Small molecules: 2020 vision

Expert insights from the small molecule company

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2019 has been a truly transformational year and one of the most eventful in our 39-year history. We are excited that Cambrex can now offer the capabilities and services as a true end-to-end CDMO across the whole product lifecycle.

More opportunities

Following the successful integration of Halo Pharma and Avista Pharma Solutions over the last 12 months, we can now offer expertise across drug substance, drug product and analytical services. These advances have significantly increased our customer base and the interest in the services we can now offer from preclinical development through to commercial launch.

This extensive broadening of our toolkit is part of our ongoing mission to become the world’s leading small molecule CDMO. Now, in partnership with Permira — a global private equity firm — Chairman of the Board of Directors Wayne Hewett believes:

“Being a company with a strong brand and great reputation in the pharmaceutical industry with world-class expertise, we remain fully focused on our mission to grow our leadership position in the industry and continue to be regarded as the small molecule company.”

More insights

The industry trend of outsourcing to CDMOs continues. With more services, capabilities, facilities and employees than ever before, our experts have contributed more articles to our biggest eBook yet.

Enjoy Part 1 of our latest Cambrex expert insights.
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Market & Outsourcing Trends

Michele Cioffi  
Raw Materials and Intermediates  
Warehouse Operator

Malika Mohamed  
Packaging Specialist

Experts you’ll enjoy working with
The preclinical and clinical pipeline has shifted away from being dominated by the large multinational pharmaceutical companies, with the majority of therapies now coming from smaller and virtual biotech companies. This trend seems to align with the new focus on smaller patient populations that require niche volumes as well as faster market access and penetration.

Due to the market conditions of these new therapies, small biotech companies now find themselves taking on more of the clinical development, with some even having the option to consider launching a product on their own. This new model moves away from the historical practice, whereby small and virtual companies lacked the resource and capabilities to support late-stage clinical trials and would typically seek to out-license or divest the product soon after completing Phase II trials. The financial requirements have been somewhat eased, largely driven by the reduction in required patient numbers, leading to more affordable clinical trials.

With the rise of orphan therapies, the path to commercialization is also simplified, as fewer patients only require a streamlined sales team. These factors allow a project to be kept in-house for a longer period of time compared with legacy drugs that required much larger sales teams to call on thousands of primary care physicians.

Whilst these companies wrestle with the increased requirements of late-phase clinical trials or planning for commercial launch, they often lack the resources and experience to manage large numbers of suppliers and outsourcing partners, so need to rely upon a smaller number of CDMOs to provide support and expertise to get a product to market. CDMOs, therefore, need to be prepared for the more niche volume requirement of API and drug product demand that are typical for these products, and to be flexible in terms of forecast fluctuations and speed to meet these requirements.

CDMOs, which can cater for a wide range of customers, can benefit from this changing landscape. There will always be a place for transactional services such as standalone manufacturing and development; however, being in a position to offer integrated services to assist in the whole lifecycle of a drug from development to commercialization is crucial to forge partnerships with the growing number of smaller and virtual companies.

For CDMOs looking to support the development of new small molecule drugs, it is important to recognize the changing nature and profile of the customers and the services they require.
But, given the geography, politics, population, regulation and funding that are unique to the United States, Dr Kevin Robinson looked west to the Land of the Free to find out how the pharmaceutical industry is faring amongst all the milk and honey.

The US pharma and biotech market remains the biggest in the world. The hub where marketing is based in Cambridge/Boston is a particular hot spot with some incredible biotech drug development. New York and Raleigh-Durham also remain major hubs on the east coast for pharma and life sciences. San Francisco and San Diego on the West Coast are equally active, particularly for med device and biotech.

As part of its global manufacturing network, Cambrex has a number of API manufacturing sites in the US. "What is noticeable at the national level in the US is that there is increasing consolidation between contract development and manufacturing service providers," says Brian Swierenga, Vice President, Operations and Site Director, Cambrex High Point, "especially those supporting the clinical phases of development."

"This is true of both US-based companies looking to build market share, but also overseas companies looking for a stronger US presence. Previously, whereas a small CMO could build a business around a specific offering such as Phase I GMP supply, solid-state property characterisation and control, or analytical testing, larger integrated CDMOs are consolidating these services. These integrated service providers offer customers a simpler supply chain and a more coherent development package."

"Additionally," he adds, "we’ve seen a rise in interest from pharmaceutical companies looking to harness breakthrough technologies that have the potential to reduce costs and increase the speed to market for new molecular entities. In the post-blockbuster era, which the industry now faces, companies are dealing with development portfolios of low-dose, high-potency compounds with smaller potential patient populations. This combination of lower manufacturing costs and niche molecules has prompted significant interest and investment in new chemical manufacturing technologies such as continuous processing."

