BioTe21

Genetic Laboratory BioTe21 (BioTe21 Adam Master) was created in September 2005 as a result of realization of the project co-financed by the European Union under the European Regional Development Fund and the State Budget within Measure 3.4 of the Integrated Regional Development Programme (ZPORR 3.4)[1] and also with support of the Second Branch of the Bank PKO BP in Cracow. BioTe21 is now a modern, innovative and quickly growing company, joining in its activity business, academic and social elements, integrated thanks to the owner and founder of the company and the team of qualified scientists working with him.

The laboratory provides services to the research institutions including solving difficult science and technology problems, based on following methodologies: DNA synthesis and sequencing, microarray analysis, RNA interference (RNAi), genetic engineering as well as developing new technologies for molecular diagnostics and therapy, carried out by the Laboratory of Molecular Medical Biology BioTe21. The result of research cooperation are numerous projects implemented in cooperation with Polish and foreign research institutions. However the main activitiy of the divisional Laboratory of Genetic Identification is focused on conducting genetic paternity and family relationship tests, genealogical analysis and providing courts and prosecutors with criminal expertise along with an opinion of the company's owner, who has rights of legal expert in the area of genetic and biochemical identification. Another activity of BioTe21 is ArtGen21 project entitled "Science for Art, Art for Science", where the results of examination of individual genetic profiles are visualized by artists of Cracow in form of a picture or placed by jewelers on wedding rings. In the public eye, BioTe21 is known primarily for studies such as: genetic tests of predisposition to melanoma, thyroid cancer, lung cancer, breast cancer as well as diagnosis of hereditary predisposition to Alzheimer's disease. In addition, as a part of its activity, the company is looking for new applications and possibilities of implementation in biotechnology and medicine of scientific discoveries resulting from basic research of genome, transcriptome and proteome.[2]

The founder of BioTe21 took **strategic aim** at "creation of a scientific and technological base, allowing developing useful bioinformatic projections as well as creation and implementation of new biotechnologies, particularly applications used in molecular medicine."[3] These ambitious plans are a part of Adam Master's words, which can stand for the **company's motto** - "*we must get down to work and begin to change this world for better because it only depends on us how it will look like!*"[4] This statement has been said during one of the most important projects initiated by BioTe21's request to the Ministry of Health regarding creation of a new field of Medical Biology and Laboratory Medical Biology, and their inscription on the list of areas applicable in health care and laboratory diagnostics. Appointment of a new field by an appropriate regulation of the Minister of Health will enable creation of an institution of the national consultant in this field and creation of medical specialization for further directional education of biologists, biotechnologists, molecular biologists, biochemists, biophysicists, without need to retrain the graduates of these faculties toward areas already inscribed on the list of the Minister of Health (a*), which are often divergent from the object of real education of biologists and biotechnologists. Adam Master, explaining the reasons of the request to the Ministry of Health, says that the medical market growth based on the latest biomedical technologies requires from scientific institutions and the government greater involvement in creation of programs and structures enabling a systematic and ordered development of fields such as medical biology and constant education in the area of the latest medical biotechnologies, which will undoubtedly contribute not only to the development of molecular medicine and general improvement of public health but also to improvement of economic, human and social capital, and thus will enhance the science and technology competitiveness of Poland in the world. The new field of education will refer to fastly changing labor market needs, which consequently will improve the attractiveness of science related to biology and biotechnology, at the same time staying perfectly in accordance with the reform currently implemented in science and higher education.[5] It should also be mentioned that since 2007 BioTe21 is a partner of

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[1] Information received from Kamila Giżewska, PhD, from BioTe21

[2] Szcześniak A., BioTe21 Adam Master,

[3] http://www.lifescience.pl/content.php?component=com_publisher&section_id=7&article_id=247

[4] Adam Master, Specjalizacja w zakresie Biologii Medycznej, http://www.badanieojcostwa.pl/specjalizacja-biologia-medyczna.html

[5] This problem will be described in the further part of this review.

Lifescience Cluster organization and collaborates with many Polish and foreign scientific and technological institutions.

The founder and owner of BioTe21 is an extraordinary person - Adam Master, M. Sc., Eng. - young, ambitious, exceptionally diligent and active, a visionary man with desire to act spreading on his closest colleagues and business and scientific partners. Educated as molecular biologist (Jagiellonian University), chemical technologist (Cracow University of Technology), laboratory diagnostician (inscribed on the list of the National Chamber of Laboratory Diagnosticians, no. 08989), he also completed his doctoral studies in the field of medical biology (just before the thesis defense at Medical Centre for Postgraduate Education in Warsaw), a member of the Polish Forensic Association (membership card no. 0724) and British Society for Endocrinology. He has also received the award of the Minister of Health for co-authorship of one of the published works. In the past he cooperated with private and public institutions involved in research and implementations of genetic tests results where he gained experience in the field of biotechnology and molecular biology as well as in commercialization and introduction onto the market of biomedical services and technologies.

1.1. Technology - source of an innovative idea

Accordnig to the report "Bioeconomy status and development directions", developed by an interdisciplinary Team for Bioeconomy Development under the guidance of prof. Adam Dubin, PhD.: "Polish biotechnology is characterized by advanced education in the field of the so-called life sciences and engineering sciences, both at the engineering-master studies level and doctoral level, though because of the lack of experienced staff of "practitioners" associated with the industry, both teaching and researches are still not practical enough and the transfer of innovative technologies form universities to industry is insufficient."[6] In spite of about 1300 graduates of biotechnology each year, the demand for research and development of new technologies in the field of biotechnology and creation of business, which could develop and implement innovative solutions of the area mentioned above, is not decreasing in Poland.

The company BioTe21 Adam Master was created and developed in response to already mentioned constantly increasing market demand, at the same time taking into account the fact that the branch should be successful because the products of biotechnology (genetic research, protein medicines and products based on the synthesis and analysis of DNA fragments) find increasingly common use in many fields. It is enough to mention that genetic diagnosis allows obtaining medical information prior to clinical appearance of a disease. Genetic tests with high probability allow to determine the risk of certain diseases or to confirm the hereditary genetic load, and thus to give a patient and his family a chance to take preventive actions or to start an appropriate therapy.

