

Features of Building Business Strategy for Introducing Innovative Medical Technology to the Market

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Abstract

This research article is devoted to joint study of authors, conducted to develop business strategy for implementation of the developed innovative method of electrocardiologic diagnostics of coronary heart disease and acute myocardial infarction in the market of electrocardiologic devices. Business strategy is based on promotion of the product “Tozka” that is telemedicine system “DoctorPatient”. The system allows performing diagnostics in outpatient and home conditions with the highest accuracy and in real time. The prototype of the diagnostic system was created and successfully tested on 290 patients and 40 healthy people. The research included formalizing socially significant problems, solution of which the innovation is aimed at, determining ways in which the innovation will solve these problems, identifying existing competitors in the field under study and competitive advantages of a new product, identifying potential buyers and assessing demand. On this basis, the authors developed schemes for commercialization of innovation and a plan for development of project for its dissemination in national and foreign markets.

Keywords: business strategy, business model, commercialization, innovation, electrocardiologic diagnostics, medical technologies.

1. Introduction

Purpose of this study was to develop differentiated business strategy for introducing innovative system of electrocardiologic diagnostics to the market.

Development of the strategy involved description of the following elements: market research results, competitive situation and competitive advantages of a new product, market segments and commercialization schemes for innovation, product development plan and strategy implementation program.

Innovativeness of the proposed system is based on the fact that to date there are no clear quantitative criteria for assessing level of myocardial blood supply shortage in each lead of

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electrocardiologic device. The indicators used to date have a low reliability of diagnostics: in the range of 37-51%.

- Modern technology of electrocardiologic diagnostics is characterized by low reliability of results.
- Authors proposed innovative method for increasing sensitivity of electrocardiograms.
- Developed product has a relatively low cost of production and allows users to assess risks of disease occurrence independently on their own and in a timely manner.
- Developed schemes for the commercialization of innovation include sales of the device to medical institutions and individual users and sale of licenses.
- Potential markets for the new device: Russia, CIS countries, Central and Eastern Europe, potential buyers: hospitals, sanatoriums, treatment and rehabilitation centers, polyclinics, medical centers, family doctors, individual users.

2. Method

In determining methodology of the study, the authors relied on traditional for management theory works of such authors, as Aaker and McLoughlin, (2007), Vikhanskiy (2003), Lamben, Chumppatis and Schuiling (2007), who considered the need to perform certain functions of strategic management in developing the strategy: internal and external analysis, positioning, strategic planning, implementation control. In the context of innovation, the authors emphasize the need for planning stage of commercialization and cash flows. The absence of these elements of business strategy will not allow a company to assess market potential of a new product and may cause unsuccessful promotion and sales, even if there is a significant development potential.

The main hypothesis of the study was the assumption that at present time there are significant problems in electrocardiologic diagnostics technology associated with low reliability of the results and high cost. Thus, technological solution that allows solving these problems, which is the basis of a new electrocardiographic device, is required in the market and will be in demand, both from medical institutions and from individual users.

3. Research methodology

The research involved collecting data on the market and capabilities of the technology developers to form each specific element of the strategy, as well as conducting relevant analysis and assessments:

(1) analysis of problems of the technology and the market of electrocardiologic diagnostic devices – to determine strategically important properties of a new product and ways to solve market problems;

(2) analysis of the competitive situation in the market of electrocardiologic diagnostic devices – to determine competitive advantages of a new product;

(3) assessment of market parameters and identification of potential markets for sales of a new product – to formulate market positioning.

The implementation of the above research areas, as a result, allowed the authors to formulate elements of the business strategy for introducing innovation to the market.

3. Results

The description of the problem which this innovative technology resolves:

(1) High mortality level in different countries from cardiovascular diseases. In 2015 17.7 millions of people died in different countries from cardiovascular diseases (CVD), and this amounts 31% from all mortality causes. From them 7.4 millions of people died from coronary artery disease (CAD). In Europe was registered 11.3 million and in the European Union – 6.1 million new cases of CVD. CVD amounts 45% from all deaths in Europe and 37% in the European Union. In absolute values IHD is the cause of 335 000 deaths in males and more than 297 000 in females in European Union.

