Abidin Gülmüş – CEO, GEN

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Few Turkish companies are experiencing such a transformational moment as GEN. Just in 2021, the Ankara-based organization made its public debut at the Istanbul Stock Exchange and signed an exclusive collaboration agreement with a Dutch biotech company for the development and commercialization of a therapy against Alzheimer's and other neurodegenerative diseases.

GEN's CEO, Abidin Gülmüş, comments on the recent developments, their international activities to become a major global pharma company and illustrates their unique business model: being the partner of choice for rare disease therapies in Turkey, generics manufacturing, and bold R&D investment.

We interviewed you on behalf of GEN in 2018, at a moment when you were about to open a manufacturing facility and had ambitious plans. Can you walk us through the main developments and the current position of the company?

We remain one of the fastest-growing pharmaceutical companies in Turkey and are committed to helping patients and their families with difficult to treat conditions. As you mentioned, we had just opened our manufacturing facility in 2018 and I am glad to inform you that, since then, in addition to Turkey, we have received GMP approvals from Russia, Azerbaijan Kazakhstan, and the Philippines. We submitted our first generic product registrations to US FDA at the end of last year and EU countries (Germany, Austria, Sweden, Denmark, and Norway) via decentralized procedure

this year. Review of our submissions are ongoing, and we hope to receive GMP inspections very soon.

We remain the largest orphan drug supplier in Turkey by revenue, collaborating with 19 companies, including Biogen, Ipsen, Jazz, PTC, Biomarin, etc. GEN is the first door knocked by the majority of the companies working in the rare diseases space that does not have a direct presence in our country.

The most important milestone achieved by GEN happened this year, when the company became public, listing its stock on the Istanbul Stock Exchange. Although it is only our 8th week of trading, we are happy with the results and the interest from investors. This big step will get us closer to our overall objective of becoming a major global player by helping patients and developing new molecules for unmet medical needs.

In line with our globalization strategy, GEN opened an office in Russia in early 2020 and we have already registered products, with more on the way. We also opened an office in Uzbekistan to support and expand our presence in Azerbaijan and Kazakhstan, both of which have existed for more than 15 years. We are leveraging Turkey’s historical ties and advantageous geographical location to strengthen our presence in CIS countries, but, since our objective is to be a major global company, we are also targeting Europe. Therefore, we have opened our administrative and regulatory office in Germany, at the same time to our generic product submissions to EU countries.

What other business opportunities and investments are you looking for to differentiate from other Turkish companies and reach the global player status that you just outlined?

Being a major global player is not possible without substantial investment in R&D; global companies must be innovative. GEN is committed to developing novel molecules, from phase I to phase III, as part of our quest to become an innovative organization. Just two weeks ago, we announced our exclusive collaboration and license agreement with Sulfateq BV, a Dutch early-stage biotech company, for the development and commercialization of SUL-238 as a therapy against Alzheimer’s Disease and other neurodegenerative diseases. This is a great milestone for the company, but we are fully aware that it will be a long journey.

Moreover, we have been working on a novel therapeutic option for psoriasis patients. We are thrilled to mention that preclinical proof of concept animal studies have been completed successfully and we are aiming to initiate clinical development of this novel topical treatment

within a few months.

It is also important to highlight that we also acquired another R&D laboratory located in Hacettepe University Technopark in Ankara, which has tremendously accelerated our R&D capabilities. We have now more than 50 R&D specialists, including pharmacists, chemical engineers, molecular biologists, and genetic engineers.

As a founder, what was the reasoning behind making GEN a public company and how has the decision transformed the way you operate?

Being a public company brings exposure to the company, makes it more transparent, and provides a certain level of confidence from partners and investors. The company has intensified its work on compliance and ethics requirements, providing accurate reports on its operations. Before IPO, GEN had already been selected as one of Turkey’s ethical companies by an association called Ethica.

From an executive point of view, the decision has changed some important dynamics, including the delicate art of dealing with investors that expect shares to go up every day. Thankfully, the company is in a healthy financial situation and our current investments will provide value for the people and institutions that have invested in our mission. The funds raised will go towards R&D, operating capital, and other activities.

Other relevant changes in the organization have been an increase of personnel in the legal, investment, and budget departments, plus specialists reporting to Turkey’s SEC commission.

Which parts of GEN’s business are driving the growth for the company and how do you expect them to evolve?

Most of our revenue is currently coming from orphan drugs partnerships, however, we are aiming to increase our manufacturing activities with a bold objective of exporting 70% of our productions in the next three years. Part of our interest in having a direct presence in CIS countries was in fact due to this goal.

In the next five years, we hope that our products and projects will represent more than 60-65% of our total revenue.

With such a large amount of local Turkish manufacturing companies going to CIS countries, why did you decide to follow that path instead of penetrating other markets?

Because we offer difficult-to-make products; we are not just pressing tablets. We have introduced a product submission to US FDA for the same reason because we are working specifically on short-listed products in the US.

GEN is not aiming to compete in very crowded spaces, producing billions of tablets. Our objective is to produce high-cost, low-volume drugs that serve patients with unmet medical needs.

As the leader of a company that plays different roles within the Turkish pharmaceutical industry, how do you describe the current situation?

