Interview: Fabrizio Chines – Executive Chairman, SIFI, Italy

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Having successfully accomplished a four-year turnaround exercise and with a fresh capital injection from a leading Italian PE firm, SIFI executive chairman Fabrizio Chines has ambitious growth objectives for the coming years, and is investing in R&D projects including the development of an ophthalmic orphan drug.

The Italian pharmaceutical industry is currently investing more than ever in innovation; do you feel the government is effectively supporting these efforts?

There has been a significant shift in the government's legislative stance towards the pharmaceutical industry recently. Under previous governments our sector was seen largely as a target for cost-containment during spending reviews, whereas now we are seeing some efforts to support innovation. This is because the government has begun to recognize the impact the pharmaceutical industry has had on employment rates, GDP growth and export growth at the national level. For instance, the national government has introduced a specific fund for highly innovative drugs, has promised to reduce applicable corporate tax rates, and has passed legislation to introduce a 'patent box' to reduce the tax rate applied to income sourced from intellectual property.

We expected these steps to have a significant impact in the short term, but there are still bureaucratic hurdles to overcome. The patent box was introduced in late 2014 and intended to impact 2015 tax expenditures, yet we are still facing procedural uncertainties in its implementation with the tax authorities. There are of course other steps that we would like to see taken that would have a positive impact on the industry's ability to innovate and invest in R&D, such as the repeal of the pay-back mechanism both for pharmaceuticals and medical devices; not only is this mechanism conceptually incongruous, as it effectively transfers the burden of public budgetary containment on to the private sector, but it can also negatively impact employment and economic growth within the pharmaceutical and device industry. Beside stability in the legislation, I believe the innovative environment would certainly benefit from a streamlining of bureaucratic procedures.

Where within the ophthalmology segment do you see the most opportunity for SIFI to innovate?

Ophthalmology is a market that has historically been characterized by incremental innovation more than disruptive or radical innovation. Over the last 80 years SIFI has developed core competencies in the area of ophthalmic formulations, which have driven our very successful model of adapting compounds from other therapeutic areas and adapting them to ophthalmology. For example, we are the only company that offers netilmicin as a key antibiotic with ophthalmic indications, and while the API itself was developed a number of years ago we still hold patents on innovative formulations that grant us a degree of exclusivity in the market. Our top selling product Netildex, a fixed-combination of netilmicin and dexamethasone, which is widely used following cataract surgery, is a successful example of this strategy. We are confident that incremental innovations of this sort will continue to play a role in advancing the field of ophthalmology, and that our expertise will allow SIFI to continue to contribute to the field in this manner.

That said, we are seeing strong investments in the development of surgical innovations in key therapeutic areas, traditionally addressed with pharmaceuticals, with the hottest area being minimally invasive glaucoma surgery (MIGS). Large multinational players and startups backed by VC have recently made significant advances. The scale of investment has also been significant as ophthalmology is seen as a segment with unmet medical needs, where innovative therapies and technologies can offer significant improvements in terms of patient quality of life and their ability to maintain active lifestyles. When one looks to areas such as retinal diseases and presbyopia, these are noteworthy challenges to governments in terms of market access and are of critical importance to the general population.

One of SIFI's key innovative contributions in recent years has been in presbyopia, through the development of MINI Well Ready, a progressive intra-ocular lens used during cataract surgery, which offers patients clear advantages over competing products. However, access to this innovative product is limited to patients who can afford the overall cost of a private surgery, as innovation is not supported by an adequate government reimbursement policy.

Separately, I am aware of a number of initiatives to develop therapies for rare ophthalmic diseases. There are several Italian companies active in this area, including SIFI; we are currently working on developing an orphan drug for Acanthamoeba Keratitis. However, while investments in orphan drugs are certainly a positive for patients, I expect future market access issues due to limited government resources. Whilst R&D is supported through EU grants, which SIFI has also been benefiting from, orphan drug pricing may become a topic of concern. Drug-pricing is already under public scrutiny for more widespread indications like hepatitis C, and uncertainties regarding the sustainability of financing orphan drugs may come about when the current wave of innovation reaches the market.

