
 Manager of Sanju Environmental Protection (Hong Kong) Limited, coordinating the
 international projects of the controlling shareholder.
- Dmitry Kulish is an independent expert in the fields of strategic, organizational and technological development of pharmaceutical products. Dmitry holds a PhD in Biology, has been a postdoc at Harvard Medical School, earned MBA from the Wharton Business School, the Institute of Molecular Genetics of the Russian Academy of Sciences, and the Moscow State Institute of Molecular Biology Lomonosov Moscow State University.
- Dr. Alex Kosik is a successful serial technology entrepreneur. His focus is in Life Sciences, Medical Devices, FDA Compliance, Evidence-Based Medicine, Venture Capital and M&A. Alex is a recognized technology due diligence expert and senior analyst to several VC's, angels, Gerson Lehrman Group and institutional investors. He co-founded multiple businesses himself, met Bill Gates, sold his "G1 Gravitonus

- workstations" to Forbes-100, and ranked 3rd by Becker's Spine Review of "10 spine orthopedic surgeon tech entrepreneurs to know".
- Mikhail Groubman is an acting CEO of international CRO Atlant Clinical. Has graduated Lomonosov Moscow State University. Mikhail is advising project on clinical trials as well as existing procedures of biotech market.
- Ed Kanalosh has more than 20 years of experience in biotech investments and strategic consulting. Partner of venture fund "Maxwell Biotech" (Moscow), director of consulting company Candesic (London). Edward is an acting head of Investment Service of Skolkovo fund, vice-president of Investment Bank "Trust" and consultant of New Jersey office of McKinsey company. His career has started in Bill and Melinda Gates Foundation Fund. MBA from Harvard Business School, MD with PhD.
- Sönke Bartling, PD, DR MED, Board certified Radiologist, blockchain for research & healthcare / Open Science. Sönke has a tremendous background in neuroradiology at Hannover Medical School, Institute for Radiology and Interventional Therapy and other sound scientific organizations. Apart from that Sönke is well-known due to his activity in Web 2.0 for science in 00x, following by working on Blockchain for Science and Open Science (awarded in 2015, Germany land of ideas) concepts. He is author of more than 20 scientific publications, number of reviews, books and 6 patents. Holds various awards and is a member of governmental groups on radiology and tomography.
- Vladimir Savanovich has a master's degree in physics. During his professional
 experience, he worked in various business areas, mainly focusing on the active
 development of the contractual base of enterprises. He has experience in working in a
 Western consulting company, a resort development company, a Swiss investment
 fund and a Russian exploration company.
- Marina Sekacheva is a Doctor of Medical Sciences, a laureate of the Russian Government Prize in Science, a holder of post-doctoral degree in medicine of the Technical University of Munich, the Director of the Center for Personalized Oncology Sechenov OncoTarget, established as part of the Institute of Personalized Medicine in 2017.

Conclusions

ARNA Genomics offers to participate in the beginning of our ambitious journey to global markets and join the project by financing the preliminary sale of ARNA tokens.

The funds received in the course of the preliminary sale will be partially directed to finance the marketing expenses for the preparation for the main token sale. We understand that this is a big expense, but the issue that we attempt to solve is cancer - and it is larger than all of us together. So the faster we will be able to provide tools we offer – ARNA BC and ARNA Panacea – the more people lives will be probably saved and at lower cost and with high quality of life for patients.

That is why we have no moral right to divide these two products, even though each of them individually deserves its own TDE.

Our mission is not to attract as much funding as possible, our mission is to "save people's lives from cancer" and for the sake of which we would be ready to launch simultaneously and more products to the detriment of the amount of the funding raised.

We also would like to offer to our backers unprecedented right to become part of private club of early ARNA tokens' holders and in future get an opportunity to benefit from Arna Token buyout program outlined on page 42. We will not forget about out backers, we will keep engaging with you as actively as we do right now.

And if you've made it this far (a feat only select few will ever achieve!!!) please know that now we want to see you, yes you among our backers. And if there's one thing we'd want you to remember from this long WhitePaper is that ARNA Genomics creates specific cancer screening tests ARNA BC and ARNA Platform within a framework of a revolutionary blockchain ecosystem ARNA Panacea, which will act as a unified protected and distributed platform for communication of the members of the market of clinical studies and will allow to enhance trust in evidence-based medicine, and therewith to move closer to the solution of cancer problem for all humanity. Together with regulatory authorities of the developed countries, as well as with other members, ARNA Genomics is going to bring a detailed system of collection, storage and presentation of data, being an evidentiary base of conducted studies, to a unified standard in the world market.

Legal information and disclaimer

This White Paper has been prepared by ARNA Genomics ('Company') for use by a limited number of prospective backers, both private persons and legal entities in considering the potential purchase of ARNA Tokens ("Tokens") backing Company business activities. The sole purpose of this White Paper is to provide information about the Company in order to assist the baker in deciding whether to proceed with a further investigation of the Company and its tokens. Each recipient acknowledges that this Whitepaper will be used solely for such purpose and is not intended to form the basis of any purchase decision relating to tokens of the Company.

