

# Aris Mitsopoulos – Vice President, RAFARM

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Our country has the potential to emerge as a manufacturing and research hub for the wider region of Southeastern Europe

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*One of Greece's leading domestic pharmaceutical companies, RAFARM has had a stellar recent history, including a momentous entry into the US market. Now looking to establish itself as one of Europe's major players in ophthalmics and complex injectables, VP Aris Mitsopoulos outlines his ambitious growth plan for the firm and why Greece stands to become a significant pharma manufacturing hub for Europe post-COVID.*

**When we last spoke in 2017, RAFARM had undergone a staggering transformation, seen stellar growth and doubled its export activity. Can you give us an overview of the company's progression since then?**

Over the last five years, driven by innovation and growing dynamically, RAFARM has continually invested in expanding both its expertise and international footprint. Our exports, which have doubled since 2017, today represent over 75 percent of our production. To continue expanding our exports we develop new products, increase our market penetration and enter new markets. Moreover, we invest ten percent of our net turnover in R&D to unlock our full potential by investing in the development and production of complex pharmaceutical products, in particular ophthalmic products (solutions, suspensions and emulsions) and complex injectable products.

We accomplished a 63 percent increase in our consolidated turnover over the last five years (2017-2021), and a 15 percent growth in turnover from 2020 to 2021. RAFARM has doubled its headcount and reinforced its position in the European market. Moreover, in the last year (2022 vs 2021) we

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achieved a 40 percent growth in exports. We own more than 1,200 approved licenses worldwide and export to more than 60 countries across five continents. The major milestone of recent years was RAFARM's entrance into the US market, which required a great deal of effort and investment. This has been a great success, with our production site having been FDA-approved since 2018 and the company already having six high-performing products in the US market. Moreover, we have ongoing development and registrations for a further 15 new ANDA filings.

### **How different was this experience of taking RAFARM to the US compared to its previous internationalisation efforts?**

At the beginning, it was challenging. RAFARM has traditionally operated as a European company, primarily exporting to other countries within Europe, where we are used to the fragmentation of the markets, the demands of both customers and local authorities, the stock-keeping units (SKUs), and the intellectual property (IP) situation.

The USA offers great opportunities in terms of market size as the biggest market in the world, but competition is fierce and the generic drug industry has been experiencing challenges around value creation. To be more exact, US generic prices are eroding rapidly, new competitors are accessing the market with low-price products, and pharmacies are joining forces with wholesalers to leverage purchasing power.

What we do to succeed is focus our efforts on being first-to-file and first-to-market, as well as offering value-added medicines and differentiated complex products. Additionally, we grow our necessary capabilities, including navigating PIV and 505(b)2 filings.

### **Presumably, these market entry challenges necessitate the striking of several partnership deals with service providers?**

Absolutely, for example, we had a lot of consulting in the initial stages. RAFARM is not an established multinational company with all the capabilities needed to enter a market like the US in-house. We carefully select our partners to establish win-win deals.

Over the last five years, we have struck up several joint ventures (JVs), as well as other collaborations. We offer our know-how in research & development and production of complex generics (ophthalmics and injectables), while our US partners offer their experience in dealing with the FDA to get final product approval and their deep knowledge of market dynamics which are completely different from what we are used to seeing in the EU and other countries. To succeed in today's highly competitive pharmaceutical landscape, time is of the essence. As I previously mentioned, obtaining an early market entrance is essential for capturing value. Differentiation is also another key driver: we develop and produce products with incremental innovation—for example, alternative dosage forms, new formulations and combinations—opening a path to profitable growth.

### **Will RAFARM's securing of FDA approval — the global gold standard in terms of regulation — assist its internationalisation efforts in new markets?**

It will, and already has. For example, RAFARM has managed to achieve rapid approval for its products in Saudi Arabia, thanks to the mutual agreement in place, between the Saudi and US FDAs. The entry into these new markets not only affects our bottom line but also helps develop our internal capabilities in areas like production and operations.

Following this, we have been able to look even further afield to even bigger, but even more challenging, markets. China, for instance, has long been one of the most demanding markets for European companies due to the country's shifting regulatory requirements and the need to strike up joint ventures with local firms. After working for almost five years on two projects in China, we hope to launch our first products in the Chinese market in 2023, which will be another significant milestone for RAFARM.

**Given RAFARM's strong manufacturing footprint and the rhetoric about the nearshoring of essential medicine and ingredient supply chains in Europe post-COVID, what role do you foresee for RAFARM and for Greek pharma manufacturing in Europe moving forward?**

This pandemic has given our industry a lot of positives as well as some challenging matters to address. In terms of challenges, it showed that the whole world, including Europe, was dependent on suppliers from outside Europe for basic materials, active pharmaceutical ingredients (APIs), as well as packaging such as vials and plastic bottles. There was a huge disruption in the supply chain, which we have all had to become even more agile and flexible to deal with. I am proud to say that during the pandemic, RAFARM was one of the very few companies that managed to overcome all these challenges without any impact on our delivery schedules.

On a positive note, this situation pushed the European Union (EU), as well as local governments to identify the sectors necessary for a sustainable and healthy society. Europe has realised that it has been too dependent on imports and can easily experience shortages of vital products. We are therefore seeing a political shift from the EU towards establishing a more supportive and robust pharmaceutical manufacturing ecosystem within Europe. This is crucial both in economic terms as well as on health security grounds.

**This surely represents a big opportunity for countries in Southern Europe like Greece that have retained generic and API manufacturing facilities. How do you see it?**

It is a great opportunity. Greece was one of the few EU countries that did not experience any major medicine shortages during the pandemic, in part thanks to its strong local manufacturing industry.