According to one of Stephen Sondheim’s most well-known lyrics, “I like to be in America! OK by me in America!”
Small molecules hold sway at DCAT week

Annual event showcases chemistry’s strength despite the growth of biologics.

The Drug, Chemical, & Associated Technologies Association (DCAT) Week, an annual meeting for the pharmaceutical services sector and the drug companies it serves, has dispersed to several New York City locations now that its traditional home, the Waldorf Astoria New York, is under renovation. But the bustle of conference talks and private meetings culminating in a black-tie dinner on March 21 has lost none of its intensity, nor its focus.

The same might be said for the sector, which in recent years has seen contract development and manufacturing organizations (CDMOs) add nonchemistry services such as biologics and final-dose formulation to their traditional business of synthesizing active pharmaceutical ingredients (APIs). Investments announced at DCAT Week make clear that small molecule drug production is still central.

Cambrex epitomizes the expanding CDMO. The US company recently acquired Avista Pharma Solutions, an early-stage drug development firm, and Halo Pharma, a finished-dose drug contractor, for almost $700 million combined. But Shawn Cavanagh, Cambrex’s President and Chief Operating Officer, says the company remains a small molecule stalwart. “We’ve integrated service offerings across the small molecule platform,” he said at a March 18 forum that launched the event.

The Swiss giant Lonza is also investing heavily in chemistry. It’s two years into a three-year, $100 million program centered on expanding highly potent oncology drug production, according to Lee Newton, head of API development and manufacturing. “There is a growing demand for high-containment facilities for the production of highly potent APIs,” he said. Seques, the contract services division of Novacap, is targeting oncology with a $30 million investment in highly potent API production near Paris as a client advances a compound to Phase III clinical trials.

And the Swiss CDMO Cerbios said it is investing $5.5 million in highly potent API production. It’s also finishing up a $2.5 million investment in a suite where it will put together antibody-drug conjugates.

Other firms at DCAT announced investments in producing and packaging biologic drugs. Lonza itself is quite active in biologics, but Newton stated his allegiance to the chemistry side of the business. “Small molecules have never really gone out of fashion,” he said.

About the author
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Contributor
Shawn Cavanagh, President and Chief Operating Officer, Cambrex

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Title: Small molecules hold sway at DCAT week
Date: March 25, 2019
With the acquisitions, Cambrex has created the opportunity to broaden the company’s service offering in its continued mission to become the leading small molecule company.

The acquisitions significantly increase the customer base and funnel of projects, allowing Cambrex to offer an integrated service offering for small molecules from preclinical development through to commercial launch.

The small molecule pharmaceutical market continues to grow at the fastest rate seen in more than a decade, with a robust funding environment for early-stage clinical programs as well as an increasing trend for pharmaceutical customers to outsource more of their small molecule requirements. Halo Pharma has added drug development and drug product manufacturing capabilities, while Avista Pharma Solutions brought early-stage development and discovery, standalone analytical services, solid-state sciences and microbiology testing to our portfolio of services, and we have structured the business into four main business units accordingly: drug substance, drug product, early-stage development and testing and generic APIs.

As the CDMO space becomes increasingly consolidated, what is your value proposition to the industry?

The company’s global manufacturing offering now stretches from milligram scale through to multi-ton supply, as well as integrated services that can support a project from discovery — through preclinical development and clinical trials and on to commercial launch. This offering supports customers involved in all types of pharmaceutical products, ranging from niche or orphan drugs, to global blockbusters, in both patent-protected branded and generic medicines.

What will be Cambrex’s key objectives for 2019?

The company is focused on delivering the integration of the recently acquired drug product and early-stage development and testing businesses with the existing drug substance manufacturing capability, which has added over 800 employees and six new facilities to the Cambrex business.

About the author

Steven Klosk, President and Chief Executive Officer, Cambrex

First published: Global Business Report
Title: United States Biopharmaceuticals 2019
Date: April 24, 2019
Aging populations and an improving quality of life are still driving demand for pharmaceuticals on a macro level, attendees say. Trends the pharma industry, meanwhile, are driving business to contract manufacturers and ingredients suppliers.

Foremost among those trends is the steady rise of small pharmaceutical companies. “Most launches come out of small companies,” notes Garrett Dilley, Senior Director/Global Commercial with Johnson Matthey. Over half of new drugs are now developed by small pharma, up from about a third in 2011, according to IQVia (Durham, North Carolina), a consultancy. This increases demand for contract manufacturing services.

