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— MALTA 2018

Preface

The two Mediterranean island nations of Malta and Cyprus have much to recommend them in terms of life science investment opportunities.

Malta, tucked away underneath Sicily, has a population of only 450,000 and an area of 316 km2. However, the country has managed to establish itself as the fastest growing economy in the EU with 6.6 percent GDP growth in 2017, thanks in large part to its willingness and ability to capitalize on niches ignored or disregarded by others.

This opportunistic and entrepreneurial mindset is especially prevalent in Malta's healthcare and life sciences industries. A light regulatory touch has long attracted many companies to establish R&D and manufacturing plants for generic pharmaceuticals on the island in the knowledge that products developed in Malta can be launched globally immediately on the expiry of the originator drug – a massive draw factor for cost- and time-concious generics companies.

Building on this robust base, Malta continues to seek niches in which it can establish competitive advantages. The key opinion leaders, government officials and company heads featured in this report touch on many of these new niches – including medical tourism, the highly promising albeit controversial field of medical cannabis production, clinical research, as well as distribution and logistics – capitalizing on Malta's highly strategic geographic position as a link between Europe and Africa.

With a population of just 1.2 million and a proportionately small pharmaceutical market by EU standards, Cyprus is often overlooked as a healthcare and life sciences investment destination. However, with the island now on the road to economic recovery, an air of confidence is again beginning to permeate Cyprus, bolstered by the country's key selling points: a geostrategic location close to the rest of Europe as well as the Middle East and Africa, full EU membership and norms, a favourable tax regime, a business environment conducive to growth, a large, well-educated and internationally experienced talent pool, and comparatively low costs.

Low government expenditure on healthcare has been a persistent problem for Cypriot patients for several years, restricting their access to drugs and creating some of the highest out-of-pocket expenditure levels in Europe. However, change appears to be on the horizon with the implementation of a universal healthcare system – GeSY – set to be fully complete by 2020.

The industry insiders whose comments form the basis of this new report give their take on the potential impact that GeSY will have on their operations and on Cyprus as a whole. Other topics discussed include Cypriot companies' internationalization strategies, the country's tentative steps into medical cannabis, and how Cyprus is establishing a name for itself as a premier medical tourism hotspot.

Cyprus

The Comeback Kid?

A 9,251 km2 outpost in the far-flung Eastern reaches of the Mediterranean, strategically straddling the fault-line linking the continents of Europe, Asia and Africa, the culturally diverse and economically dynamic island of Cyprus has long presented an intriguing, but nonetheless alluring prospect for the international investment community.

Recent times have, of course, been somewhat turbulent for the 1.2 million population-strong market. In 2013, the island was controversially subjected to harsh austerity measures including an infamous EUR ten billion bailout deal by the IMF-ECB-EU troika notable for being the first and, to date, only bailout worldwide with a condition to impose a bail-in of bank deposits.

Since then, however, the local economy has rebounded strongly. Not only is the Economic Research Center of the State University of Cyprus projecting robust GDP growth of 3.9 percent and 3.3 percent for 2018 and 2019 respectively, but the national unemployment rate is now registering significantly below the EU average: developments that have not gone unnoticed by the ratings agency Fitch which has correspondingly upgraded its valuation of the investability of the country to a respectable BB+. "It is abundantly clear that we are now well on the path to reclaiming investment grade and the very tangible progress we have been making is now starting to achieve international recognition," enthuses Finance Minister Harris Georgiades.

NICOS ANASTASIADES
president of Cyprus

Meanwhile, Cyprus' underlying strong points remain very much in evidence. An EU state since 2004 and member of the Eurozone since 2008, the country not only boasts a common law legal system fully aligned with international norms but possesses many of the core ingredients that render doing business easy. Indeed, the country currently ranks a commendable 45th place out of 190 on the World Bank's annual 'Ease of Doing Business' index. "Whether it is our strategic geographical positioning, the abundant availability of talented human capital, our well-developed infrastructure or favorable tax regime, there is certainly much to excite international investors," reflects George Campanellas, executive director of the Cyprus Investment Promotion Agency (CIPA).