The financial projections that appear in this White Paper are estimated revenues, expenses, token values and cash flow, which are based on research and the assumptions discussed throughout this White Paper. They represent the best of management's knowledge and belief and also are based on actual operations in the pilot clinical trials of ARNA BC lab prototype. The Company's expected revenues, expenses, and cash flow for the post-TDE projected periods are subject to the Company's ability to develop the FDA and other regulatory approvals, sales and production levels at the price and costs estimated by management. Accordingly, these projections reflect management's estimates, and its expected course of action if such sales and production levels are attained at the price and costs anticipated. These projected financial statements are for the purpose of providing updated information to existing and new backers. These projected financial statements should not be considered to be a presentation to forecast future results. Accordingly, these projections may not be useful for other purposes. The assumptions disclosed herein are those that management believes are significant to the projections. Furthermore, even if the sales and production levels as well as projected price and costs are attained, there will usually be differences between projected and actual results because circumstances frequently do not occur as expected, and those differences may be material.

While this White Paper has been prepared in good faith, Company doesn't make any representation or warranty, express or implied, as to the accuracy, reliability or completeness of any of the information or projections in the White Paper, or of any other written or oral communication transmitted or made available at any time to a prospective backer, and each of such parties expressly disclaims any and all liability relating to or resulting from the use of such information and communications by the prospective backer or any of its affiliates or representatives. No information set out in this White Paper or referred to in such other written or oral information will form the basis of any contract. This White Paper has been delivered to interested parties for information purpose only and upon the express understanding that such parties will use it only for the purpose set out above. Company undertakes no obligation to provide the recipient with access to any additional information or to update this White Paper or any additional information or to correct any inaccuracies in that may become apparent. Company reserves the right, without giving reasons, at any time and in any respect, to amend or terminate the procedure for the issue of new tokens of Company. The issue of this White Paper does not constitute an offer or an invitation for the sale or purchase of company tokens and shall not be considered as the basis of forming any contract between Company and any prospective backer.

The ARNA Token has not been, and will not be, registered under the U.S. Securities Act of 1933, as amended (the "Securities Act"), or any state or other securities laws. In an abundance of caution, ARNA Genomics shall seek to treat the ARNA Tokens as it would "securities" and will thus comply with exemptions from the registration requirements of the Securities Act provided by Regulation D and Regulation S promulgated thereunder, but ARNA Genomics takes no position as to the determinations that any other parties, including any applicable securities regulators, may make regarding the Tokens or a public offering of the tokens and the applicability of the Securities Act to any of the foregoing. Potential token purchasers are urged to consult their own legal advisors. This document

does not constitute or form part of, and should not be construed as, any offer for sale or subscription of, or any invitation to offer to buy or subscribe for, any securities, nor should it or any part of it form the basis of, or be relied on in any connection with, any contract or commitment whatsoever. ARNA Genomics expressly disclaims any and all responsibility for any direct or consequential loss or damage of any kind whatsoever arising directly or indirectly from: (i) reliance on any information contained in this document, (ii) any error, omission or inaccuracy in any such information or (iii) any action resulting therefrom. Certain information contained in this document constitutes "forward-looking statements," which can be identified by the use of forward-looking terminology such as "may," "will," "should," "expect," "anticipate," "project," "estimate," "intend" or "believe" or the negatives thereof or other variations thereon or comparable terminology. Due to various risks and uncertainties, including those risk disclosures described herein and made available at http://arnagenomics.com and https://token.arnagenomics.com/ prior to the beginning of the token sale, actual events or results or the actual performance of the tokens may differ materially from those reflected or contemplated in such forward-looking statements.

ARNA VIP Rewards program

ARNA VIP Rewards program is subject to the approval of applicable regulatory bodies (e.g. Securities and Exchanges Committee). To the best of our current understanding such program does not create in any circumstances ability for any entity or individual to treat in any possible ways ARNA tokens as securities instead of utility tokens which they really are. Immediately after main TDE ARNA Genomics will consult with such regulatory bodies in order to get approval from them that actions under such program can be performed according to the defined limitations and guidelines, and such actions will not in any case affect other ARNA tokens holders or the tokens themselves by any chance of treating them as securities. Whilst such reward program will be rejected or in any other way not approved by regulatory bodies, ARNA Genomics will not be pursuing such reward program and waives all responsibility, as well as potential participant completely indemnifies ARNA Genomics from all and any responsibility to perform actions under such rewards program in case they are not approved by regulatory authorities and may lead to treatment of ARNA token as a security.

- As per our current understanding of laws, the "Futures contract" is the only possible way to avoid a risk
 for ARNA tokens to be considered as security tokens (which they are not in any way) versus utility, (which
 they are). There are only four items on the list of items that are not securities:
- Fixed Insurance, endowment or annuities policies
- Retirement plans
- Commodities or futures contracts
- Condominiums when used as personal residences

Futures contracts (that don't exist yet, so to speak, but would be made available immediately after trigger event) are not securities. Futures are financial contracts obligating the seller (us) to sell an asset, such as a physical commodity or a financial instrument (ARNA BC new security company Common Stock), at a predetermined future date (90 days after trigger event) and price (0.00001 U.S. cent) to buyer (you). Also, we can not use a term stock "option" because as soon term "option" is added to futures contract, then the instrument becomes a security.