“A lot of these companies are small start-ups,” says Elliot Berger, Vice President Global Marketing with Catalent (Somerset, New Jersey), a pharma services provider. “They don’t have formulation or manufacturing expertise, and usually don’t want to invest in a physical asset until late in the development process, if ever.”

Contract manufacturing is core to the small-pharma business model, CPhI attendees say. This has created growing demand for ‘end-to-end’ services, in which a contract manufacturer gets involved in early-stage development, clinical trials, and even commercial-scale manufacturing. The rise in end-to-end services is “driven by small-to-mid-size pharma companies,” says Alex Maw, Senior Director, Marketing and Communications with Cambrex. The company recently acquired capability to get involved in early-stage drug development and is seeing more demand for commercial contract manufacturing, as well. The latter is driven by specialized drugs with small target markets.

“The quantities are small... the market is moving to smaller-scale manufacturing because of these drugs,” Maw says.

“Overall volumes are down,” says Paul Quigley, head of drug substances with Arcinova (Alnwick, UK), a contract manufacturer. “Our clients are looking for small quantities.” Arcinova has grown significantly — the company was founded in 2014 and now has about 150 employees — chiefly by working with small pharma companies.

Such specialized drugs are part of a trend toward ‘personalized medicine,’ which is underscoring an increase in complexity for new pharma products. These products target smaller markets, often using genetic markers. Suppliers of ingredients and contract manufacturing services are looking to add these capabilities. Evonik, for example, recently acquired Transfera Bioscience, a company specializing in lipid nanoparticle formulation. “The technology is a way to formulate a large molecule into a system that targets a specific genetic cluster,” says Jeff Smith, Vice President/Healthcare Sales and Services with Evonik.

Meanwhile, manufacturing for many ingredients continues to move back to the US and Europe from Asia. “There’s definitely reshoring,” Smith says. “For advanced intermediates and active ingredients, companies are moving back to the US and Europe due to the risk of a supplier getting shut down in Asia.” This can be due to audits by the US Food and Drug Administration (FDA; Washington), which monitors facilities globally if they supply the US market. It can also be for...
environmental problems, as China, in particular, continues to level-up enforcement of environmental rules. “Many facilities in Asia don’t properly handle solvents or waste products,” Smith says.

Costs also play a role, as both labor costs and regulatory compliance costs are rising in China and India. For companies based in the US and Europe, the cost advantage of Asia can now easily be outweighed by other factors. “When the cost difference starts to close, the other issues become more important,” says Philip Chalabi, General Manager with Umicore.

Looking to the future, artificial intelligence (AI) and machine learning are playing a bigger role in both developing new drugs and optimizing manufacturing processes. “It’s still in its infancy,” Dilley says. “But we see the potential.” Early-stage pharma companies are often using AI algorithms to identify molecules for particular therapies — some even start as AI firms rather than pharma firms — and manufacturers are putting big data to use moving from patch processes to continuous processes. “You can use AI to optimize your system,” Quigley says. “It ties in with continuous processing.”

About the author

Alex Maw,
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Title: CPhI North America: Pharma contract manufacturers look to growth
Date: May 2, 2019
Pharmaceutical services firms attending the CPhI North America trade show in Chicago earlier this month were virtually unanimous in reporting another year of strong growth in a business that has seen no direction other than up for nearly a decade. Investment continues apace, as do acquisitions, with many firms claiming their manufacturing assets are at or near full capacity.

Tied as it is to the drug industry, the sector has long defied traditional economic cycles. Contract manufacturers of active pharmaceutical ingredients (APIs) have also added services, developed expertise in complex chemistry, and generally taken risks to grow businesses in the direction required by customers developing the drugs of the future.

Results this year indicate that many of these risks have paid off. And ongoing investments hint at another round of risk-taking on new technologies and service models.

The small molecule specialist Cambrex is also putting recent acquisitions together. The company brought in early-stage API development when it bought PharmaCore in 2016 and added early-stage API capabilities and sites in the US and Scotland when it acquired Avista Pharma Solutions last year. It also bought Halo Pharma, a finished-drug producer, for $425 million last year. Cambrex is now better positioned to address the changing needs of innovative drug companies, according to Alex Maw, Senior Director, Marketing and Communications.

Meanwhile, Cambrex continues to invest in large-scale API production. It completed an expansion of its high-potency API plant in Charles City, Iowa, last year. The company is now ramping up continuous manufacturing capabilities at its Highpoint, North Carolina, facility — the former PharmaCore — and its factory in Karlskoga, Sweden.

“To make a long story short, we are excited about what we’ve done over the last six months,” Maw says. “Now it’s all about delivering.”