CONSTANTINOS IOANNOU
minister of health

"The comparatively low cost of doing business here is one of the key attributes that marks us out from the crowd whether we're talking about average hourly wages, expenses relating to social security and rent or the attractive financial benefits that we extend to those corporations that elect to domicile locally," he explains. Certainly the island's low corporate tax rate of a mere 12.5 percent and the fact that dual tax agreements have been concluded with over 60 countries, set Cyprus apart from much of the rest of Europe, and perhaps go some way to explaining why FDI levels surged by 9.1 percent in 2016, marking a return to pre-crisis levels.

WHETHER IT IS OUR STRATEGIC GEOGRAPHICAL POSITIONING, THE ABUNDANT AVAILABILITY OF TALENTED HUMAN CAPITAL, OUR WELL-DEVELOPED INFRASTRUCTURE OR FAVORABLE TAX REGIME, THERE IS CERTAINLY MUCH TO EXCITE INTERNATIONAL INVESTORS — George Campanellas CIPA

From a life sciences industry perspective, Cyprus' diminutive market size will always be a somewhat limiting factor. "To be frank, our country's tiny domestic market doesn't have much headroom to expand by very much and even in the unlikely scenario that our fractured nation becomes reunited, which would potentially open the door to exporting to Turkey, we are still going to be a minnow in the grand scheme of things," candidly admits renowned Cypriot entrepreneur, Dr. Andreas Pittas, the founder of homegrown generics and consumer health powerhouse, Medochemie.

That said, pharmaceuticals remain a critical pillar of the national economy especially when it comes to exports. If EFPIA's 2016 calculations valued the Cypriot internal pharma market at only EUR 180 million at ex-factory prices, last year pharmaceutical exports from Cyprus alone generated some EUR 436 million, up from EUR 392 million the year before according to Central Bank data. This not only renders pharma Cyprus' lead export industry today, constituting almost half of the total value of the country's exports, but also marks a feisty 11 percent growth rate, thus hinting at a certain internal momentum and dynamism within the sector. "This positive performance is neither accidental nor the product of conjunctures... It is the result of the focused and coordinated actions of entrepreneurs and the state, which, among others, enabled the penetration of Cypriot products into new third-country markets like China, Jordan and Lebanon," affirms President Nicos Anastasiades.

Firstly, as an export platform, Cyprus, which manages to concentrate more than 45 pharma production facilities certified by the EMA, FDA or both, offers a slightly different formula to that of many of its European peers. Ranking as one of the most important maritime registries worldwide, the biggest third-party ship management center in the EU, and situated on the crossroads dividing three continents, Cyprus is undoubtedly strategically well placed to serve a broad array of markets stretching from Africa and the Middle East all the way to the Far East.

GeSY: Lowdown on a Landmark Reform

Major health system reform that would provide universal healthcare coverage has been mooted since the early 1990s. The legislation for the National Health Insurance System was adopted in June 2017. Implementation of the new Healthcare System is expected to be fully complete by 2020.

• The principles of Universality (Universal coverage of the population), Equality (Equal access of beneficiaries to healthcare services), Solidarity (Contributions based on income) and Free Choice (the patients choose freely their healthcare providers) are enshrined in law.

• The system will be financed through large-scale contributions from employees, employers, government, incomes and retirees. Beneficiaries will also pay a small user fee for the services they receive in order to avoid abuse of the system.

• There will be one purchaser, the Health Insurance Organization (HIO), an autonomous public provider and several private providers who will have the option to contract with the HIO.

• The establishment of a National Pharmaceutical Authority in Cyprus will allow for the concentration of expertise in the field of pharmaceuticals & medical devices.

• Administrative and financial autonomy will be awarded to public hospitals through the reorganization of medical & paramedical staff and valid pricing of public healthcare services

• Thorough reorganization and upgrading of public primary healthcare apparatus encompassing cluster-ization of small healthcare facilities, extending opening hours, standardizing procedures and improved synergies and coordination with ambulance services and community care centers.

• Rollout of an Integrated Healthcare Information System (IHCIS) to all public hospitals and health centers in the Republic of Cyprus ensure transparency of transactions and activities.

