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## Regional Initiatives

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### Italian biotech too reliant on big pharma

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#### Academics in Italy need to launch more startups before its biotech sector can expand any further.

The Rome-based Congregation of the Sons of the Immaculate Conception (CSIC), a religious group that owns a network of hospitals and that markets dermatological products, bought Pfizer's Italian R&D center in Nerviano, near Milan, for an undisclosed amount on May 14. Although this deal will create one of the largest commercial biotech research centers in Italy, the country's biotech sector relies too much on pharma spinouts for growth. Italian biotech will stall unless universities and public research institutes spin out more biotech companies.

The newly created entity, called Nerviano Medical Science (NMS), is now the biggest private oncology center in Europe, with over 700 scientists. Endowed by Pfizer with enough money to stay alive for a couple of years, the NMS will conduct internal programs and provide contract research to third parties. In particular, the new company will continue R&D activities focused on kinase inhibitors, with a plan to license any resulting potential products to biotech and pharma companies. As part of the deal, Pfizer retains preemption rights on the center's product pipeline.

Francesco Sinigaglia, CEO of BioXcell, says that quality of biotech companies is more important than quantity.

The creation of NMS is typical of the way most Italian biotech companies have been created in the past. For example, seven out of the twelve companies in the Lombardy region—which is home to Italy's biggest biotech cluster, housing nearly half of the country's biotech companies and employing 72% of its workforce<sup>1</sup> (#B1)—were created as spin-offs or management buyouts from multinational corporations. Biosearch and Novuspharma come from Hoechst Marion Roussel (now Aventis) and Boehringer Mannheim, respectively. And Newron Pharmaceuticals and BioXcell were originally Pharmacia and Roche's Italian subsidiaries.

As a result, Italian biotech companies have strengths, such as advanced pipelines and experienced management, which make them competitive internationally. "We have fewer companies than Germany but more products in clinical trials," says Leonardo Vingiani, director of Assobiotech, the Italian association of biotech industries, in Milan. "Public support in Germany brought into being [many] uncompetitive companies, while the [business] environment here is so hostile that selection is darwinian." Francesco Sinigaglia, CEO of BioXcell, agrees: "Quality is more important than quantity."

Italy's historical dependence on big pharma creating quality biotech startups is unsustainable, however. Simply put, there are too few remaining pharma R&D centers to ensure that Italy's biotech sector can continue to grow through such spinouts. Instead, the sector hinges on the creation of startups from research institutes or universities.

But because of financing shortages and a lack of entrepreneurs, startups from academia remain few and far between. "Small companies need the management experience of VC [venture capital]," says Marina Del Bue, general manager of molecular medicine company MolMed, which is located in the San Raffaele Biomedical Science Park. "But Italian VC is almost nonexistent and international funds go only to mature companies."

One ray of hope stems from the creation of GenExtra, an investment holding company that was initiated in November 2003 by the Milan-based European Institute of Oncology (EIO). A group of leading Italian entrepreneurs invested €30 (\$36.5) million in the holding's capital to finance biotech startups. "The holding has an aggressive temperament and plans to start three or four companies" in the near future, says Pier Giuseppe Pelicci, research head at EIO. GenExtra announced its first investment when it launched: €6 (\$7.3) million into Congenia, a biotech firm in Milan that is developing new treatments for diseases linked to aging. Another similar initiative, called Eporgen, was launched in July with €5 (\$6) million to provide seed funding to four or five biotech startups in the Bioindustry Park Canavese, near Turin.

Early stage funding, however, is still scarce in Italy. For example, Rome-based Lay Line Genomics, a neurodegenerative disease firm, is still waiting for public funds that it applied for when it spun out of the International School for Advanced Studies in Trieste in 2000. Luckily, the company remains in operations thanks to financial injections from its own founders and some funds from the Lazio regional government.

Small-scale efforts like the allocation of €26 (\$32) million to develop the Lombardy biotech cluster by the region's president Roberto Formigoni and Italy's national research minister Letizia Moratti in March 2004, may not be enough to shake up the system. Luca Benatti, CEO of Newron Pharmaceuticals in Milan, believes that the lack of VCs in Italy is a reflection of Italy's historical lack of trust in technology and scientific research. Unless the slow Italian funding system is made more efficient and the country's legal framework is amended to perfect rules on intellectual property rights<sup>2</sup> (#B2) and to allow researchers more mobility between public institutions and private companies, investors will continue to invest in other sectors.

#### Web links

San Raffaele Biomedical Science Park

<http://www.spr.it/> (<http://www.spr.it/>)

Assobiotech

<http://www.assobiotech.it/> (<http://www.assobiotech.it/>)

GenExtra

<http://www.genextra.it/> (<http://www.genextra.it/>)

Bioindustry Park Canavese

<http://www.bioindustrypark.com/> (<http://www.bioindustrypark.com/>)

#### References

- 1. Chiesa, V. Il Cluster biotecnologico Lombardo. (Politecnico di Milano, Milan, 2004).
- 2. Meldolesi, A. Bungled law threatens Italian tech transfer. *Nat. Biotechnol.* **19**,996–997 (2001). | [Article \(http://dx.doi.org/10.1038/nbt1101-996\)](http://dx.doi.org/10.1038/nbt1101-996) | [ISI \(http://links.isiglobalnet2.com/gateway/Gateway.cgi?&GWVersion=2&SrcAuth=Nature&SrcApp=Nature&DestLinkType=FullRecord&KeyUT=000172002600003&DestApp=WOS\\_CPL\)](http://links.isiglobalnet2.com/gateway/Gateway.cgi?&GWVersion=2&SrcAuth=Nature&SrcApp=Nature&DestLinkType=FullRecord&KeyUT=000172002600003&DestApp=WOS_CPL) | [ChemPort \(http://chemport.cas.org/cgi-bin/sdcgi?APP=ftslink&action=reflink&origin=np&version=1.0&coi=1:CAS:528:DC%2BD3Mxot1elbt4%3D&pissn={printIssn}&year=&md5=6af7a67df4266e4f3f9e250b30586fe1\)](http://chemport.cas.org/cgi-bin/sdcgi?APP=ftslink&action=reflink&origin=np&version=1.0&coi=1:CAS:528:DC%2BD3Mxot1elbt4%3D&pissn={printIssn}&year=&md5=6af7a67df4266e4f3f9e250b30586fe1) |