In the drug services industry, growth has no end in sight

Transformative investments, and capacity expansions abound at CPhI North America.
Secondly, the clinical pipeline is a more homogenous mix of big pharma innovators with small and virtual pharma companies. Alex Maw, Senior Director, Marketing and Communications, Cambrex, reports.

Despite the plethora of new molecule entities, the industry is as reliant as ever on small molecules — with its resurgent clinical pipeline and the highest number of FDA approvals for decades. However, the shifting focus of drugs that are launched for the benefit of hundreds of millions of patients to smaller patient subgroups has led to a need for manufacturing assets to cater for smaller volumes (and not to produce hundreds of metric tons of API annually).

With this change, the nature of the sponsoring company has changed too; from around 50 years ago until very recently, most small molecules in the clinical pipeline were being developed by the top 30 pharmaceutical companies. Now, most molecules are in the hands of small and virtual pharma companies, many of which are backed by venture capital or private equity funding.

For CDMOs looking to support the development of new small molecule drugs, it is important to recognise the changing profile of the customer base and the services they require. Historically, smaller biotech companies lacked the expertise and investment to support late-stage clinical trials and their focus would be to outlicence or divest a product soon after successfully completing Phase II trials.

The product would then be licenced by a larger pharmaceutical company with the resources and clinical know-how to conduct the expensive and time-intensive Phase III trials, as well as co-ordinating production to ensure a successful product launch.

Recently, the rise in orphan drugs aimed at targeted patient populations has resulted in more of the development now being taken on by these smaller companies. The reduced clinical burden and expense of testing their therapies on a reduced subset of patients — rather than conducting several trials in multiple indications as well as co-ordinating hundreds if not thousands of patients — has made the possibility of advancing the product to commercial launch a viable prospect.

Unlike large pharmaceutical companies, smaller companies typically have little or no manufacturing capabilities and are therefore wholly reliant on their CDMO partners; they typically outsource most of their drug substance and drug product needs. With limited internal resources to manage suppliers, this usually means working with fully integrated CDMOs that can offer a broad range of services and expertise throughout early-stage development as well as manufacturing.

CDMOs, therefore, need to offer a broad range of manufacturing volumes, but also need to be prepared for the more niche volume requirements of API and drug product that are typical for these applications. Additionally, they should be flexible and able to respond to sudden changes in volumes owing to additional clinical trials or changes in market demand.

The pharmaceutical industry continues to evolve in two interesting ways: firstly, the development pipeline sees a variety of alternative treatment modalities advancing through it.

Small molecule CDMOs reacting to changing market demands
The focus on certain therapeutic areas such as oncology has fuelled the rise in the development of highly potent molecules. These too require lower overall volumes in terms of API demand... but also require manufacturing within dedicated, contained assets with experienced staff to undertake the safe handling and production.

This changing landscape offers opportunities for contract manufacturers. The broadening of the customer base means that those CDMOs in a position to offer integrated solutions during the lifecycle of a drug can benefit from strong partnerships with the growing number of new companies who are taking their products through the clinical pipeline and to market.

About the author

Alex Maw,
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Title: Small molecule CDMOs reacting to changing market demands
Date: May 30, 2019
These are among recent investment trends by contract development and manufacturing organizations/contract manufacturing organizations (CDMOs/CMOs) of intermediates and small molecule active pharmaceutical ingredients (APIs). DCAT Value Chain Insights takes an inside look.

Some key investments, announced in 2019 to date and late 2018, are highlighted below.

Cambrex

Earlier this year (April 2019), Cambrex completed the construction of a $24 million highly potent API (HPAPI) manufacturing facility at its site in Charles City, Iowa. The 6,000 sq. ft. facility was scheduled to commence customer projects in May 2019. In addition, in 2018, the company announced the expansion of its clinical supply and process-development capacity with the purchase of a new 45,000 sq. ft. building in High Point, North Carolina, to expand its operations there.

Cambrex also opened a new 120 sq. m. quality control (QC) laboratory at its site in Paullo, Milan, Italy. The laboratory expands on the current QC facilities that analyze and test its portfolio of APIs during development and manufacturing. The QC laboratory is now fully operational, having been authorized by the Agenzia Italiana Del Farmaco (AIFA). Earlier this month (June 2019), the company completed a new 600 sq. m. facility at its site in Karlskoga, Sweden, which incorporates new laboratories for process and analytical development.

