

Making a success

2015 was a stellar year for Hovione. Roger Viney, senior business director, off-patent API, outlines some of the key achievements leading to the company's success

What were the highs for Hovione in 2015?

2015 has been a record year for the company. Our CAGR over the last five years has been 11% and this shows no signs of slowing. Our financial year does not finish until March 2016, however we are on track to record growth compared with the previous year of 15%. Our business is split roughly 50/50 between contract manufacturing services and off-patent APIs and both business segments are growing at a similar rate.

Hovione recently acquired a formulation plant. How will this affect business going forward? What gains do you envisage?

We bought a formulation plant adjacent to our existing manufacturing facilities in Portugal. It will be part of our contract manufacturing business allowing Hovione to offer customers an integrated service from API to formulated dose that expedites the development process. This is particularly attuned with the need for speed in breakthrough therapies. The facility will be able to provide oral solid dosages and precision capsule filling. It will be capable of handling potent products up to Safebridge category 3a. It will focus on development projects of 0.5 to 4 million tablets or capsules per year.

How do you see the pharma sector at the moment – its strengths and weaknesses?

Medicine use is forecast to grow by a quarter in the next five years with half of that growth being in the emerging economies. The FDA approved 41 new drugs in 2014 of which over a third were first-in-class and 41% are used to treat rare or orphan diseases, so innovation is alive and well. These new drugs will one day become generic giving a further boost to the industry. It is also important to note that of the new approvals 75% were small molecules so chemical synthesis still has a bright future. The global economic situation has improved and the pharma industry is well funded. Most innovation is coming from smaller companies and they have ready access to capital. This should mean a continuing flow of new drugs at least in the short term. There have been a large number of mergers driven by large US companies having significant profits held abroad and by the positive response of the stock market to these deals, particularly in the generic sector. The peak of this activity may now have passed and the question will be if these mergers ultimately meet the industry's need for both innovation and affordable medicines.

In the API manufacturing industry it is clear that the quality suppliers are experiencing favourable market conditions. The outsourcing of manufacturing has continued and many new drugs are being developed by small companies who have no intention of making their own APIs. In the generic API sector there has been a "flight to quality" caused by increased regulatory scrutiny and problems with some Indian and Chinese suppliers that have forced pharma companies to reassess their approach to risk. This has led to many API manufacturers struggling to keep up with demand. In the short term this tightness in supply is likely to continue but there have been numerous announcements of new capacity being installed.



Added assets: Hovione's new formulation facility will be able to provide oral solid dosages and precision capsule filling
Photo Hovione



What do you see as the key focal points for 2016 for both Hovione and the wider pharma industry?

The biggest issue for all of us is the increased antibiotic resistance that threatens to take our ability to fight infections back to the 1940s. There are initiatives such as the GAIN Act in the US that are designed to promote the development of new anti-microbial drugs. The whole industry will have to pull together to ensure the antibiotic void is filled as fast as possible.

Hovione is a privately-owned company and has the advantage of having a long term and consistent strategy which is to focus on providing differentiated products and services to the pharma industry. We have already announced that in 2016 we will make significant investments in our facilities in the US and Portugal. This not only includes the addition of contract manufacturing of drug product as mentioned above, but also an increase in the capacity and capability of our API and particle engineering

contract manufacturing businesses. In our off-patent API business we have started a project to manufacture our actives in at least two geographically separate sites within the group thus giving our customers increased security of supply. Finally, we are using our unrivalled knowledge of particle engineering to grow our range of off-patent APIs with bespoke particle properties for inhalation applications. The new products include glycopyrrolate, fluticasone furoate, vilanterol, indacaterol and aclidinium.

Growth spurt: Hovione has already announced that in 2016 it will make significant investments in its facilities in the US and Portugal. Photo: Hovione