(2) High cost of healthcare systems in the field of CVD in different national budgets. CAD holds leading position in mortality all over the world and is the main expenditure item in healthcare systems. The total value of CVD appraises at 210 billion of euro annually. 53% (111 billion of Euro) is the direct cost of healthcare systems, 26% (54 billion of Euro) – loss of labor productivity, 21% (45 billion of euro) – informal help to the patients with CVD.

(3) The dependence of diagnostic quality and treatment of CVD, the level of mortality from CVD and the level of income of the population. Countries with low level of income of the population are characterized by high mortality rates from CAD. The mortality from CAD and stroke, in general, higher in Central and Eastern Europe, than in Northern, Southern and Western Europe. In Russian Federation mortality in absolute values estimates 385.6 people per 100 000 population, on average, annually.

For comparison, the mortality from the same cause on the territory of EU countries estimates 95.9-105 people per 100,000 population annually, what is 4 times lower, than in Russia.

(4) High level of out-hospital mortality in Russia. One of the most important mortality features in Russian Federation is the fact, that vast majority of deaths happen outside hospitals: at office, at work, at home, at country house, at social places and others. In 2014 400 000 people died from ischemic heart disease outside hospital, or 82% from all deaths from this cause. The level of out-hospital mortality in Russia in 3-5 times higher, than in Western Europe and USA.

(5) Expensive diagnostics of ischemic heart disease. The “golden standard” of diagnostics is coronary angiography. In a view of high cost of one examination, patients go to the election according their subjective complaints, rest or stress-test ECHO-cardiography results. Sometimes clinics use stress-Echocardiography, computed tomography angiography (CT angiography), but there are very expensive and have limitations. However, according to the data from USA, Canada and Germany, approximately 40% of coronary angiograms carry out with coronary artery correction (with balloon angioplasty and stent implantation), another 60% - normal or near normal coronary angiograms without treatment.

(6) High time expenditure on diagnostics of ischemic heart disease. Approximately 30-40% patients with chest pain have cardiac cause of pain, other 60-70% - other causes: more than 40 diseases. Today, for an exception of cardiac cause of pain physician needs from 8 to 72 hours at the time when every minute is vital. Additionally, 24-27% of all patients with CAD are asymptomatic before and acute myocardial infarction (AMI) development or sudden cardiac death (SCD).

(7) Comparatively low diagnostic accuracy of ischemic heart disease. Diagnostic reliability of rest electrocardiographic examination is 37-51% (a few data showed 21%) and stress-test 60-70% at best. In these conditions the most vital is the question of cost of one examination and limited time for it.

Suggested innovative diagnostic technology of electrocardiography signal processing contributes in described problems resolution. The innovation provides:

(1) The developed system increased significantly the sensitivity (85.4-96.7%) and specificity (96.87%). Examination is carried out as usual rest echocardiography, but the recording duration lasts 2-4 minutes. Total time as maximum of examination is 10 minutes, including imposing of electrodes.

(2) One of the worked out criteria has a strong correlation with the level (in percentages) of coronary lesion according percutaneous coronary angiography (correlation coefficient 0.89) on 152 cases. It gives the possibility to elect patients on coronary angiography with low number of normal or near normal angiograms. The critically high level of this criterion coincides with AMI development.

(3) Second criterion has correlation with the severity of ischemic heart disease patient. Patient's complaints and its intensity are classified according functional classes of Canadian cardiovascular society. It provides the possibility to exclude ischemic heart disease in 10 minutes.

(4) The system is simple in use it means that it can be utilized in screening of big amount of patients to reveal asymptomatic patients and patients on early stages. It means that it is possible to reveal patients with high risk according quantitative criteria and start pharmacological treatment in time or coronary angiography long before AMI and SCD.

(5) These 2 criteria are very sensitive to pharmacological influence on the heart, what gives the possibility to assess the efficacy of treatment individually.