Another element that contributed to creation of BioTe21 and its unique offer giving broad development prespectives was the fact that Adam Master during his scientific and professional career has gained a huge experience in biotechnology and molecular biology as well as commercialization and introduction of services on the biomedical technology market, he also had knowledge about the biotechnology market in Poland and in the world. He noticed how big is the demand for services in the field of synthesis and sequencing of nucleic acids and the need for new diagnostic techniques for cancer predisposition not only from the commercial market but also from the scientific staff of universities and individual clients. He used this practical knowledge and personal experience to create from the basics a dynamically developing company BioTe21.[7]

While BioTe21 was being created, it was one of a few companies specialized in medical genetics and biomolecular research. In his company Adam Master has introduced the technology including medical genetics (including diagnostics), genetic engineering and strictly biotechnologic applications (recombinant protein biosynthesis), and even though modern technologies used by BioTe21, such as DNA sequencing and synthesis, are known for many years, it should be noted that they are a basis for

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[6] "Bioeconomy status and development directions", report developed by an Interdisciplinary Team for Bioeconomy Development under the guidance of prof. Adam Dubin, PhD, the Miunistry of Science and Higher Education, Warsaw, September 2007, page 8

[7] Szcześniak A., Gene synthesis as a basis of business based on science services. Case study of BioTe21 Adam Master, in: **Enterprising University. Practical usefulness of scientific research and research and development works. Designing and conducting development researches in cooperation with economy**. Collective work edited by Mieczysław Bąk and Przemysław Kulawczuk.

realizing orders of new products and services, which are implementations of the latest scientific and technical knowledge in the area of chemistry, molecular biology and medicine. At the moment BioTe21 is conducting the final analysis of oligonucleotides used in the developed technology based on the phenomenon of RNA interference, leading however to the strengthening of gene expression, whose level is too low in organism, which can be used in treatment of cancer and other hereditary diseases.

Establishment of BioTe21 had also a positive impact on access to the technology in question and services of synthesis and sequencing of nucleic acids, which facilitated the direct contact with the supplier to researchers of other units. In 2009 the company BioTe21was in fact the only laboratory in Małopolska region, which addressed to academic units the competitive offer in comparison with the Western brands with a stable position on the scientific research market.

Through the development of new diagnostic techniques regarding examination of cancer predisposition, BioTe21 could address its offer to people not connected with the branch represented by the company nor the science community, and thus it became the first commercial laboratory of genetic diagnosis in Małopolska, open for all interested customers, thanks to the prices available for an average patient.

1.2. R&D activity and cooperation with the academic community

Adam Master graduated from Jagiellonian University with a master's degree at the Faculty of Biology and Earth Sciences (currently the Faculty of Biotechnology, Institute of Biology, specialization: Molecular Biology, Department of Cell Biology), Cracow University of Technology - with the title of engineer at the Faculty of Engineering and Chemical Technology (Institute of Chemical Technology, specialization: Light Organic Synthesis). The owner of BioTe21 in 2010 finished stationary PhD studies in the Department of Biochemistry and Molecular Biology at the Centre for Postgraduate Education in Warsaw, where he is awaiting his doctoral thesis defense entitled "Effect of non-translated regions of mRNA (UTR) on the expression of a beta-1 isoform of nuclear T3 (TRβ1) receptor in clear cell type renal cell carcinoma (ccRCC)". The researches conducted by Adam Master with research team specialized in metabolism and thyroid hormone action at the molecular level, and first of all the influence of thyroid hormone (triiodothyronine) on neogenesis, are impressive, according to prof. Alicja Macke-Nauman, the thesis supervisor.[8] Prof. Macke-Nauman also very highly estimates the knowledge of Adam Master regarding the most modern techniques of molecular biology. It should be mentioned additionally that the young scientist Adam Master is a co-author of three patents[9] and several more in preparation. During his proffessional career, Adam Master worked in the best scientific centers in Poland (Institute of Pharmacology of Polish Academy of Sciences in Cracow and M. Nencki Institute of Experimental Biology of Polish Academy of Sciences in Warsaw), as well as in DNA Research Institute Sp. z o.o. in Warsaw, at the same time providing technology design services to other institutions.

The knowledge acquired during studies, doctoral studies and working in the above mentioned institutions regarding the Polish and foreign biotechnological market, ability to critically evaluate the procedures used and desire to change them as well as drawing attention to the growing demand for services in the area of DNA synthesis and sequencing and proffessional experience, including commercialization and introduction onto the market of biomedical services, undoubtedly facilitated

[8] According to the opinion of prof. Alicja Macke-Nauman, PhD, MD.

[9] 1. Master Adam, Skrzypczak Magdalena, Master Aneta, Nowacka Joanna, Płucienniczak Andrzej, Wróblewska Sylwia. Authorship of patented technology: „Oligonucleotide and polynucleotide dedicated for detection and identification of mutations, especially hereditary, in the human p53 gene, a method for producing the polynucleotide and a method and kit for the detection and identification of mutations in the human p53 gene". Publication of the Polish Patent Office dated 18-09-2006 no. 19/2006, app.no.: 373443.

2. Master Adam, Skrzypczak Magdalena, Master Aneta, Nowacka Joanna, Płucienniczak Andrzej, Wróblewska Sylwia. Authorship of patented technology: „Oligonucleotide and polynucleotide dedicated for detection and identification of mutations, especially hereditary, in human genes: BRCA1 and BRCA2, a method for producing a polynucleotide and a method and kit for detection and identification of mutations in human BRCA1 and BRCA2". Publication of the Polish Patent Office dated 18-09-2006 no. 19/2006 app.no.: 373442.

3. Master Adam, Skrzypczak Magdalena, authorship of patented technology: „Oligonucleotide, its use and method and kit for detecting the presence of DNA Toxoplasma gondii". Publication of the Polish Patent Office dated 2004-09-06, Publication no.: PL358894 (A1), International classification: C07K14/45; C12P19/34; C12Q1/68; C07K14/435; C12P19/00; C12Q1/68; (IPC1-7): C07K14/45; C12Q1/68; C12P19/34; nr zgł.: PL20030358894 20030226.

creation of the strategy of BioTe21 and finally creation of the company by Adam Master. The owner, while creating his company, was well aware of the major problems faced by academic institutions trying to implement innovative technologies as well as how difficult it is in Poland to obtain funding for scientific research which often absorb most of the revenues. However creating his own business, employing excellent professionals and science enthusiasts, constantly improving their qualifications, gave a better chance of realization of ambitions and scientific interests of its founder, especially because it was the only company with such a profile of activity in 2005 in Małopolska region.

Thanks to the financing obtained for the **project "Synthesis of genes using the methode of submission of oligonucleotides in the Polymerase Chain Reaction"** within the Integrated Regional Development Programme under Measure 3.4. "Microenterprises" and signing agreements with Jagiellonian University and Jagiellonian Centre of Innovation, the company has equipped the rented rooms with the necessary equipment, fully implemented the scientific objectives of the project and thus entered on the market, gaining such a good reputation that after finishing the project it was possible to continue an independent business activity and acquiring new customers by the company. From the beginning BioTe21 attaches great importance to the control of the company's research. Confirmation of their quality are the international **GEDNAP Certificates** (*German DNA Profiling Group*) obtained after passing through a difficult certification procedures in 2007, awarded by the German Genetic Institute. These certificates are renewed every year, giving the company's customers confidence of the work quality.

The **fourth thematic laboratory - Genetic Diagnostics Laboratory** was created in 2008 in BioTe21. Furthermore the company has also received another confirmation of its reliability, it was inscribed on the register of Health Care Institutions (February 2008) and the register of laboratories run by the National Chamber of Laboratory Diagnosticians (March 2008). Moreover the District Court in Cracow (November 2008) and Warsaw (March 2011) assigned Adam Master as a court expert in the area of genetic and biochemical identification, and in December 2008, the *Society for Endocrinology* accepted his membership in the organization.