The Turkish pharmaceutical market has been losing ground for a few years due to the pricing policy in place; it is the 18th largest market in the world, which is still significant. However, it used to be larger. Having said that, we also have to emphasize that around 95% of the Turkish population is covered by the public healthcare system and Turkey’s Social Security reimbursement is one of the best and most humanitarian systems in the world. At some level, it is understandable that the government gets concerned about the size of the budget when it must cover and pay for health services to 85 million people. Price pressure has been implemented as an alternative to a healthcare budget increase.

This situation can be interpreted in a variety of ways, with both positive and negative elements. For example, many companies, particularly in the orphan drugs space, are unwilling to register their products in Turkey due to a big concern that the low prices could have a ripple effect in other markets. For that reason, many high-priced products are not available in Turkey.

However, Turkey’s legislation allows products to be introduced through a named-patient access program if a drug is not available in the market and addresses an unmet medical need; that right is recognized by the Constitution of the Republic. While not all products are using that path, some niche products for rare diseases are being introduced with financial help from the government and foundations.

According to executives overseeing the Middle East for multinational companies, diagnosis for rare diseases can take from 3 to 6 years in that region. Is that the case in

Turkey?

The situation here is different since Turkish healthcare infrastructure, including hospitals and laboratories, is very well developed. Diagnosis is far from perfect, but the country is in a good position; it is not a big issue, particularly in urban centers.

And even when the right equipment is not available inside the country, GEN is supporting patients and patient associations to send their samples abroad for testing.

Our patient-centric approach means that we will help patients with rare conditions regardless of the number of patients. We help patients with accurate diagnosis and work hard to find ways for them to receive the right treatment, if available.

How do you ensure a certain level of sustainability for your orphan drugs business and protect against changing dynamics that can affect your partners' plans?

GEN is not approaching rare disease companies after the product has been approved, but instead, we usually initiate our first contact with potential partners immediately after completion of phase I or phase II clinical development stages. In rare diseases, clinical trials can be an access pathway for patients with unmet medical needs. Accordingly, in some cases, we even support global companies for conducting their clinical development partially in Turkish centers. In this way, patients can obtain early access to treatment and companies can prove the efficacy of their assets, and we are rewarded later on if the candidate treatment option is found to be effective and safe. When a product is approved by the FDA and/or EMA, we immediately communicate with both the authorities and all stakeholders to share the scientific information and search for possible ways to provide access to patients. In the case of approval by the Ministry of Health and SGK (Social Security Institution), patients can be treated via the Named Patient Program.

What role will GEN play in the R&D process within the collaboration with Sulfateq for the development of the SUL-238 Alzheimer's disease asset?

The preclinical phase is ongoing, and I am glad that more than halfway is already done. The majority of the preclinical studies are conducted in the University of Groningen and Free University of Amsterdam in The Netherlands. Our objective is to initiate phase I clinical studies at the end of next year.

Why did you decide to go for that particular project considering that no other therapy had been approved for Alzheimer's Disease over the past 20 years?

Development in Alzheimer's Disease space has received large coverage lately, and almost all have been failed, but our approach is different. Mitochondrial health has not been investigated in detail in Alzheimer's Disease, however, our candidate molecule has a mechanism of action on mitochondrial biology. We also aim to explore the potential of candidate molecule in Parkinson's Disease and other neurodegenerative diseases. We worked on many other molecules and found Sulfateq's asset quite promising because of their novel approach. Effective treatment for Alzheimer's Disease and other neurodegenerative diseases has been elusive, yes, but we must continue searching for it. This project's upside is massive, we are talking about a potentially big reward for humanity. So far, there are reasons to be optimistic because of the first safety profile indicators in laboratory animals.

Regarding the different R&D pathways, you can take for the SUL-238 project, what is the current plan of action for regulatory applications and the location of the clinical trials?

Our preclinical phase will be completed based on EMA registration requirements. A multinational multicenter Phase II study is planned after a successful phase I. Many different options are on the table for the moment, but we must wait and adapt to the actual progress of the asset. Drug development is a matter of commitment and perseverance, it might fail but we are committed to making it work.

And the plan is to support the project through your current parentship business and expansion of the manufacturing business?

Yes. We are waiting for the approvals from EU countries, but we are already very active in Russia and CIS, especially in Azerbaijan and Kazakhstan. Our infrastructure will be very helpful to our expansion plans. As of today, we have approximately 60 employees in our operations based in Azerbaijan, Kazakhstan, Russia, and Uzbekistan.

Obtaining the GMP approval by the German Health Authority is significant as it will facilitate our penetration to other European markets. We decided to apply via Germany since it is known to be one of the well-accepted authorities worldwide and mutually recognized by most of the regulated market authorities.

Reflecting on the evolution of Turkey's industry over the years and the impacts of the pandemic, what makes you confident that the ecosystem will prevail?

The pharma industry is very well established in Turkey, we have incredible infrastructure, human resources, and R&D capabilities. The country rose to the challenge during the COVID-19 pandemic because the ecosystem united behind a common goal, saving our people, without looking at the cost and timelines, working day and night to supply the market.

There are many high-quality manufacturers in Turkey which have good business, but we could do even better if we are seen as a strategically important sector and supported more by the Turkish authorities. GEN is looking to overcome those challenges by becoming a truly innovative Turkish company.

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