Secondly, the island manages to serve up a certain degree of credibility and assuredness. "Cyprus is a contained, but nonetheless interesting market for outside investors. While firms certainly wouldn't necessarily expect huge turnovers and massive windfalls, this is the sort of market that can be relied upon to deliver the goods at the end of the day... Business here is decidedly less risky compared to many European countries thanks to the dependable systems in place, high levels of predictability and the low risks to operate in the current ecosystem," attests George Limbouris, managing director of pharmacy third party logistics service Pharmalink and distributor, Novagem.

Some analysts point out that Cyprus actually offers an appealing combination of incentives juxtaposed with security. Unlike high-risk, high-reward markets that provide little in the way of protection for investments, or safe-bets that fail to excite, Cyprus would appear to successfully square the circle. "This is the sort of marketplace where you can benefit from 80 percent tax relief for intellectual property and yet it still adheres to English common-law, which adds fluidity and certainty to the system, harnessing a strong sense of legality," muses CIPA's George Campanellas.

GEORGE LIMBOURIS
managing director, Pharmalink

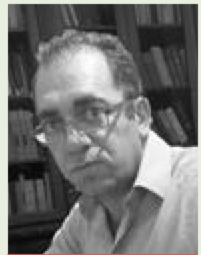
HEALTHCARE PROVISION: ON THE ROCKS

Overall increases in life expectancy over the past decades have kept Cyprus among the top European performers in terms of wellness. In 2015, life expectancy at birth was 81.8 years: well above the EU average of 80.6 and seventh highest among all EU countries. When it comes to healthcare provision, however, the market appears astonishingly underdeveloped

PETROS AGATHANGELOU

president, Cyprus Medical Association (CyMA)

and embryonic. "It may well surprise you to hear that Cyprus holds the dubious distinction of being the only European country still without a fully-fledged universal healthcare system… We are peculiar for possessing some of the highest out-of-pocket expenditures in the EU, coming in at approximately 50 percent of total health spending, and simultaneously having one of the lowest allocations of healthcare spending in ratio to GDP," laments Christos Vasiliou, deputy-managing director at KPMG.



THOMAS ANTONIOU

chairman, Health Insurance Organization (HIO)

Indeed, according to Euro Health Consumer Index (EHCI) data, in 2016, Cyprus spent a mere EUR 1,592 per capita on healthcare, compared with an EU average of EUR 2,797. Meanwhile total health spending was a lowly 6.8 percent of GDP with the portion paid from private insurance companies coming in at about 11.4 percent, while out-of-pocket household spending on a fee-for-service basis made up a whopping 44 percent! Overall, total health expenditure as a share of GDP has increased or remained stable since 2004, but this obscures the considerable decline in GDP during the financial crisis.

"The rather unusual healthcare landscape that you encounter in Cyprus today is comprised of parallel public and private systems of comparable size that operate in isolation and are almost completely disconnected from one another… and this in turn leads to a predicament in which only about one-fifth of the population enjoys coverage through voluntary healthcare insurances," explains Dr. Petros Agathangelou, president of the Cyprus Medical Association (CyMA).

Thomas Antoniou, chairman of the Health Insurance Organization (HIO) very much concurs. "The need for the reform is imminent and is underlined by various factors," he warns. "In particular, out-of-pocket expenditure is currently approximately 50 percent of the total health expenditure, when we know that anything over 15 percent is catastrophic, whilst the healthcare sector is fragmented into the public and the private sector, which operate completely separately to each other. As a result, the public sector is overloaded as it struggles to serve the needs of approximately 75 percent of the population whilst its capacity can only serve 50 percent, leading to long waiting lists and other significant problems in the provision of services to patients. At the same time, the private sector is expanding in an unregulated manner leading to an endemic supplier induced demand and the beneficiaries paying out of pocket to cover their healthcare needs."

Unsurprisingly such a state of affairs leads to lopsided infrastructure and inefficient healthcare provision. According to the European Observatory on Health Systems and Policies, examples of poor resource allocation abound. For example, Cyprus boasts a very high number of scanners for computed tomography (one for every 30,000 inhabitants) and magnetic resonance imaging (one for every 50,000 inhabitants) compared with other EU Member States, with most of these scanners concentrated in the private sector, and so are largely inaccessible to patients within the public system. The public sector has only one magnetic resonance imaging scanner, whereas there are 17 in the private sector, and public sector magnetic resonance imaging waiting lists are long.