In 2008 the company also started implementation of an innovative project **"Skin cancer - diagnostic of genetic predisposition to melanoma"**, an original idea of BioTe21, which as the only one in Poland has introduced a complex assessment of predisposition to hereditary and UV-dependent skin cancer on the market of diagnostic services. The research is based on the latest biomedical knowledge in the field of genetic mutations predisposing to malignant melanoma and taking into account the knowledge regarding possibility of undertaking preventive actions by persons burdened with these mutations.[10]

BioTe21 has also established other **tests for diagnosis of predisposition to genetic diseases of high public interest**, such as predisposition to: lung cancer (the test includes 5 independent genes: CHRNA3, CHRNA5, GSTP1, GSTM1 and ELA2), **medullary thyroid carcinoma** (analysis of RET gene sequence), **breast cancer** including diagnosis of up to 15 BRCA1 mutations (in Poland usually 3 to 7 major mutations are tested), 9 mutations of BRCA2 (analysis of NBS1 and CHEK2 gene) and **cardiovascular diseases** (LDLR gene mutation analysis).[11]

All above mentioned tests are available not only for research institutes and medical institutions, but also for individuals, because thanks to innovative technologies used by BioTe21 they are relatively cheap. In case of diagnosis of mutation in one of the patient's tested genes he is always directed to a specialist genetic clinic, cooperating with BioTe21, which offers professional help and appropriate treatment of patient.

BioTe21, through **continuation of research and development works**, takes into account the needs of medicine, including individual customer's expectations, who wants to know the threats of his own

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[10] Szcześniak A., Gene synthesis as a basis of business based on science services. Case study of BioTe21 Adam Master, in: **Enterprising University. Practical usefulness of scientific research and research and development works. Designing and conducting development researches in cooperation with economy**. Collective work edited by Mieczysław Bąk and Przemysław Kulawczuk

[11] Szcześniak A., Gene synthesis as a basis of business based on science services. Case study of BioTe21 Adam Master, in: **Enterprising University. Practical usefulness of scientific research and research and development works. Designing and conducting development researches in cooperation with economy**. Collective work edited by Mieczysław Bąk and Przemysław Kulawczuk

genome, so that he could undertake the most effective preventive and prophylactic actions in time. BioTe21's pride is among others the technology of detecting up to 21 breast cancer mutations (while competing laboratories analyze usually 2-7 mutations), significantly increasing the probability of detecting even rare changes in DNA. Within implementation works the company also conducts diagnosis of colorectal cancer, expected from years on the medical research market. BioTe21 has also developed a safe kit for self-collection of genetic material BioTest-21, which allows collecting and sending the protected DNA to the laboratory, often hundreds of kilometers away from the person interested in tests, without need to visit it. Such kits are available for purchase in selected pharmacies as well as through the Web site of BioTe21, along with the instructional film. Self-collecting of genetic material can help to find answers to the questions of customers, for example, regarding paternity, but can not be a prove in court which requires the protocol of collection of DNA in one of biological material sampling points in Poland.

"The laboratory has also prepared many innovative investment projects in the field of medical biology, molecular medicine and pharmaceutical biotechnology. However their implementation requires much higher investment funds, enabling scientific and technological progress of the entire biomedical industry in Poland and abroad."[12] One of these projects is a developed business plan and program of "Creation of the first center and network of medical DNA testing and diagnosis of genetic predisposition to hereditary diseases (genetic testing network)", which implementation will require an agreement with a strategic investor.

The company has also started an innovative and unique project of Adam Master - **ArtGen21 "Science for Art - Art for science"** which "offers an artistic and durable form of presentation of individual genetic profile or a pair of profiles (i.e. marriage profile), determined only on the basis of nucleated cells smear from the buccal part of the oral cavity." Presentation of the genetic profiles can be developed as e.g. graphics, oil painting, painting on glass or relief, it can also be engraved on marriage rings (in the form of STR systems describing DNA) and other items and given as a present. Within this project BioTe21 cooperates with artists who are willing to suggest an appropriate form of presentation of the ordered profiles.[13]

The company and its founder, Adam Master, have won numerous awards for their achievements. In 2008 according to the decision of the Kronenberg Foundation Chapter in the contest for the title of **MICROENTERPRENEUR OF THE YEAR 2008**, the company **BIOTE21 ADAM MASTER** was honored in the MAIN category. The prize is awarded by the Banking Foundation of Leopold Kronenberg, assisted by the founder of the prize – Citi-Handlowy and international Capital Group Citi.[14]

Moreover, on 16 April 2009 the jury of the contest **Leaders of the National Health Care System**, which aim is to honor individuals and institutions who have particularly contributed to improve the quality of health care in Poland, acting ahead of existing standards and with determination and commitment, being inspiration and example for other participants of the health care market", awarded **BioTe21 with the first place** in the category of Innovative Ideas in Health Care.[15]
What is more, on 16 November 2009, the chapter of the contest "Innovator of Małopolska 2009" awarded BioTe21 Adam Master laboratory with the title: "**INNOVATOR OF MAŁOPOLSKA 2009**" and the main prize in the category of "microenterprises". The competition organized by the Government of Małopolska region and Technology Transfer Centre of Cracow University of Technology was designed to honor companies distinguishing by considerable dynamism of development, innovation and enthusiasm. The prizes were awarded during the Jubilee Gala of CTT PK accompanying the conference "Science for Business".

In 2010 Adam Master was appointed by the Rector of the Cracow University of Technology as one of the five members of the committee evaluating requests within the contest "Young Scientist - Creator of Economic Reality" organized by the Technology Transfer Centre of Cracow University of Technology. The contest was organized within the project "**Young Scientist** - creator of economic reality" funded

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[12] Laboratory BioTe21, http://www.badanieojcostwa.pl/laboratorium-BioTe21.html
[13] http://www.artgen21.com/start.php
[14] http://www.BioTe21.com/html/pl/kryminalistyczne.html
[15] http://www.BioTe21.com/html/pl/kryminalistyczne.html

under the program of the Ministry of Science and Higher Education "Creator of innovation – support of innovative academic enterpreneurship."
In 2010 Adam Master was also **awarded by the Minister of Health** for coparticipation in the publication "Disturbed Expression of Type 1 Iodothyronine Deiodinase Splice Variants in Human Renal Cancer".[16]

Within the principal activity of the laboratory, BioTe21 offers services in the field of synthesis and sequencing of DNA for medical and scientific institutions, genetic engineering and genetic identification including diagnosis of predisposition to genetic diseases and cancer as well as paternity testing for private and court purposes and paternity testing of microtraces (if collection of genetic material for analysis is impossible). Moreover BioTe21 allows biochemical or genetic tests, helpful in stating truth in case of suspicion of partner's adultery, blackmail or sabotage. The company also offers researches determining genealogical roots by verifying family ties, inherited names, identifying the origin of ancestral groups, family branches and migration routes over thousands of years ago. The laboratory has a unique in Poland proficiency certificates in the **mitochondrial DNA** testing (GEDNAP-mtDNA). These tests enable genetic identification even with damaged biological microtraces, including samples from the exhumed corpses.

