September 9, 2016

Dear clients and colleagues,

Every election cycle rekindles private sector complaints about excessive Washington regulation. This year is no different, even with a businessman as one of the presidential candidates. Tensions between innovation and regulation and entrepreneurs and regulators have been worsening. Entrepreneurs are getting bolder. Regulators are getting tougher. Nowhere is this more evident and cash sensitive than in the health care sector.

Consider these: Once a $9 billion blood-testing startup, Theranos voided all 2014 and 2015 tests on its Edison blood-testing machines, leaving thousands of patients with unreliable results which possibly resulted in incorrect treatments. Another start-up, Zenefits, a health benefits broker valued at $4.5 billion, was found to have used in-house software to enable salespeople to qualify for licenses in less time than legally required in many states.

As with many current issues, the public is divided on the value of regulation. In a recent poll conducted for STAT and the Harvard School of Public Health, 60 percent of Americans opposed loosening government safety standards to permit faster drug approvals by the Food and Drug Administration (FDA). A similar percentage wanted the FDA to conduct its own assessments of new drugs and devices rather than relying on a foreign government agency that may have already approved the product.

For drugs, it all begins at the Active Pharmaceutical Ingredient (API) manufacturing level. An industry that is highly sensitive to regulation, the slightest product recall or launch delay may lead to significant present and future cash flow changes for their large pharma clients. Needless to say, the regulatory pedigree of an API manufacturer is its brand, a track record that carries an important weight when trying to obtain the production rights to large, high profile drugs.

Global demand for the active pharmaceutical ingredient market was valued at USD $148.22 billion in 2015, it is expected to reach USD $213.84 billion in 2021 and is anticipated to grow at a CAGR of 6.3% between 2016 and 2021. The increasing prevalence of diabetes, neurological disorders, and other chronic diseases are the major factors driving growth in the global API market.

To reduce manufacturing and infrastructure costs, pharmaceutical companies have increased outsourcing the manufacture of active pharmaceutical ingredients resulting in one of the key drivers to the growth in the API market. On average, pharmaceutical companies outsource 60% of their non-marketing activities, a rate which is anticipated to rise to the mid 70's in the near future. With increased outsourcing and increased regulation, market dynamics for industry leaders are expected to remain favorable in a strong secular trend.

This week, we profile Cambrex Corporation (NYSE: CBM), an API manufacturer based in East Rutherford, New Jersey. In the last couple of years, Cambrex has successfully gained a foothold in the leading group of manufacturers capable of producing large blockbuster drugs while holding the highest regulatory standards.

Business Description

Leading active pharmaceutical ingredients (API) manufacturer

6 facilities throughout the US, Germany, Sweden, Italy and Estonia

3 categories: 64% Innovators, 22% generics and 14% controlled substance

- Focused on large drugs discovered by pharma companies, contractual relationship starting at Ph1-2 levels where Cambrex takes over all drug production and cGMP regulatory activity, plant and NDA filings
- Produces 30-35 products under supplier agreements, in-house drug delivery and controlled substances specialties
- Largest clients: Gilead, 34% of sales (Gilead antivirals $8B in sales), Celgene (Revlemid), Biogen (Tecfidera)
- Volume dependent not drug price related contracts
- Top competitors: BASF, Evonik, Lonza

Investment Theme – Outsourcing

Secular trend by pharma is to not own production facilities due to increased complexity in production and regulations. The trend is strong in US and just starting in Europe.

Target Pharma Market Size: API $148B

- Innovator Drugs: API $10B, growing 8%, 5% on prescriptions volumes, 3% on increased outsourcing
- Outsourcing penetration rates: downstream processing 52%, fill and finish 80%, cell banking 75%, assay development 65%, formulation 60% and drug development 50%
- 2016 growth guidance 14%

- Generic Drugs: API Total Addressable Markets (TAM) is $6B growing 5%
- Generic outsourcing above 80%
- Growing in Brazil, Japan, eastern Europe
- 2016 growth guidance 4%

- Controlled substances: API TAM $300M, controlled by DEA
- Growth guidance 5%

Growth Strategy - Product

SWOT

Strengths

- Ability to scale. Build and fill expertise, portfolio large enough for strategic new facility ramp ups
- Track record. Clients pay premium for performing facilities
- Limited API manufacturing facilities in US
- Large scale facilities attract larger products
- High level of FDA violations at OUS facilities

Weaknesses
- Product concentration
- Mid-market supplier
- Sold India division with $15M restructure charge

Opportunities
- 2015 $60M increased capex in Charles City completed, $50M in revenue capacity
- 14 active large late-stage projects
- 13 API in generics in development, 10 annual
- 1 controlled substance in development
- Further expansions vs new builds

Threats
- New HCV market entrants
- Customer concentration

Management – Insiders own 1.5%
- President 2008. Average tenure 18.5 vs 5.7 years for peers, compensations in line $2.5M
- 7 independents on a board of directors of 9

ESG Score – 3.0
- ESG Report – 0.5 (description), Environment – 0.5, Social – 0.5, Governance – 1
- Awards – 0.5 (ChemAwards for responsibility)

Capital Allocation:
- $200M capacity capex spend since 2009
- Next expansion in 2017 $50M, maintenance $25M

Have a great weekend.

The Global Alpha team