Earlier this year (January 2019), Cambrex completed its acquisition of Avista Pharma Solutions, a Durham, North Carolina-headquartered contract testing, development, and manufacturing organization, for approximately $252 million. Cambrex had announced the acquisition in late November 2018. With this acquisition, Cambrex gains capabilities for early-stage small molecule development and testing services. Avista offers a suite of services ranging from API and drug-product development and cGMP manufacturing to stand-alone analytical, microbiology testing and solid-state sciences. The acquisition of Avista supports Cambrex as a fully integrated small molecule contract development and manufacturing organization across the entire drug lifecycle. Avista operates four facilities located in the following: Durham, North Carolina, Longmont, Colorado; Agawam, Massachusetts; and Edinburgh, Scotland; in total comprising over 200,000 sq. ft. of space.

About the author

Steven Klosk, President and Chief Executive Officer, Cambrex

First published: DCAT Value Chain Insights
Title: What is trending: Fine chemicals
Date: June 5, 2019
As small molecules continue to dominate industry approvals, API manufacturing rises in importance

Small molecule drugs continue to dominate approvals by the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA)...

...despite commercial interest in biologics, which represent four of the five top-selling drugs globally in 2018, according to the GlobaData Pharma Intelligence Center Drugs Database.

NME approvals 2018

GlobalData’s recently published PharmSource report, CMO Scorecard: Outsourcing of NDA Approvals and CMO Performance, states that 64% of New Molecule Entity (NME) approvals in 2018 were small molecules.

The report further reveals that over the last decade, there has been an industry-wide decline in the proportion of Biologics License Approval (BLA) manufacturing outsourced, while biologic contract manufacturing overall has increased.

The relative decline can be attributed to the majority of biologic sponsors being large market capitalisation companies, which are less likely to outsource manufacture than small companies. This factor, as well as the high number of small molecule NME approvals, highlights the importance of small molecule API manufacture for CMOs.

As the demand for API contract manufacturing is continuously growing, contract manufacturing revenues of publicly traded dedicated CMOs with small molecule API manufacturing facilities continue to increase.

Figure 1 shows revenue band distribution across 41 dedicated contract and public CMOs with small molecule API manufacturing facilities with either FDA or EMA regulatory approval. The revenue bands show a fairly even distribution among bands, despite the increasing consolidation of the CMO industry in recent years.

According to experts in the GlobalData PharmSource Trend Report M&A in the Contract Manufacturing Industry: Implications and Outlook – 2018 Edition (December 2018), the current CMO marketplace is highly fragmented, and significant consolidation would be expected in the near future, especially of CMOs with revenue greater than $5 million per year.

Figure 1’s equal distribution among bands can also be explained by the fact that private company revenue estimates are not included and, as the majority of CMOs are small privately owned companies, the number of CMOs in the lower revenue ranges would be much larger had these been included in the analysis.

The top three companies by revenue, Lonza Group Ltd (Basel, Switzerland), Catalent Inc. (Somerset, NJ, US), and Apeloa (Jinhua, China), achieved revenue growth of 22%, 19% and 15%, respectively, from 2017 to 2018.

They are continuing to invest heavily in their API operations: for example, Lonza has invested $100 million in two major small molecule manufacturing projects based at its Visp, Switzerland site (B/POR, March 2019). The investment will fund two manufacturing lines at four cubic meter scale for highly potent active pharmaceutical ingredients (HPAPI), and small molecule manufacturing automation.
Likewise, Catalent has strengthened its small molecule API business unit through its $133-million acquisition of Juniper Pharmaceuticals (Boston, MA, US) and its plans to invest $5 million at the company’s Somerset, NJ, drug development Center of Excellence, where it will expand its OptiMelt hot melt extrusion capabilities.

Apeloa, a Chinese CMO, has seven commercial API/chemical facilities across several Chinese provinces, of which only one is approved by the FDA and EMA.

Smaller CMOs are also looking to invest and expand their API operations. For example, in January 2019, Cambrex Corp (East Rutherford, NJ, US) acquired the small molecule CMO Avista Pharma Solutions Inc. (Durham, NC, US), from Ampersand Capital Partners (Wellesley, MA, US) (B/POR, January 2019). Figure 2 shows the geographic distribution by headquarter location of 41 public CMOs with small molecule API manufacturing facilities.

Asia-Pacific is a significant geographic region which boasts several emerging countries in terms of API manufacturing. As seen in Figure 2, India has 15 public CMOs with small molecule API facilities as a result of its position as a low-cost supplier, providing low labour costs as well as plentiful raw material readily available to make API. However, GlobalData PharmSource previously reported the Indian CMO market may face challenges as the US government considers withdrawing the Generalised System of Preferences (GSP) from India, leading to tariffs on Indian exports to the US (E/MOR, March 2019). This may reduce the demand for outsourcing raw material procurement and manufacturing activities from CMOs in India.