A very important area of activity of BioTe21 is cooperation and help in developing difficult, scientific and technological solutions for bio-medical sciences.

These are only a few elements of a wide range of services of BioTe21, available at the Web site of the company.[17]

When BioTe21 has been created there were only a few companies engaged in medical genetics and molecular medical biology on the Polish market. The market was just developing, so the company was created in perfect time, though it was connected with overcoming many difficulties, among others, regarding role of the promoter of a new market of genetic testing, which was unknown to an average person. Adam Master took a chance offered by a **niche connected with usage of modern tools and research methods in the field of genetic medicine and bio-molecular research**, growing together with the development of science and technology. One of the first areas where the developing potential of BioTe21 could be exploited was jurisdiction, namely cooperation with courts and prosecutors on tests of genetic identification determining paternity. In 2005, during establishment of the company, the courts generally did not benefit from such services. BioTe21 offered tests at the highest level of resolution, using modern research methods, unique in Poland. Then e.g. genetic paternity testing was relatively innovative, currently they are routine tests which can be performed at home using BioTest-21 kit sent by the company. The only drawback of the test based on self-collected genetic material is that the results of such a test can not be a proof in a court, but it does not change the fact that it allows many people to obtain information important to them. In addition to paternity testing, the distinctive element of BioTe21 different from similar companies on the market is introduction of genetic identification with routinely conducted mitochondrial DNA testing.

While choosing areas of business development and creating the current offer BioTe21 benefited from studies on the market research and its needs. The company looked and is still looking for niches, where it could offer its services with an emphasis on new technologies not used anywhere yet. This approach to the market and business development strategy meant that within six years the company created four highly specialized thematic sections covering the fields of molecular medical biology: Laboratory of Synthesis and Sequencing of Nucleic Acids, Laboratory of Genetic Identification and Paternity Testing, Laboratory of Genetic Diagnostics and Laboratory of New Biotechnology. Currently Laboratory of New Biotechnology allows to adjust and help cooperating units in the implementation of almost every project that is associated with the development of scientific and diagnostic technologies using high definition methods of analysis in terms of cancer research, identification, neurodegenerative, genetic identification of protected microbiological signs and other genome, transcriptome and proteome researches.

[16] https://www.badanieojcostwa.pl/wiarygodnosccertyfikaty.html

[17] More details at: http://www.medycynasadowa.com/ , http://www.badanieojcostwa.pl/test-dna-dla-celow-prywatnych.html, http://www.asvalia.pl/

A completely new direction of development of the company was also entering into a new area of using knowledge for the purpose of art - implemented in the project ArtGen21. The company offered its customers an artistic presentation of the individual genetic profile or a pair of profiles, as souvenirs, expression of love and belonging or an exclusive gift.

In case of BioTe21 it is impossible to identify the first contact between the company and the scientific community, because Adam Master, the owner and founder of the company, comes from this community and throughout his career he maintained and still maintains close contacts with the scientific community, primarily as a student, later as a doctoral student, employee of research centers and then as a scientist and owner of an innovative biotechnological company.

The founder of BioTe21 graduated from Jagiellonian University with a master's degree at the Faculty of Biology and Earth Sciences (currently the Faculty of Biotechnology, Institute of Biology, specialization: Molecular Biology, Department of Cell Biology), Cracow University of Technology - with the title of engineer at the Faculty of Engineering and Chemical Technology (Institute of Chemical Technology, specialization: Light Organic Synthesis).[18] After graduation A. Master started working in famous Polish scientific centers such as the Institute of Pharmacology of Polish Academy of Sciences in Cracow and M. Nencki Institute of Experimental Biology of Polish Academy of Sciences in Warsaw and The Institute for DNA Research Sp. z o.o. in Warsaw - a commercial enterprise oriented on implementation of genetic testing. The next step and great challenge in a professional career of Adam Master was undertaking doctoral studies and then starting his own businesses, where he can now realize his academic and professional projects as well as promote and develop science, even among people not associated with medical or scientific community.

Early contact of the newly established company with the scientific community of Jagiellonian University was also caused by other than scientific aspects. For BioTe21 - the company beginning in the biotechnology branch, it was important to locate its offices in "Academic Incubator of Entrepreneurship" in Cracow in the Third Campus of Jagiellonian University. This location of the company was an opportunity of BioTe21 inclusion in the activities of the Technology Park in the Special Economic Zone in Cracow, whose construction is carried out within the funds granted to Jagiellonian Centre of Innovation (JCI).[19]

Due to the planned activity of BioTe21, involving the development, implementation and commercialization of new technologies in molecular biology and medical genetics as well as due to the basic services of DNA synthesis, the newly established company was also an interesting partner for JCI, which mission is first of all promotion of new Polish biotechnology projects in Poland and in the world.

Cooperation of BioTe21with the csientific community contributed to creation of a project and granting funds from the European Union, European Regional Development Fund and the state budget under Measure 3.4. "Microenterprises" of the Integrated Regional Development Programme (implemented by the Marshal Office of Małopolskie Voivodeship), which allowed a purchase of the expensive but necessary equipment for the growing company. Substantial value of the project as well as cooperation with Jagiellonian University, JCI and other scientific and economic institutions which issued letters of intent (promises), regarding among others providing BioTe21 with offices and laboratories in case of granting funds for the project of BioTe21, certainly raised the company's reliability as an applicant. The aim of the project was to introduce on the market and sale of genes and DNA oligonucleotides synthese services, gene cloning and perform genetic constructs (gene sets) for commercial and non-commercial scientific, medical and analytical institutions. Within the project implemented from 1 March 2006 in offices rented from Jagiellonian University and Jagiellonian Centre of Innovation, specialized machinery and equipment was purchased, enabling chemical and enzymatic synthesis of DNA. During realization of the first project there was also created a team of research workers, specialists in

[18] Szcześniak A., Gene synthesis as a basis of business based on science services. Case study of BioTe21 Adam Master, in: **Enterprising University. Practical usefulness of scientific research and research and development works. Designing and conducting development researches in cooperation with economy**. Collective work edited by Mieczysław Bąk and Przemysław Kulawczuk.

[19] Jagiellonian Centre of Innovation Sp. z o. o. (JCI) was founded in 2004 as an initiative of the Authorities of Jagiellonian University (UJ) in connection with the project of creating a specialized Park and Incubator of Life Science profile in Cracow, which is currently managed by the academic company. JCI facilitates cooperation between companies of the Life Science sector using the resources of UJ, offers favorable conditions for start-up.

biochemistry, biotechnology, molecular medicine and genetic analysis in order to guarantee the highest quality of services offered by the company.

The project implemented by BioTe21 was recognized by the Marshal Office in Cracow as one of the best realized and summed up projects within IRDOP 3.4. for years 2004-2006.