(6) Utilizing dynamic examination (every week or month) it is possible with mathematical accuracy to assess the time of AMI development individually according to the growth rate of criterion from one examination to another and achievement its critical level for AMI.

(7) Early and authentic diagnostics of ischemic heart disease allows significantly lowering the costs on additional examinations (for example, stress tests) and monitoring patients in emergency departments for better results.

The developed new product on this technology – “Tozka 6” is individual diagnostic device, which gives remote self-monitoring patient's heart everywhere and every time for those, who take care of their health.

4. The concept of the new product “Tozka-6”

Goal of the mobile diagnostic device “Tozka-6” is adaptation of existing breakthrough approaches in professional medicine for individual use, with a great deal of attention paid to the non-invasive method, simplicity of tests and visibility of diagnostic results.

The developed device “Tozka-6” will allow self-examination of heart, registration and analysis of main medical indicators of electrocardiography, as well as receiving recommendations for therapy and lifestyle, including normalize health status through Biological Feedback. This procedure consists in the continuous monitoring in real time of clinically relevant indicators and conscious control (normalization) by them using multimedia and other techniques.

Using “Tozka-6” device during biological feedback sessions will make it safe, as high sensitivity of diagnostic system “Tozka” allows adjusting therapy to a patient in time.

“Tozka-6” is a software and hardware complex, which includes software and hardware components divided into 4 groups according to their functional purpose:

- (1) Main focus is on the analysis of electrocardiogram image;
- (2) Compact docking station;

(3) Software for smartphones with operating systems iOS, Android;

(4) Cloud data storage.

The concept assumes that there are two categories of measurements performed by the new device: continuous measurements of human indices in motion and measurements performed in quiet condition of sitting or lying down. Body movement control channel is used for:

- monitoring work of heart;
- exclusion of artifacts in removal of electrocardiograms caused by patient movements;
- measuring time and nature of response to incentives;
- monitoring phases of sleep, forming optimal “sleep-wake” schedule; MEMS accelerometer. Possible supplier: Analog Devices, ST Microelectronics.

The authors studied main technological and market trends in the industry under consideration. They are the following:

(1) Improving visualization of condition of coronary arteries by coronary angiography, computed tomography with contrasting coronary arteries. Development of intracoronary investigation technology of atherosclerotic plaques and their injuries, as well as pharmacological test with visualization on a computer tomography or magnetic resonance tomograph. These methods are very expensive, require availability of qualified personnel and do not have ability to evaluate physiological processes in the myocardium in dynamics.

(2) Non-invasive methods use conventional electrocardiography at rest and with exercise (veloergometer, treadmill test, pharmacological test). Stress-ECHOCardiography is used to detect violations of myocardial contractility in places of possible coronary heart disease. The essence of the modern electrocardiographic study consists in recording patient within 10-15 seconds with subsequent construction of averaged complex over all leads and calculation of diagnostic criteria with high error rate in diagnostics.

(3) According to innovative scenario of experts forecasting volumes of the Russian market of electrocardiographic devices, in 2018-2022, there will be stabilization and steady increase in sales volumes. In general, Russian producers offer more attractive pricing conditions for supplied electrocardiographic devices to foreign customers, in comparison with price conditions for supply of devices to Russia by foreign manufacturers.

(4) Starting from 2015, market began to show clearly a trend of growth in domestic production of devices with relatively stable volumes of imports of electrocardiographic devices to Russia. Volume of imports is, on average over the past three years, tenth or less of volume of Russian production.

(5) Rating of devices by country of production in the order of increasing average price is as follows: China, Russia, Japan, Europe, USA. In the Russian market there are already quite a large number of users of Chinese devices.

(6) Currently, Russian market includes cardiographs from leading European companies: Schiller Cardiovit (Switzerland), Innomed Medical (Hungary), Cardioline (Italy), Esaote (Italy), GE Marquette Hellige (Germany). In addition, cardiographs produced in Asia and Japan, are widely represented in Russian market: Fukuda Denshi (Japan), Nihon Kohden Corporation (Japan), Bionet (Korea), Trismed (Korea), Biocare (China). Domestic producers (Altonika, Valenta) also occupy their own niche, offering budget inexpensive models of electrocardiographic devices.