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Date: May 15, 2019

About the author

Steven Klosk, President and Chief Executive Officer, Cambrex

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Title: As small molecules continue to dominate industry approvals, API manufacturing rises in importance
Date: June 5, 2019

Figure 1: Revenue band distribution across 41 dedicated contract and public CMOs with small molecule API manufacturing facilities

Figure 2: Geographic distribution by headquarters of 41 public dedicated contract CMOs with small molecule API manufacturing facilities

Despite the UK, France, and Germany being home to large economies, between them they do not have any public dedicated contract CMOs with small molecule API manufacturing facilities with revenue over $500 million.

In comparison, Switzerland, which is a much smaller economy and a smaller player within the Pharma world, has two >$500 million small molecule API CMOs, including the largest CMO, Lonza Group (Basel, Switzerland), as well as Siegfried Holding AG (Zofingen, Switzerland).
Cambrex provides pharmaceutical products, expertise and technologies that accelerate small molecule therapeutics into markets across the world. It currently employs 2,000 people at 13 locations across North America and Europe.

The company has a strong history of small molecule API manufacturing and a global network of development and manufacturing plants. In the past year, Cambrex acquired both Halo Pharma and Avista Pharma Services, diversifying the company’s offering to include formulation development and finished dose clinical and commercial manufacturing, as well as analytical development services.

Its team of experts offers an end-to-end partnership for the research, development and manufacture of small molecule at every stage of the lifecycle. From IND enabling through to generic, Cambrex offers classic chemistry, formulation and testing in addition to specialized technologies including: enzymatic biotransformations, high potency APIs, continuous processing, pediatric, bi-layer and fixed dose combination formulations, and has experts dedicated to solid-state science and material characterization.

Contract Pharma had the chance to sit down with Cambrex’s President and Chief Operating Officer, Shawn Cavanagh, to talk about how the company has integrated the new services and businesses into its existing operational structure, and the current nature of the small molecule market.

Contract Pharma (CP): What was the strategy behind the acquisitions of Halo and Avista?

Shawn Cavanagh (SC): The two companies offered the opportunity for Cambrex to broaden and diversify our service offering in what is our continued mission to become the leading small molecule company. The acquisitions significantly increased the customer base and funnel of projects, and we now look to partner with customers for projects across the whole lifecycle of small molecule drugs, from preclinical development through to commercial launch.

CP: How have these new services been integrated into Cambrex?

SC: The integration of Halo and Avista into Cambrex has allowed us to structure the business into three key offerings for innovator customers:

The drug substance offering incorporates the majority of the legacy Cambrex API business which includes the development and manufacturing of innovator APIs; the scale-up and technical transfer of projects and analytical development; and also includes specialist capabilities such as handling of controlled and highly potent substances, continuous flow chemistry, biocatalysis and solid-state science.

The drug product offering has expertise in formulation and development of conventional dosage forms including oral solids, liquids, creams, sterile and non-sterile ointments;
as well as specialist drug product capabilities including developing and manufacturing highly complex and difficult to produce formulations, products for pediatric indications, and controlled substances.

Finally, our extensive analytical capabilities support our drug substance and drug product projects but are also provided as stand-alone services. Analytical services include capabilities such as microbiology testing, cleanroom services, material characterization, method development and validation, compendial and release testing, as well as stability storage and testing.

Both of the new capabilities in drug product and analytical services complement our existing capabilities and expertise in contract manufacturing of APIs. The businesses were a natural fit, and have increased the opportunities for us to offer a wide range of services to new and existing customers.

**CP:** What demand are you seeing for the outsourcing of small molecules? Why strengthen in this space?

**SC:** As a company, Cambrex's history and expertise is very much in small molecules and as I mentioned, our long-term strategy is to be the leading small molecule CDMO partner with the ability to serve customers across the pharmaceutical industry, from small and virtual biotech to large pharma.

What we have seen from the market data available is that the small molecule pharmaceutical market continues to grow at the fastest rate seen in more than a decade, and there is a healthy clinical pipeline as well as high numbers of FDA approvals for small molecules. Additionally, there is a robust funding environment for early-stage clinical programs available, as well as an increasing trend for pharmaceutical customers to outsource more of their small molecule requirements.

These factors were the basis to make the acquisitions and expand Cambrex into new markets, while maintaining our focus on our expertise of small molecule therapeutics. Customers will now have the choice of selecting the appropriate service or services to fit their needs. For some customers, this may be for just one aspect, but for those companies who may not have the time or resource to manage multiple service providers, they also have the option of partnering with Cambrex as its sole CDMO supplier for both drug substance and drug product. The services we now offer mean that we can work with a drug throughout its entire lifecycle, from early preclinical development to late clinical phase and commercial launch.