At the moment BioTe21 cooperates with various scientific and research units, mainly in Cracow (Agricultural University, Jagiellonian University) and Warsaw (Medical Centre for Postgraduate Education, University of Warsaw), according to the place of registration of the company, the same as the owner's residence registration (Warsaw) and place of principal business performance (Krakow). The fast rail transport between both cities definitely helps the owner to work in these cities.

Cooperation of BioTe21 with Jagiellonian University and Jagiellonian Centre of Innovation formally began in 2005 by signing contracts regarding renting by BioTe21 administrative rooms and laboratories, in which the parties precisely defined the rights and obligations arising from the mutual cooperation in the foreseeable period of 5 years. Jagiellonian Centre of Innovation supported BioTe21 also in marketing and promotional activities, including the company's nomination for the contest "Microentrepreneur the Year 2008" and also recommended for the award in the category "Innovative ideas in health care" in the competition OSOZ LEADERS 2008.[20]

However the main scientific cooperation is based on projects realized with Faculty of Biochemistry, Biophysics and Biotechnology and Collegium Medicum of Jagiellonian University in Cracow, Department of Human Nutrition of Faculty of Food Technology of Agricultural University in Cracow, Medical University in Lublin, Department of Biochemistry and Molecular Biology of Medical Centre for Postgraduate Education in Warsaw as well as projects realized in collaboration with laboratories of molecular biology in Europe and in the USA.

BioTe21 also realizes orders of scientists of Jagiellonian University, many other Polish universities and research institutes, which are carried out professionally and in a very short time.

The company has also established a close cooperation with the Centre of Genetic Research and Nutrigenomics, which is being developed within a project coordinated by the Academic Centre for Science and Technology ACCENT, involving creation by the largest universities of Cracow (Jagiellonian University and Agricultural Academy) of Małopolska Biotechnology Centre in Krakow (MCB) - "the common center, centralized scientific research and development park, enabling performance of complex research at different levels of functioning of the organism, resulting in increasing the competitiveness of Polish science of biotechnology as well as strengthening cooperation between R&D sector and economy. Małopolska Biotechnology Centre will create 6 centers with diverse but complementary research subject areas. Areas of scientific activity of MCB (biotechnology, food safety, genomics, nutrigenomics and bioinformatics) are included in the Bio thematic group which is one of four "strategic thematic areas of research and technology development in Poland."[21]

Prof. Aldona Dembińska-Kieć, PhD, MD, head of the Department of Clinical Biochemistry of Collegium Medium of Jagiellonian University,[22] was also involved in works on the establishment of MCB. She cooperated with BioTe21 as well within the company's participation in international scientific consortium led by the professor who among others developed the project: "Beta-Carotene metabolism as the risk of liver fat accumulation. Search for the new NAFLD risk markers", submitted to the competition of the Seventh Framework Programme of the European Union, priority "Health".[23] It is worth to emphasize that the projects of the Seventh Framework Programme of the European Union required participation of small and medium enterprises (SMEs) in international consortias of submitted

[20] OSOZ – National Health Care System (Ogólnopolski System Ochrony Zdrowia). More details at: www.osoz.pl

[21] For more information about establishment and further stages of the project of creation of Małopolska Biotechnology Centre in Cracow, please visit: http://www.macebio.yoyo.pl/?sub=1

[22] According to the letter of recommendation of prof. Aldona Dembińska-Kieć, PhD, MD, dated 3.02.2009. More information about the project: www.macebio.yoyo.pl/, www.akcent.malopolska.pl/index.htm, www.lifescience.pl/ content.php?component=com_publisher&section_id=6&article_id=191

[23] According to the letter of recommendation of prof. Aldona Dembińska-Kieć, PhD, MD, dated 3.02.2009. More information about the project: www.macebio.yoyo.pl/, www.akcent.malopolska.pl/index.htm, www.lifescience.pl/ content.php?component=com_publisher&section_id=6&article_id=191

projects, which indicates the priorities of the European Union aimed at connecting science and business, especially related to small and medium enterprises able to commercialize the research results.

BioTe21, thanks to the cooperation in another consortium with participation of specialized laboratories, prepared the offer of over 2000 tests in the diagnosis of genetic predisposition to many diseases.

Since June 2007 BioTe21 is a partner of the LifeScience Cluster in Cracow, which operates under the thematic group "Health". The initiator of the project is Jagiellonian University and the administrator and coordinator of the project of the Cluster is Jagiellonian Innovation Centre Sp. z o.o. LifeScience Cluster Krakow was founded in 2006 as a joint venture of entities connected by an aspiration for achieving a common mission of supporting entrepreneurship and innovation in the field of Life Science and creating conditions for effective commercialization of research and development works effects.[24]

Since 2005 Adam Master is also working with prof. Alicja Macke-Nauman from Department of Biochemistry and Molecular Biology of the Centre for Postgraduate Education in Warsaw and, what it is worth noting, the professor very highly estimates knowledge, experience and achievements of Adam Master, according to the letter of reference issued by the professor.

Master Adam also participates in events related to health promotion and the possibility to present the company's offer and its scientific achievements, such as showing the company's offer on fairs, taking part in conferences and other fora, giving the opportunity to present the achievements of the company as well as to establish contacts with potential partners and customers. BioTe21 had its stand during the Polish Congress of Genetics in Warsaw, at the cooperative exchange EMU-BIO in Kuala Lumpur (Malaysia) and at a symposium in the framework of the Winter School of Biotechnology of Jagiellonian University in Zakopane, Poland where the cooperation was also continued in 2008. In 2008 BioTe21 was also presented during the Bio-Forum fair in Łódź and the Central European Congress of Life Sciences in Krakow Eurobiotech in Cracow. In 2010[25] Adam Master, as a legal expert in the area of genetic and biochemical identification, also participated in the congress of legal experts of the First Congress of Legal Sciences in Warsaw.

1.3. Barriers in development

Since the company's beginning cooperation with the scientific community was very good and it is not possible to talk about any barriers, because both the owner of the company and workers employed by him come from this environment and the company's offer is mostly addressed to specialists. However some difficulties have occurred, e.g. a different point of view on property rights and its protection. Universities and scientific workers attach great value to publications, for which they receive points, while from the company's point of view the unpopular at universities patents and commercialization of scientific discoveries are important. Lack of greater interest of scientists in patenting the inventions and practical application of their research effects is also caused (not only in Poland) by a clear conflict of patent offices and scientific journals, which is based on a prohibition of publication of practical applications of scientific researches, required by patent offices before the patent application and at the same time prohibition of patenting these applications required by editors of most of the world's major editors of scientific journals, which consider patents covering at least part of the published work as a conflict of interest and undesirable case, although they often publish the highly applicable works themselves! In this case scientists must often choose between the patent publication, for which sometimes they have to wait for several years to be announced, and publication in a scientific journal, usually issued in a few months. The presented conflict of the ways of documentation and protection of copyright of application scientific works applicable in economy, including biotechnology and medicine, is structural and will be difficult to remove without the appropriate legislative acts which would have to be accepted at the international level. Moreover, in the Polish assessment system of scientific workers, a patent is usually not classified as scientific achievement equivalent to publication, even though the patent procedures often require more detailed description and documentation. This situation contributes to the lack of understanding between science and business, particularly it reduces