These sorts of discrepancies even extend to personnel staffing: In 2017, the island possessed more than 3.6 physicians per 1,000 population, well above the EU average, however, the number of nurses per 1,000 population (5.2) was well below the average, resulting in a ratio of 1.5 nurses for every doctor – the lowest of any EU member state.

"We have tried all these years to convince other stakeholders and the decision-making bodies that the new system must provide better services in comparison to what the people get today. I hope that this message got through and decisions will be taken towards that direction. We know that different committees will be established and we would appreciate seeing them work in a transparent way with specific regulations, clear timelines and procedures. If this can be achieved, we believe that patient access to innovation will be easier and faster," appeals Kyriakos Mikellis, Pfizer's country lead for Cyprus and Malta and president of the Cyprus Association of Research and Development Pharmaceutical Companies (KEFEA).

"Cyprus sorely needs a modern universal healthcare system. Indeed, our current system dates back to the British colonial times and it is now reaching its breaking point," concludes Pantis Papaloizou, managing director of Papaloisou Limited.

KYRIAKOS MIKELIS

country lead Cyprus and Malta, president, KEFEA

GAME-CHANGER?

Help would belatedly appear to be at hand. After three decades of squabbling and stalling, parliament, in June 2017, finally put the finishing touches to legislation to enact a General Healthcare Scheme (GeSY), providing universal access to care, that will be implemented by the autonomous entity, the State Health Services Organisation (OKYY), before 2020. According to the newly approved law, the first step in this flagship healthcare reform to provide a fully-functional national health system to Cypriot citizens will consist of awarding administrative and financial autonomy to public hospitals, while the reimbursement segment will be executed in two stages starting with out-of-hospital care and continuing with hospital treatment until full implementation.

Under the government roadmap, contributions for the GeSY will begin being collected as of March 2019. The initial stage of the scheme is to be rolled out on June 1 of the same year and concerns outpatient care provided by personal physicians, specialists, pharmacies and labs. The system will subsequently come into full swing as of the first of June 2020 when it is extended to inpatient care. As stipulated by the terms of the agreement, a mix of contributions from employees and pensioners, employers and the self-employed, in addition to the state budget will fund this new health system representing a sweeping diversification of the public health revenue base. Beneficiaries will further pay a small user fee for the services they receive in order to avoid abuse of the system, though the maximum co-pay for patients has been capped at EUR 300 per year. Once that threshold is exceeded, citizens will continue to receive full care regardless.

Unsurprisingly most pharma MNCs are delighted by the prospect of a more highly capitalized healthcare environment that ensures a minimum of quality care for each and every citizen. "Cyprus is on the cusp of entering a hugely exciting phase. Firstly, GeSY, will allow for an increased budget which will improve access to innovative drugs.

A Proud History

PETROS PETROU

executive director, George Petrou Limited

George Petrou Limited was established in 1965, when, as current executive director Petros Petrou notes, "At the time, my father, George Petrou was a medical representative working for the American company, Winthrop. He was the one to introduce Panadol to the island and after its very successful results on the market, the company offered him a position in Greece. However, he refused it as he believed it was the moment for him to start his own company in Cyprus." George Petrou's crisis moment came in 1991 when, as Petros describes, "we parted ways with Bristol-Myers Squibb, who we had originally partnered with, as they decided to establish their own offices in Cyprus. Considering that we lost 75 percent of our business overnight, it led to a significant crisis for our company and there was a need to redefine our business strategy to survive."

Petros, who returned to the company during this period after graduating from university in the UK, explains that he and his father "decided to invest and managed to retain all of our employees who believed that the business will grow again." This faith in its employees has served George Petrou well; indeed, the Petrou family values extend throughout the company. Petros concludes, "George Petrou is a family business, so my father and I consider our employees part of our own family. As we continuously invest in people, we are proud to see area managers working with us for more than 30 years and not a lot of employees leave us."