**CP:** What challenges does the industry face, and how is Cambrex looking to address these?

**SC:** As is always the case, the pharmaceutical industry continues to evolve, and although we see a healthy clinical pipeline and a high number of FDA approvals for small molecules, the nature of these molecules has changed. Commercial products are not just the blockbusters that require large volume assets producing hundreds of metric tons of API annually. Today’s drug substance requirements for a drug may be no larger than a metric ton in order to facilitate an orphan drug launch, or require contained manufacturing due to their high potency. As a CDMO, we must recognize these changing needs and adapt accordingly to be able to offer the most suitable solutions in terms of capacity, expertise and technologies to customers. This has been the principle behind our investment strategy over the last five years, ensuring that as a company we not only have the capacity available for new projects, but the right capacity to ensure that projects can be carried out efficiently and economically throughout their development and lifecycle.

As well as the projects, customers change too. Alongside the multinational pharmaceutical companies are the small and virtual companies that are investing greater resources and progressing products further down the clinical pipeline. The needs of each customer are different, but some common themes exist in that they are looking to reduce the burden of managing complex supply chains and work with a smaller number of strategic outsourcing partners and suppliers. This has led to consolidation in the service sector, and again, has been pivotal in the strategic decisions Cambrex has taken with our investment in technologies, manufacturing capabilities and our recent acquisitions to broaden our service offering.

**CP:** What is next for Cambrex?

**SC:** The two acquisitions added over 800 employees and six new facilities to the company, so short-term, we are focused on ensuring the values of the companies and the expertise we have across the businesses are aligned so that we can continue to deliver on the promise we have to our customers.

Aside to the acquisitions, we see no let-up in the momentum of our existing drug substance business. At our Charles City, Iowa site, we have recently opened a new $24 million, 4,500 sq. ft. facility for the manufacture of highly potent APIs, with an occupational exposure limit (OEL) down to 0.1 μg/m³.

We began this project in 2017 to accommodate the needs of the growing pipeline of drugs which require specialist manufacturing capabilities. The new facility in Charles City, Iowa has the flexibility to support all phases of development as well as all scales of drug substance manufacture across the full OEL high potency continuum.

Additionally, we have purchased a new 45,000 sq. ft. building in High Point, North Carolina, giving the site the flexibility to expand its clinical supply and process development capabilities. We are in the process of looking at the options and assessing the market demand so that we can continue with our strategy of providing best-in-class services to meet the needs of our global pharmaceutical, biotech and generic customers.

**About the author**

Shawn Cavanagh, President and Chief Operating Officer, Cambrex

**First published:** Contract Pharma  
**Title:** Catching up with Cambrex  
**Date:** June 13, 2019
Inside the trenches: End-to-end CDMOs/CMOs

What does it take to implement an end-to-end-business model, meaning a single CDMO/CMO providing development and manufacturing services for both active pharmaceutical ingredients (APIs) and drug products?

An inside view

To gain a better understanding of the implementation of the end-to-end service model in terms of sponsor relationships, project management, and supplier metrics, DCAT Value Chain Insights, gained the input of some end-to-end providers for an “inside-the-trenches” view.

Early-stage versus late-stage development

DCAT Value Chain Insights (VCI): From your experience, do you find that the use of the end-to-end service model is applied more frequently for early-stage development as opposed to late-stage development or commercial manufacture? Can you comment on the use of the end-to-end model across development stages?

Alex Maw (AM): The nature of the customer base for the CDMO industry has evolved and shifted away from being dominated by traditional Big Pharma companies, to the new paradigm, where the majority of new drugs in development are being developed by smaller and virtual companies. While Big Pharma companies were increasingly outsourcing more and more of their internal activities, there was always a captive component that was slow to supplant. However, with these smaller companies that often lack the necessary manufacturing assets to produce the material required for clinical or commercial supply, this dynamic has led to increased demand for outsourcing services among CDMOs. These smaller companies are often less resourced in terms of procurement teams, and this role is typically undertaken by the scientific or operational teams fulfilling multiple roles, and in some cases, it is even handled by the C-suite management or company founders. Consequently, the capacity to manage numerous suppliers across multiple parts of the supply chain is typically time-intensive and can lead to strains upon resources, and is one of the main drivers that the industry has benefited from in the birth of the ‘full-service’ CDMO.

It is still in the early days of this approach, but there have been some attempts to quantify the true cost benefits within the industry, and some recent studies are extremely bullish about the advantages. While the data are still being generated, in its simplest sense, the industry is increasingly recognizing that it is beneficial to all customers, whether big or small, to deal with just one supplier for all of its products and services as opposed to many.