[24] http://www.lifescience.pl/content.php?component=com_publisher&section_id=1

[25] Szcześniak A., Gene synthesis as a basis of business based on science services. Case study of BioTe21 Adam Master, in: **Enterprising University. Practical usefulness of scientific research and research and development works. Designing and conducting development researches in cooperation with economy**. Collective work edited by Mieczysław Bąk and Przemysław Kulawczuk.

the ability and motivation of science to commercialization of scientific research results.[26] Unfortunately at many Polish universities cooperation of scientific institutions and business is still considered as something bad. Adam Master still remembers a letter from the lawyer of the university where he led his doctoral dissertation, who stated that his business activity "is not compatibile with doctoral oath". Many legal interpretations indicating that universities are even obliged to promote entrepreneurship among doctoral students, according to the Higher Education Act, as well as the guidelines of the Lisbon Strategy 2000 of the European Union priorities were necessary to positively close the subject of scientific and business work. Surprisingly, in 2005 private practices of medicine doctoral students were not a problem to the majority of university staff, while running "business" was no longer "compatibile with doctoral oath". It directly shows the approach of university staff to business activity and research results commercialization opportunities through business in the years 2005-2007. This approach has evolved naturally over the next years, but according to the owner of BioTe21, a lot of work of both science and business is necessary to fully understand each other and act for the common good.

On the other hand, the economy is looking for innovative solutions and it is not interested in simply funding science for science, thus still noticable in Poland lack of openness of business towards science.

The most often problems in cooperation of companies and scientific community are associated with underfunding of "young" scientific and technological units and their research and projects which commercialization is difficult to finance. Lack of funds for research projects which could be realized by BioTe21 in cooperation with Polish universities, is also caused by **lack of understanding by persons who decide about the funds allocation of the subject of market mechanisms which influence companies**, which consequently makes it difficult or even impossible to implement certain projects with Polish research institutions.[27]

1.4. The milestones

- **2005** (September) – foundation of the company BioTe21 Adam Master
- **2006** (1 March to 1 October) – realization of the start project "Synthesis of genes using oligonucleotides submission in the Polymerase Chain Reaction" financed under the Integrated Regional Development Programme, Measure 3.4. "Microenterprises":
  - purchase of equipment necessary to carry out the planned business and office equipment, signing a contract in the Jagiellonian Centre of Innovation regarding the rental of office;
  - dividing three specialized laboratories: Laboratory of Genetic Identification and Paternity Testing, Laboratory of New Biotechnology, Laboratory of Synthesis and Sequencing of Nucleic Acids;
  - creation of a team of employees with experience in biochemistry, biotechnology, molecular medicine and genetic analysis.
- **2006 r.** (June) – the laboratory BioTe21 starts its activity at the Faculty of Biochemistry, Biophysics and Biotechnology of Jagiellonian University; the office opens in Jagiellonian Innovation Centre, Gronostajowa Street 7 in Cracow.
- **2007 -** obtaining by BioTe21 the international certificates confirming the quality of the conducted genetic researches “GEDNAP32, GEDNAP33 (2006), GEDNAP34, GEDNAP35 (2007) and the latest GEDNAP36, GEDNAP37 (2008) - German DNA Profiling Group in the genetic analysis of DNA of 18 somatic STR type systems + gender marker (Short Tandem Repeats)".[28]
- **2008 -** obtaining by BioTe21 the unique in Poland certificates of "Mitochondrial DNA sequence analysis in variable regions of mtDNA-HVI and mtDNA-HVII and certificate of biochemical identification of biological microtraces.”[29]
- **2008** (February) – inscription on the register of Health Care Institutions in February 2008.
- **2008** (March) – inscription on the register of laboratories run by the National Chamber of Laboratory Diagnosticians,

[26] Information received from Kamila Giżewska, PhD, from BioTe21
[27] Information received from Kamila Giżewska, PhD, from BioTe21
[28] https://www.badanieojcostwa.pl/wiarygodnosccertyfikaty.html
[29] https://www.badanieojcostwa.pl/wiarygodnosccertyfikaty.html

- **2008 –** starting realization of the project "Skin cancer - diagnostic of genetic predisposition to melanoma", an original idea of BioTe21.
- **2008** (February) – creation of the fourth laboratory – of Medical Genetic Diagnostics.
- **2008** (18 November) **–** awarding Adam Master with the distinction in the main category of the 4th edition of the contest for the title of the Microentrepreneur of the Year 2008.[30]
- **2008 –** awarding prize in the category Innovatiove Ideas in Health Care in the contest Leaders of the National Health Care System.
- **2008** (25 November) – assinging Adam Master as a legal expert in the area of genetic and biochemical identification by the District Court in Cracow.
- **2008** (December) - assinging Adam Master as a member of Society for Endocrinology.
- **2008 -** creation within the wide health promotion and a campaign "Examine your DNA before it's too late!" an authorial "project Artgen21 "Science for Art - Art for Science" where the laboratory in cooperation with artists of Cracow creates **Pictures of DNA Code of customers**, mostly realized to order as original gifts (…)"[31]
- **2009** (November) **–** awarding BioTe21 Adam Master with the title of „INNOVATOR OF MAŁOPOLSKA 2009" and the main prize in the cathegoty "microenterprises".
- **2010** (24 September) – prize of the Minister of Health for Adam Master as a co-author of the publication „Disturbed Expression of Type 1 Iodothyronine Deiodinase Splice Variants In Human Renal Cancer"
- **2011** (February) – opening new point of NZOZ BioTe21 and the office in Cracow
- **2011** (March) **-** assinging Adam Master as a legal expert in the area of genetic and biochemical identification by the District Court in Warsaw.
- **2011** (September) **–** the date assigned by the Misnistry of Health for the meeting of experts and consultants of national related fields, initiated by the request of Adam Master to the Ministry of Health regarding the appointment of a new field of Medical Biology and Laboratory Medical Biology, applicable in health care and laboratory diagnostics.

At the moment of its founding, the biggest problem of BioTe21 was administrative formalities connected with creation of the company and the formal requirements regarding the scope of its activity (i.e. meeting certain standards, obtaining required permits for NZOZ BioTe21 activity, etc.). Moreover a significant problem was a very high initial financial outlay, which was necessary to start business, i.e. to conduct laboratory works on its own. These costs were connected with renting suitable rooms and purchasing specialized analytical equipment, especially synthesizer - the basic synthesis device. At Jagiellonian University it was possible to rent additional equipment, however it was a solution really hindering the work, because the development and implementation of subsequent technologies, required twenty-four hour access to the equipment, enabling the owner of BioTe21 working at night and preparing technology before the staff comes in the morning to continue Adam Master's work. The problem of access to the necessary equipment was partially solved when the company received funding for realization of the project "Synthesis of genes using the methode of submission of oligonucleotides in the Polymerase Chain Reaction" within the Integrated Regional Development Programme under Measure 3.4. "Microenterprises" supported by the second branch of PKO BP in Cracow, which allowed the necessary investments in equipment.