RAFARM, for its part, was able to cover all the needs based on the government demand, including dexamethasone, which was included in the protocol for the treatment of COVID patients. Beyond our borders, we were able to support the Italian and British governments with large quantities of this drug at very short notice.

**Greece seems to be on its surest economic footing for several years, with nine percent GDP growth in 2021, unemployment down to under 15 percent, and an administration rolling out several business-friendly measures. What is your view on this positive economic upturn?**

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Greece, coming out recently from a long period of financial stress and dealing with the pandemic, is showing positive signs of returning to social and economic normality. The country has remained resilient and achieved more than six percent GDP growth in 2022, with two percent growth projected for 2023. The return of tourism has had an impact, but the whole economy is moving again. There is a substantial increase in investments, both from foreign and local actors, which is creating a rise in labour productivity and a reduction in unemployment. Moreover, structural reforms – including the digitalisation of the public sector – are already having an impact, and I am optimistic that the country’s growth momentum will continue.

However, we should not forget that recent economic and geopolitical crises continue to have an impact and that inflation remains, although this is not affecting Greece as heavily as many other European countries. Moreover, increased energy costs are hampering the pace of growth. Nevertheless, compared to other countries in Europe, I feel that Greece is in a good position.

### **And what are your thoughts on the prospects for the Greek pharmaceutical industry?**

In Greece, the pharmaceutical industry is at the centre of its development effort as it is a sector of critical importance for public health and the local economy. Investments by the domestic pharmaceutical industry bring multiple benefits to society and the national economy, as they create new employment and ensure adequate supply and availability of medicines in the local market with first-line medicines to address the needs of Greek patients. In addition, through the implementation of the domestic pharmaceutical industry’s investment planning, our country has the potential to emerge as a manufacturing and research hub for the wider region of Southeastern Europe.

The proof of this comes from the significant investment plans that were announced. Greek pharma companies are investing EUR 1.2 billion in the coming years, which will transform the face of our country’s pharma manufacturing footprint, as well as that of Europe.

As part of the EU Recovery & Resilience Facility (RRF) funding, pharmaceutical manufacturers in Greece are now entitled to an offset of part of their outstanding clawback [returns paid by pharma companies to cover the amount in excess of the budget of the public sector – Ed.]. This has led RAFARM – building on its existing investments – to add significant new capacity in ophthalmology and become one of the top European ophthalmology manufacturers, growing from the current 25 million units per year in this niche to 45 million.

Just one million of the current 25 million is sold in Greece, the rest is going to Europe – US and 60 more countries, showing trust from both Greek and other authorities all over the world.

### **What about the major challenges within Greek pharma?**

The uncontrollable level of rebates and clawbacks in the local market remains an issue and a restriction on expansion and growth. The State needs to increase spending gradually and in parallel to control the pharmaceutical budget, so that pharmaceutical companies do not pay back huge amounts in clawbacks. The clawback was supposed to be a temporary measure but has become a permanent one. The State allocates the excess among the companies rather than addressing the basic problem: control of the initial stage of pharmaceutical expenditure.

Moreover, a lot of substitution goes on in the Greek market, which creates a challenging situation for older, more affordable generic products. Economic incentives for both the patient and the

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pharmaceutical supply chain, as well as administrative control of the unjustified switching towards more expensive alternatives, could lead to significant savings that generics can produce, releasing financial pressure from constrained public budgets.

Despite many discussions with the State, a way to manage and control prescriptions while respecting innovation was not found. After several years of reform, we need to find a way out of this. We ask the State to enact effective policy measures that can create a functioning market with win-win relationships for all stakeholders, a sustainable pharmaceutical ecosystem and a healthy society.

**Given that RAFARM has increased its headcount to over 650, could you comment on how challenging it has been to bring in sufficient talent, especially given the brain drain that Greece experienced during the crisis years?**

This is an important point. During the crisis, RAFARM saw significant numbers of scientists leaving for career opportunities in Germany, Switzerland, and elsewhere. Greece is a country with highly talented and driven people, which were in demand and knew they could be better compensated for their talents in other countries.

However, in the past two years, this trend has shifted. People that previously left Greece are now coming back as new career opportunities emerge. Brain gain brings knowledge, expertise, and a lot of value for the Greek society and economy.

Despite this positive trend, one of RAFARM's major problems remains the recruitment of talented people. Especially on the R&D front, the Greek market lacks enough senior and experienced scientists, meaning that we also look outside of our borders to fill these roles. This situation is the same for other companies, meaning that a battle for talent is underway.

A solution here is to work more closely with the universities and the government to implement a training plan so that students develop their skills to match career paths in the pharmaceutical industry.

**What would you like to achieve with RAFARM in the coming years?**

A lot! RAFARM will continue to evolve beyond the obvious and invest intensely in R&D in line with our culture of more innovation. We will see more innovation that is born internally as well as coming through partnerships with institutions outside Greece.

Many people still think that the generic industry is very simple, but beyond simple generics there is incremental innovation in value-added medicines, with reformulation, repositioning, and fixed combinations.

Beyond innovation, RAFARM will continue expanding its footprint in the US, and in parallel, in Greece since RAFARM has a dynamically growing local Commercial activity. RAFARM is one of the top three Greek pharmaceutical companies with outward-looking orientation and collaborations with global pharma leaders, driving the local industry forward. We have represented some multinationals for years, and we continue to strengthen our presence in the local market through the expansion of our product portfolio and partnerships with strong international players (21 newly promoted products in the last three years and 14 scheduled new product launches in the next three years).

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Furthermore, we are transforming the company in terms of digitalisation and environmental, social, and corporate governance (ESG) to better position RAFARM in the dynamic and demanding environment.

At RAFARM, we evolve beyond the obvious to strengthen our company and make a positive impact on people's lives.

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