Another contribution SIFI has made to Italian life science innovation is Adaptica. After we licensed some diagnostic technology from an American company and invested in the development of a first prototype, we had to shift our business focus away from diagnostics. Therefore we contributed to a start-up in Padua called Adaptica who finally succeeded in launching a highly innovative electronic phoropter on the market. We are proud to have brought this technology into Italy and also proud that it was an Italian company that developed and launched the resulting product; this is a great example of how innovation can be done collaboratively between companies with very different profiles, and this collaborative spirit is certainly a part of SIFI's DNA. Now SIFI is a strategic shareholder with a minority stake in Adaptica.

SIFI is a family company; given your experience, is the family business model an effective way forward for Italian pharmaceutical companies as they are working to become more innovative?

First of all, when companies are growing in size, bringing in outside management capabilities is a must. In Italy, it has become increasingly common for family owned companies to be run by non-family CEOs. The more relevant issue at present is not that of management, but of investment capacity. Some family companies like Menarini and Angelini may have the critical mass necessary to compete effectively, but for others it is critical to consider equity financing to support innovative product development or M&A strategies, as bank financing is no longer what it used to be. SIFI has taken this step by securing equity funding from a leading Italian PE firm, 21 Investimenti, and I

would say that some Italian companies should look at opportunities to raise capital from PE or VC firms.

The investment from 21 Investmenti followed a period of significant restructuring within SIFI; could you give us an overview of the changes that were made?

Over the last six years SIFI has completely reoriented itself as a company. I became chairman in 2010, and at that time the company faced some significant issues and there was an unfortunate dispute between shareholders that resulted in litigation. At that time, we appointed a non-family CEO and together we executed an operational and financial turnaround that ensured the continuity of our business and achieved an EBITDA margin in line with peers.

Key milestones in this effort include dismissal of underperforming sites (Treviso and Rome), agreements with trade unions to lower labor costs, disposal of non-core assets (diagnostics) was also done through out-licensing and refocusing our R&D activities towards shorter term pharma and surgical projects. In 2011 we transferred the commercial rights on our Mexican product portfolio to a local distributor and cut unsustainable fixed costs, but we regained direct access to the market in 2015.

From a financial standpoint, the rescheduling of debt with our creditors was a critical exercise in the daily routine until in 2013 we reached an agreement with our banks that improved our financial position. After having executed this complex turnaround we were able to attract an investment from the PE firm 21 Investimenti in 2015 that also allowed us to end the litigation between shareholders that started in 2010 through the buyout of a minority shareholding.

Now that this turnaround and recapitalization has been completed, what strategies have you implemented to drive growth going forward?

Firstly we aim at driving organic growth across our two business lines (pharma and medtech) in Italy and abroad through our subsidiaries in Mexico and Romania and our distribution partners. In 2015 our export sales grew by 40 percent and this year’s objective is to continue such a trend. After significant investments, medtech represents a clear growth opportunity going forward. In 2015 we achieved a 16 percent growth rate in this business line, doubling our export sales, but we expect to do much better this year.

In 2015 we also in-licensed Iluvien, an innovative pharmaceutical treatment for diabetic macular edema from Alimera Sciences, and are currently working on obtaining reimbursement in Italy. If successful in this effort, SIFI will enter the retinal pharma market, a major milestone for our

company’s competitive position in Italy.

Our longer term goal is to become a leader in the European ophthalmic market by 2020. Our key growth assets are our bestselling drugs in Italy and our advanced technology intraocular lenses. Moreover we are actively looking at M&A opportunities in the major European markets (aside from Italy) leveraging on the capital injection from 21 Investimenti to accelerate our organic growth.

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