(7) Main advantage of Chinese cardiographers is their low price, which for medical institutions with a small budget in some cases is determining factor of purchase. For comparison,

average cost of Chinese device is \$700, while the average price of device of Japanese or European production is about \$ 2,000. According to statistics, the share of Chinese electrocardiographs imported into Russia is currently approaching 20%.

(8) Domestic cardiographs are traditionally in demand, both among Russian consumers and in CIS countries. They are more expensive than Chinese devices, but cheaper than similar European ones. Consumers of Russian models are attracted by quick and inexpensive repairs, as well as affordability, compared to products from companies with well-known brands. According to reviews of practicing doctors, the less electronic functionality is in the domestic apparatus, the more stable and trouble-free its work is.

(9) There is still a shortage of certified medical devices for measuring cardiac activity in Russian market: most clinics and hospitals use wearable monitors to record a long-term electrocardiography. Patient carries it with him for a certain period of time, after that a doctor decodes the data. Mobile cardiogadgets are not yet widely used.

5. Discussion

The conducted research allowed allocating competitive advantages of the innovative electrocardiologic system and the new product "Tozka-6". Among the companies conducting the same or similar developments, the following were distinguished:

- Schiller AG (Switzerland);
- General Electric (GE), (USA, China, India);
- Mortara Instrument Inc., Welch Allyn Inc., Philips Medical Systems (USA);
- Fukuda Denshi Co. Ltd., Nihon Kohden Corp., Suzuken Co., Ltd. (Japan);
- Kaden Yasen Medical Electronics Co., Ltd., Edan Instruments Inc., Shenzhen Comen Medical Instruments Co., Ltd. (Comen), Shenzhen ECGMAC Medical Electronics Co., Ltd. (China);
- OOO NPP Monitor, JSC Concern Axion, LLC Altonika (Russia).

Advantages of new product are the following:

(1) Electrocardiologic test is suitable for mass examination of patients.

(2) The developed diagnostic criteria are calculated in automatic mode, their calculation by a doctor is impossible, but he can check correctness of the calculation at the first stages of system work.

High performance, reliability and low cost are due to the fact that most of processing and analysis of research results are carried out automatically. Calculation of diagnostic criteria is performed only by computer technology without the participation of a doctor.

(3) These criteria more than 2 times increase diagnostic value of electrocardiologic study.

(4) The developed diagnostic criteria make it possible to quantify depth of ischemic process on a scale of 1.4 to 11.5.

(5) Diagnostic criteria allow identifying high-risk patients at preclinical stage and beginning medical treatment.

(6) Sensitivity of the criteria to pharmacological effects on the myocardium will allow a doctor to evaluate effect of drugs on heart for minutes, hours or days.

Using telesystem in combination with automatic analysis allows monitoring patient's heart condition over days and months. In this case, in the case of worsening heart function, an alarm system is automatically switched on regardless of clinical manifestations of disease.

(7) Possibility of early selection of patients for coronary angiography.

(8) Lower production costs.

Formulation of competitive advantages of the product allowed the authors to determine main market parameters for promoting innovation. In particular, as an element of the business strategy, markets were identified where the new product could potentially be realized: geographic markets, main consumers, approximate market volume, market dynamics and future product positioning.

(1) Russia (Moscow, Moscow region and other regions)

Main consumers: hospitals, sanatoriums, treatment and rehabilitation centers, polyclinics, medical centers, family doctors, individual users.

Approximate volume of the market: 90 million rubles a year with estimated growth of 5-10%.

Positioning: low price compared to devices made in Europe and United States, high reliability of measurements, presence of only basic necessary functional of devices.

(2) CIS countries (Belarus, Moldova, Tatarstan, Uzbekistan, Kazakhstan, etc.)

Main consumers: hospitals, treatment and rehabilitation centers, polyclinics, medical centers, individual users.