Other critical moments are the problems with financing of implemented projects, but with active and systematic actions, the company manages to attract partners and external resources to run their work, researches and implemented projects. A good reputation of BioTe21 resulting from the perfectly summed up starting project was also helpful when applying for financing of the next authorial project of BioTe21 entitled "Skin cancer - diagnostic of genetic predisposition to melanoma" for which the company has also obtained the necessary measures.

Among the problems directly related to the implementation of research projects and their further commercialization are: the low level of knowledge about the importance of preventive genetic diagnosis of both patients and doctors as well as the lack of appropriate information, hindering correct understanding of purpose of such researches and the need to expand and introduce new diagnostics. Actions undertaken by the company focus among others on broad promotion and information activities addressed to both scientific communities, medicine doctors and to an average patient, which absorb

[30] Microentrepreneur of the Year 2008 - 4th edition, http://www.citibank.com/poland/kronenberg/polish/6158_9552.htm

[31] Marta Kowalczyk, Examine your DNA before it's too late. Part I, 7 December 2009, http://www.razemztoba.pl/index.php?NS=srodek&nrartyk=4659&slowostart=800

the most of the company's budget. The task of creating the genetic research market in Poland is facilitated by information posted on the Web site of BioTe21, training videos regarding collection of genetic material, user friendly informational materials and many awards and honors acquired by BioTe21.

It should also be mentioned that the financial incomes are seasonal, because of the specificity of the scientific community, to which the company mainly addresses its offer. In summer, when the holiday period begins at the universities and the demand for specialized services sales and the synthesis and sequencing of nucleic acid falls down, BioTe21 focuses on other areas of its business, such as services connected with the genetic identification, genetic diagnostics or paternity tests, which are addressed also to private customers and on orders regarding criminal expertises received from courts and prosecutor's offices.

Thanks to the wide range of services, addressed to a variety of clients, clearly defined rules of operation, affordability and openness for the average patient and the individual client and thanks to the ability to cope with arising problems, as well as thanks to skills of applying for and acquiring external funds, BioTe21 is a very quickly developing company with an impressive scientific achievements and a huge substantial and development potential.

The economy and principles of free market force BioTe21 to increase the competitiveness and to realize very innovative projects such as e.g. new technologies connected with gene therapy of cancer, however with a high level of risk. After the development of technology at the laboratory level the company has to find a big receiver, who will have a sufficient financial and substantial capital to implement these technologies. It should be reminded also that it usually takes at least 5 years from the development of technology till its implementation on the medical market, due to the different requirements of medical products registration. In this time the company has to invest a very large part of its budget, having no income from investments, which for small and medium companies in unfavourable economic conditions may be a problem threatening their financial liquidity and stability. Unlike universities and research institutions, companies do not receive statutory funds from the state budget for conducting researches and their "to be or not to be" is a result of interaction with the market in context of effectiveness and relevance of the choices and decisions.

1.5. Sources of financing.

The company was created involving its owner's own resources and obtaining funds for realization of the investment project "Synthesis of genes using oligonucleotides submission in the Polymerase Chain Reaction". The funds obtained from the Integrated Regional Development Programme under Measure 3.4. "Microenterprises" have given the opportunity to create basis for business activity, including purchase of necessary, expensive apparatus and equipment. The start of small, innovative company was also facilitated by the cooperation of BioTe21 with Jagiellonian University and Jagiellonian Centre of Innovation. The company has signed the first contracts with them, which allowed reducing the initial costs and part of the administrative costs. The contract with Jagiellonian University concerned access of BioTe21 to laboratory rooms, however the company had to provide all the equipment on its own (which was possible thanks to obtaining the above mentioned funds). The contract with Jagiellonian Centre of Innovation allowed the company to use the offices, including the equipment (photocopiers, printers, binding machines) and conference rooms (free for 2 hours daily, longer for an additional charge added to the rent).

After finishing realization of the project, which required BioTe21 to take a bank loan and acquire funding from the Integrated Regional Development Programme under Measure 3.4. "Microenterprises", which aim was, among others, to start a business through introducing on the market and sales of services offered by the company in the area of sale of following services: genes and DNA oligonucleotides synthesis, cloning vectors and performing genetic constructs (gene sets) for commercial and non-commercial scientific, medical and analytical institutions, the company was established so well that it was possible to finance its activities, among others, basing on measures developed by the company. Specialist research and development works however are so expensive that a lot of time in the company is spent on searching partners for cooperation, which for BioTe21 are research institutions, and common applying in adequate EU and national programs for external funds. Thanks to good opinions about BioTe21 during realization of the start project, the company managed to obtain investment financing for another authorial project "Skin cancer - diagnostic of genetic

predisposition to melanoma" which alike the first project was supported by PKO BP. The company attaches great attention to preparation of grant applications - and though completing the documentation requires time and additional expenses from the small team of BioTe21, it gives expected results. Adam Master assumes that it is necessary to devote time and effort to search for funding sources available for the company. Although it is a continuous process, it is necessary to ensure the company's stability and further growth opportunities.[32]

However it should be noted, that fast growth and established position of BioTe21 is also connected with the fact that the company addresses its offer not only to specialized institutions but also to the client, who previously, due to high costs of appropriate technologies in the industry represented by the company, practically was not taken into account - an average patient. Application of new technologies reducing costs so that anyone interested could benefit from the services offered by BioTe21 resulted in receiving another source of financing by the company.[33]

The company addresses its offer to universities, scientific, medical and analytical institutions, both commercial and non-commercial and private persons, which, thanks to a huge concern for quality of services and constantly expanding offer, allows diversifying sources of business financing and thus provides the company with financial security.

1.6. Benefits of cooperation between science and business

Running business at the Faculty of Biochemistry, Biophysics and Biotechnology of Jagiellonian University (UJ), i.e. in Incubator of Jagiellonian Centre of Innovation (JCI), from the beginning was important for BioTe21. First of all because the services of DNA synthesis and sequencing offered by the newly established company had (and still have) regular customers among scientific workers of Jagiellonian University. Moreover, Jagiellonian Centre of Innovation has let offices to the beginning company on very favorable terms and Jagiellonian University made laboratory rooms meeting the sanitary-epidemiological requirements accessible for BioTe21, so the company did not have to pay for adapting individual laboratories to the requirements determined by the specific regulations.

