Federal State Educational Institution

of Higher Professional Education

St. Petersburg State University

Institute "Graduate School of Management"

**Individual report of the participant on the contribution to the startup project**

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St. Petersburg

2021

**1. Introduction**

Within the framework of the competition for interdisciplinary student and postgraduate projects "Start-up St. Petersburg State University - 2020", a start-up project GenomeX was presented, dedicated to the development and commercialization of a technique for high-throughput genetic screening of newborns for the presence of the disease "Spinal muscular atrophy" (hereinafter referred to as SMA). Spinal muscular atrophy (hereinafter referred to as SMA) is a group of neuromuscular diseases characterized by degeneration of alpha-motor neurons in the spinal cord, and as a result, progressive muscle atrophy, weakness and paralysis, leading to death.

Global demand for a diagnostic test for SMA in 2018 amounted to 1.9 million tests / year. As SMA treatment programs are approved, the demand for the test will increase to 131.4 million tests / year.

During the period of work on a startup project for three months, the team worked to achieve the following results:

* Development of a neonatal genetic screening technique for Spinal Muscular Atrophy;
* Evaluation of the developed technology for diagnostics of SMA for sensitivity and specificity;
* List of interested buyers and contractors of diagnostic kits, negotiation, receiving letters of interest and marketing plan for bringing the product to market;
* Preparation of a business plan and financial model;
* Assessment of the company's value;
* Preparation of materials for registration and patenting for test technology;

The responsibilities of the members of the GenomeX startup project team were divided in such a way that my role in the project was to draw up a business plan and financial model, find and establish contacts with buyers and contractors, prepare a patent and licensing strategy, and estimate the value of the company.

**2. Purpose and objectives**

As part of individual work in a startup project, my responsibilities included drawing up a business case for the effectiveness of a business idea and plans for its implementation, as well as achieving the following goals:

As part of an individual work in a startup project, my responsibilities included achieving the following goals:

* Economic justification of the feasibility of a business idea and the profitability of its unit economy
* Drawing up a general strategy for commercializing the development and attracting external funding

To achieve these goals, the following tasks were set:

* Prepare an analysis for the spinal muscular atrophy screening market
* Draw up a technology commercialization strategy
* Make a list of potential clients and suppliers and negotiate
* Create a financial model
* Select methods for assessing the value of the company and apply valuation techniques to our financial model

**3. Results**

As part of the implementation of the tasks, the following results were obtained:

**3.1. Prepare an analysis for the spinal muscular atrophy screening market**

According to prescient & strategic intelligence, the screening market, to which they attributed 5 diseases, including SMA, will grow by 10.9% per year from 2020 to 20301. Also according to the publication, Fortune Business Insight is expected to the annual growth of the market for the treatment of spinal muscular atrophy by 28.9%. Such an increase in the treatment market implies an expansion of the patient base, which can be effectively achieved through the introduction of mass neonatal screening. Based on the above two figures, we assume that the growth of the SMA screening market will be approximately equal to the arithmetic mean between the two markets described above and will be about 19.9% under the baseline scenario, under the optimistic scenario, namely, with the introduction of mass neonatal screening for SMA in China, we we expect the market to grow by an average of 30% per year over the next ten years. It should be noted that the growth of the market will be of a spasmodic nature.

Currently the bulk of the market is in the United States of America, since so far only the United States has launched a nationwide screening program for spinal muscular atrophy. A number of countries are already in the process of conducting pilot screening programs. For example, a pilot program of mass screening for spinal muscular atrophy has been launched in three perinatal centers in Moscow. The same program is available in Germany, Belgium, Taiwan and a number of other countries.

**3.2. Draw up a technology commercialization strategy**

The business model of the project involves the wholesale of diagnostic test systems for spinal muscular atrophy. One box contains a 96 well plate with a set of reagents required for 96 diagnostic tests.

The price of such a kit will be 24,000 rubles (250 price per test \* 96 the number of tests in one box). The kits will be shipped across the country through logistics companies directly to the genetics centers.

After the preparation of the production line, Genomex LLC plans to launch a pilot screening program at several points in Russia. In the first year, it is planned to cover up to 100,000 newborns, through the launch of pilot programs in conjunction with Novartis. After confirming the work of our business processes and the benefits of neonatal screening for SMA, it is planned to enter the neonatal screening program for SMA in Russia on a federal scale. According to our sources, a similar project is being discussed in the health committee of the State Duma. Further, we plan to enter foreign markets by means of the methods specified in the strategy for promoting the product to the market.

Commercialization is also planned in the following ways:

* Participation in public procurement after the introduction of the screening program for SMA;
* Launch of pilot screening programs in cooperation with Novartis and regional medical genetic centers. Novartis is providing funding to regional genetics centers to launch SMA screening, while expanding its patient base. The regional ministry of health, through the regional medical genetic center, provides the population with screening services for SMA, without spending the budget. Genomex LLC, the most cost-effective and productive supplier, provides the supply of test systems for CMA. A similar scheme of work was proposed to us by the management of Novartis in Russia. In addition to Novartis, other drug manufacturers may be involved, such as Roche or Biogen;
* Sale of a license to use the technology;
* Participation in acceleration programs, for example, the corporate Sanofi accelerator, the Skolkovo accelerator, the largest IndieBio accelerator;
* Participation in specialized exhibitions and conferences.