Approximate volume of the market: 80 million rubles a year with estimated growth of 3-5%.

Positioning: relatively low sale price; analysis of main medical electrocardiographic indicators and obtaining recommendations for healthy lifestyle, including normalization of human health condition through Biological Feedback; high level of measurement reliability.

(3) Countries in Central and Eastern Europe

Main consumers: hospitals, treatment and rehabilitation centers, polyclinics, medical centers, family doctors, individual users.

Approximate volume of the market: 120 million rubles a year with estimated growth of 2-3%.

Positioning: relatively low sale price; analysis of main medical electrocardiographic indicators and obtaining recommendations for healthy lifestyle, including normalization of human health condition through Biological Feedback; high level of measurement reliability.

In accordance with selected market segments, the authors developed a differentiated model for commercialization of innovation in format of sales of new product "Tozka"'s versions and license for technology.

(1) Segment "business-to-customer": sale of experimental lots of "Tozka-6" device

Product description: mobile diagnostic electrocardiographic device for remote monitoring of patients at risk and anyone who worries about their health.

Application: for individual use.

Scheme of income generation: sale through distributors.

Planned retail price: 45 thousand rubles.

Status of the scheme: preliminary negotiations with 7 profile distributors of medical equipment and gadgets were held, agreement with MED Llc (<http://maximed.pro/en>) on the implementation of the device in the markets of Russia, CIS and EU, was reached.

Forecast of financial flows for the period 2020-2021: 2020 – 10 million rubles, 2021 – at least 50 million rubles.

(2) “Business-to-business” segment: sale of “Tozka-1” device

Product description: outpatient electrocardiographic device for early diagnostics of patients with coronary heart disease (reliability about 96%) and control of therapy effectiveness.

Scheme of income generation: sale through distributors.

Application: for treatment and prevention institutions.

Planned retail price: 140 thousand rubles (at production cost of about 42 thousand rubles).

Status of the scheme: preliminary negotiations with 5 profile distributors of medical equipment were held, agreement with the company 10 MED Llc (<http://maximed.pro/en>) on sales in the markets of Russia, CIS and EU, was reached.

Forecast of financial flows for the period 2020-2021: 210 million rubles.

(3) Sale of the license

The main commercial goal of the developer’s activity will be building portfolio of intellectual assets that protect technology, as well as refinement and commercialization of technology, mainly through licensing of relevant intellectual property. By 2022, it is planned to sell IP for at least 200 million rubles, or reaching license agreement with major industrial partner with the payment of royalties in the amount of 5-7% of sale turnover of the developed medical equipment and gadgets.

6. Conclusions

Thus, the formed elements of the business strategy for the commercialization of innovative medical technology took into account main known theoretical approaches to strategic and business planning. As peculiarity of the proposed strategy was consideration of problems of modern technology of electrocardiologic diagnostics and corresponding social problems in general. In addition, the model of commercialization has differentiated character, depending on specifics problems to be solved for each market segment. This condition determines anticipated high speed of innovation distribution process in format of the new device “Tozka”.

As a result, the authors formulated main directions for technology and new product development, taking into account findings of the research:

(1) Creating and preclinical testing device versions in 2019-2020;

(2) Developing of Russian market with a turnover of about 90 million rubles in 2020-2021;

(3) Scaling of the product in the international market: entering markets of CIS countries in 2020-2021, and countries of Central and Eastern Europe – in 2021-2022, with a turnover of about 200 million rubles by 2022.

Generalized plan for subsequent development for the next few years includes the following stages:

By 2020 – creation of distribution network in the markets of CIS and countries of Central and Eastern Europe. Sales in Russia - not less than 500 devices of “Tozka-1” and 1000 devices of “Tozka-6”.

In 2021 – sales in the Russian Federation, test sales in the markets of the CIS and countries of Central and Eastern Europe, in total number of not less than 1000 devices of “Tozka-1” and 5000 devices of “Tozka-6”.

In 2022 – sales of technology license to a large industrial partner from among such well-known companies, as: Siemens, Medtronic, Roshe, Philips, Samsung.

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