From the company's point of view it was also important that the location of its premises enabled easy access to highly qualified human resources, i.e. potential employees of the company. Today the most employees of BioTe21 are graduates of Jagiellonian University. It is also worth to mentoion that thanks to good cooperation with universities, the company offers organization of internships for outstanding students in BioTe21, which are usually much different from the traditional, theoretical approach of the university and show the practice of achieving significant scientific discoveries, which can be commercialized.[34]

Thanks to the cooperation of BioTe21 with scientific community in a broad sense, the company has the opportunity to take part in interesting and challenging research projects and solving scientific and technical problems, and thus the fast expansion of the company's know-how. In addition, the company's involvement in prestigious projects affects its recognition in Poland and abroad as well as the increasing interest in its activities among potential customers, it also gives the opportunity to establish contacts with the scientific community and to access the group of specialists with whom the company may begin cooperation in the future.

Research centers through cooperation with BioTe21 win a partner having knowledge about the market and its needs, a partner able to implement the technologies developed together, to optimize and / or

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[32] Szcześniak A., Gene synthesis as a basis of business based on science services. Case study of BioTe21 Adam Master, in: **Enterprising University. Practical usefulness of scientific research and research and development works. Designing and conducting development researches in cooperation with economy**. Collective work edited by Mieczysław Bąk and Przemysław Kulawczuk.

[33] Szcześniak A., Gene synthesis as a basis of business based on science services. Case study of BioTe21 Adam Master, in: **Enterprising University. Practical usefulness of scientific research and research and development works. Designing and conducting development researches in cooperation with economy**. Collective work edited by Mieczysław Bąk and Przemysław Kulawczuk.

[34] Szcześniak A., Gene synthesis as a basis of business based on science services. Case study of BioTe21 Adam Master, in: **Enterprising University. Practical usefulness of scientific research and research and development works. Designing and conducting development researches in cooperation with economy**. Collective work edited by Mieczysław Bąk and Przemysław Kulawczuk.

accelerate some of the technical works, among others by taking in charge of the projects. For the scientific community it is also important that projects or tasks ordered at the company are done well and quickly.

BioTe21 by supporting research institutions with its knowledge and skills also benefits from the cooperation with ideas for new projects and has the opportunity to use the experiences of other scientists and scientific background of the university. At the same time, by both parties it is not considered as a competition but as a perfectly complementary cooperation.[35]

For scientific institutions BioTe21 was (and is) also a partner for R&D projects, also co-financed with European Union funds.

1.7. Plans for the future

Plans for the future of BioTe21 are: further cooperation with scientific and technical centers and the scientific community of Polish universities as well as the development of diagnostic technologies using high definition methods of SNP-type mutations analysis in the aspect of oncological, identification, neurodegenerative and other genome researches. Currently Laboratory of Biotechnology offers creation of new biotechnologies mainly for molecular medicine, particularly for genetic diagnosis, based on the latest scientific researches and advanced, high definition analitical laboratory equipment. The divided thematic laboratory works on the development of useful bioinformatic projections as well as the development and implementation of new biotechnologies. One of the results of work of this department of BioTe21 was development of a completely new technology of changing the gene expression which can be used in gene therapy of various genetic diseases including cancer. Cooperation with scientific institutions enabled to test this technology on the cancer cells and the results of these works will soon be jointly published. However, implementation of this technology in medicine will require a larger strategic partner, who will finance the expensive efforts to introduce the product on the medical market.

The laboratory has also prepared a number of innovative investment projects in the field of medical biology, molecular medicine and pharmaceutical biotechnology. Their implementation requires much larger investment, enabling scientific and technological progress of the entire branch connected with biomedical industry in Poland and in the world.[36] One of such projects is a developed business plan and the program of "Assinging the first center and network of DNA medical testing and genetical diagnosis of predisposition to hereditary diseases (genetic testing network)", which will require an agreement with an investor interested in building such a research network.

The company employing a team of highly qualified specialists from the date of its establishment operates according to the development strategy created by its founder and owner Adam Master and in accordance with its mission, which is to search in biotechnology and medicine for applications of new scientific discoveries arising from basic research of genome, transcriptome and proteome and this direction of development is maintained by the company, despite the considerable financial outlay.[37] BioTe21 plans to intensify efforts to increase the number of customers, therefore its promotion actions are addressed to Polish and foreign institutions working on "researches of genome and proteome at different levels of scientific, clinical and analytical research. BioTe21 is interested in such institutions as: universities (molecular biology), technical universities (biotechnology), Polish Academy of Sciences, Faculty of Biological and Medical Sciences, hospital laboratories of molecular and cell biology, genetic diagnostic companies, pharmaceutical companies and foreign biotechnological companies."[38]

1.8. Summary – key factors of success

[35] Information received from Kamila Giżewska, PhD, from BioTe21

[36] Laboratory BioTe21, http://www.badanieojcostwa.pl/laboratorium-BioTe21.html

[37] Information received from Kamila Giżewska, PhD, from BioTe21

[38] Szcześniak A., Gene synthesis as a basis of business based on science services. Case study of BioTe21 Adam Master, in: **Enterprising University. Practical usefulness of scientific research and research and development works. Designing and conducting development researches in cooperation with economy**. Collective work edited by Mieczysław Bąk and Przemysław Kulawczuk.

The principal factor of success, which certainly should be mentioned in case of BioTe21, is its creator and owner Adam Master, who proved that it is possible to conduct scientific and research works and successfully commercialize their results. Adam Master is a man of unusual diligence, scientific curiosity, critical thinking skills, ability to recognize opportunities and a clear vision and idea for the future of the company, divided into concrete actions. Moreover creation of any company, especially assumed as innovative, which offer is in sptie of all addressed to a narrow circle of customers, is associated with the entrepreneur's ability to take risk.

This ability to take risk and realize unconventional actions was necessary, when in 2005 BioTe21 was the only laboratory in Małopolska, which introduced the service of synthesis and sequencing of nucleic acids for research workers, which significantly increased the availability of such services and facilitated direct contact between customer and supplier. Moreover Adam Master, thanks to successful cooperation with scientists and developing new innovative diagnostic techniques has extended the circle of his customers by the group so far not taken into account - the individual customer. Thanks to the courage of the owner the company became the first commercial laboratory of genetic diagnosis, allowing the use of its services to patients in Małopolska.

An important factor which had an impact on the final success of the company, are also its employees – a highly qualified scientific staff, experts in the field of biochemistry, biotechnology, molecular medicine and genetic analysis, which guarantee the quality of services offered by the company.

The success of BioTe21 was also affected by enormous attention to the highest quality of researches conducted in the company, confirmed by international certificates. In addition to the proficiency certificates obtained in genetic studies, the procedures of Quality Management System compliant with PN/EN 17025, and in all the company - ISO 9001:2000, are also implemented in the laboratory.

In the creation and development of BioTe21 equally important as the skills of Adam Master was and is a good cooperation with the scientific community and university and research centers, which are the main target group of customers of BioTe21. Thanks to the cooperation with Jagiellonian University the company from the beginning was provided with laboratory rooms and has participated in many projects conducted or initiated by Jagiellonian University and other research centers in Poland. Successful cooperation with scientific institutions shows that with the right approach of representatives of both parties (science and business), it is possible to realize together ambitious and complicated projects going even beyond the borders of the country.

1.9. Literature

http://www.badanieojcostwa.pl/prawo.html

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