**3.3. Make a list of potential clients and suppliers and negotiate**

As a result of negotiations with suppliers, the following agreements were reached: we will draw up a protocol - how much to excavate and types of incoming and outgoing control. They will dig out a test batch for free, make an input and output control and calculate how much it came out in terms of labor costs, so if we already order a big batch, we will know how much it costs.

As a result of negotiations with clients, the following agreements were reached: we will consider the possibility of delivering 50,000 thousand tests in the period from the 4th quarter of 2021 to the 4th quarter of 2022. If the launch is successful, then we will multiply the supply for the client.

**3.4. Create a financial model**

On the one hand, financial model is highly dependent on customer demand. Since the spinal muscular atrophy screening market is a monopsony, the financial model is highly dependent on customer demand. On the other hand, with a business marginality of about 100 percent, GenomeX has a very competitive unit economy, which allows the company to remain profitable at a price level at which competitors will operate at a loss.

Also, while increasing the scale of production, GenomeX gains the advantage of scaling due to a decrease in the share of fixed costs in the structure of production costs per unit of dough.



**Figure 1:** GenomeX Revenue and Income

**3.5. Select methods for assessing the value of the company**

Evaluating biotech startups is not easy because of the uncertainty of the business model, which leads to unpredictable future revenues, costs and profits. Moreover, since the ideas or technologies generated within a startup project are relatively new, it’s complicated to evaluate investment needs, cash flows and potential future growth. The assessment is reflected in several intangible assets, which sometimes may not even appear on the balance sheet. But more importantly, due to negative earnings and negative cash flows, multiples for both the entity and equity cannot be applied unless projected future values are used. Black's (2003) study discovered that profit does not provide enough information for evaluating startups, but becomes more important as the firm is becoming larger.

The value of the company is the sum of the present values of after-tax cash flows for n years and the terminal value at the end of the projected period (Vernimmen, 2014). For well established companies the terminal value accounts already for a large proportion of the overall value, thus for a startup it can happen that the terminal value accounts up to 90% or 100% of the value (Mills, 1998).

The free cash flows can be calculated by the next formula (Beneda, 2003):

*Free Cash Flow to the Firm (FCFF) = Operating income \* (1 - Tax rate) - Capital Expenditures + Depreciation and Amortization - Change in Net Working Capital*

TV at the end of the projected period can be calculated with the terminal multiple method or the perpetuity growth method.

*Terminal Value = Terminal Multiple \* Corresponding Financials for final forecasting period*

TV based on the FCFF at the end of the projecting period suggests that the company will grow continuously and generate FCFF for an infinite period of time. The infinite growth rate g is typically the historic inflation rate or the historic GDP growth (Vernimmen, 2014). If the growth rate is bigger than one of the two values, the company is expected to outgrow the economy forever.

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| Forecasted GenomeX EV by DCF |
| FCFF first year - 2 775 525 |
| FCFF sedond year 19 618 177 |
| FCFF third year 30 170 161 |
| WACC 20% |
| TV 8 346 000 |
| EV 37 116 380 |
| Investments 5 736 565 |
| **Required ownership 15.4%** |

Besides straightforward valuation approaches as, for example, the discounted cash flow approach, several relative assess approaches exist. Relative valuation approaches are based on multiples, which are financial ratios that have been calculated through a set of similar businesses. There are two classic kinds of multiples (Vernimmen, 2014):

* Enterprise multiples: Startup capital structure is not taken into consideration. Companies’ multiples are used to evaluate the enterprise value (EV). The most well-known multiples are the (EV/EBIT), (EV/Sales) and (EV/EBITDA).
* Price multiples: These multiples enable to calculate the market price of a startup directly. The most well-known multiples are the price-to-earnings ratio and the price-to-book ratio.

According Damodaran multiples valuation technique does not seem very applicable for start-ups, mainly due to the difficulty in comparison with regards to comparable companies, common measures, risk adjustment and equity claims (Damodaran, 2011).

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| **Deals on market of genetic testing** |
| Company | Bioneer | Mission bio | Counsyl | CardioDX |
| Country | South Korea | USA | USA | USA |
| EV  | $217M | $250M | $375M | $888.3M |
| Stage | IPO | Early venture | Venture | Venture |
| Investors |  | Stanford-StartX Fund, Mayfield Fund | Acquisition Myriad Genetics | Longitude Capital, Artiman Ventures |
| Earnings | $34M | $11.5M | $38.4M | $10M |
| **Price/sales** | **6,3** | **21,7** | **9,7** | **88,8** |

Considering multiples approach to valuation of GenomeX there is discounted average earnings was taken for the next three years. The least P/S multiple for comparable company is equal to 6.3. For calculation of GenomeX value the least multiple should be taken since GenomeX has very hish risks since its stage. So the EV of GenomeX by multiple method is equal to 57 540 760 rubles. By investing 5 736 565 rubles investor will require 10% of the company.

Thus, all the goals and objectives set within the startup project were successfully achieved. Based on the results of the achieved results, a positive conclusion was made on the feasibility of the business model, contacts were established with manufacturers, buyers and investment capital was attracted.

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