Through the recent acquisitions of Halo Pharma in 2018 and Avista Pharma Solutions in 2019, Cambrex has added drug-product manufacturing and analytical services to its expertise in drug substances, and offering end-to-end services. As well as the additional services to develop and manufacture small molecule therapeutics, these acquisitions have brought hundreds of new customers and capabilities to the company, which can benefit from a broader range of product lifecycle
Having integrated services can further improve delivery timelines for customers by efficiently transferring products to larger-scale assets and managing resources efficiently across the global network of facilities to accelerate development, manufacturing, and testing services. Additionally, early-stage customers provide a broad pipeline of clinical candidates, and the large-scale drug substance and drug product facilities are well suited to receive those products as they progress to late-stage or commercial manufacturing.

Reasons for using an end-to-end service provider

VCI: From your experience, what are some key reasons sponsor companies seek to use an end-to-end business service model compared with the traditional model having separate providers for API and drug-product development and manufacturing?

AM: From the beginning of the twentieth century until only very recently, the large proportion of small molecules in the clinical pipeline were being developed by the top pharmaceutical companies. Today, the data show that this trend has changed, and approximately 65% of the current pipeline are molecules being developed by small and virtual pharma companies, many backed by venture capital or private equity funding. Historically, smaller companies would have sought to out-license their candidates sometime in the middle of the clinical trials (usually Phase II) and then the larger clinical studies were taken on by the larger, better resourced pharmaceutical companies. However, the recent increase in drugs that are being tested in smaller patient cohorts, such as oncology or orphan diseases, has allowed the development of these molecules to be taken on by these smaller innovator companies. The reduced patient/clinical burden of the sponsor company having to conduct lengthy and complex trials involving multiple indications, as well as coordinating hundreds, if not thousands of patients, has meant that with appropriate funding and investment, the possibility of a small company commercializing its own products is now an economically viable prospect.

For companies adopting this approach, using a sole, fully integrated service provider to act as a development partner throughout the process is extremely attractive. From a resource point of view, it ultimately means less CDMO partners to manage, fewer supplier agreements to negotiate, fewer people involved in the decision-making process, and avoids multiple points of contact for each project.
CMOs and CDMOs expanded their services and facilities in the summer of 2019.

Contract manufacturing organizations (CMOs) and contract development and manufacturing organizations (CDMOs) are constantly expanding, investing, and merging in order to provide their clients with the latest advancements and breakthroughs in services and technology. This article explores recent facility expansions and industry partnerships.

New facilities, expansions, and updates

Cambrex has revealed that it is expanding its solid form screening and crystallization process development facility in Edinburgh, Scotland, to add supplementary laboratory space that will double the current footprint. In a July 30, 2019 press release, the company revealed that the expansion will enable recruitment of 40 more scientists, adding to the already employed 50, and will also allow for potential future growth. The expanded facility fit-out is expected to commence late August 2019, and the company has set a target time for completion as the end of the year.

“This strategic expansion, the increase in headcount, and the investment in new equipment will enable us to serve more customers in the solid-state screening market,” commented Mark Benger, Edinburgh Site Director, Cambrex, in a press release. “We have increasingly been asked by clients for additional services such as larger-scale crystallization, and we will now be able to provide these as well as adding greater efficiency and capacity at the Edinburgh site.”

The expanded facility will feature additional instruments and reactors for large-scale crystallization studies and solid form screening capabilities. Furthermore, the company states that plans are in place for the installation of new ultra-high-performance liquid chromatography and gas chromatography instruments, as well as additional process analytical technology tools.

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Date: July 30, 2019

About the author

Mark Benger,
Site Director,
Cambrex Edinburgh

Title: Pharma contract market update
Date: August, 2019
According to market research, over the next five years the pharma contract development and manufacturing organization (CDMO) market is expected to grow at a compound annual rate of 8%. A key driver of this growth is highlighted as the increasing need for advanced processes and production technologies that are capable of meeting regulatory requirements.

Diving deeper into the evolution of the CDMO market in pharma during the past 30 years — here is an interview with Alex Maw, Senior Director, Marketing and Communications at Cambrex.

A changing landscape

**Question (Q): Could you run through some of the key factors that have driven the most significant change in the CDMO model over the past 30 years?**

**Alex Maw (AM):** From a small molecule API and fine chemical manufacturer perspective, the past 30 years have seen numerous changes in terms of the variety of services offered, the types of chemistries and the volumes of material manufactured, the dynamic nature of the competitive landscape, and the breadth of customers we work with.

The concept of outsourcing in API manufacturing was coined at the beginning of the early blockbuster era of pharmaceuticals, at a time when volume demands outstripped pharmaceutical companies’ internal resource and capacity. Drug manufacturers turned to one or two pioneering contract manufacturing organizations (CMOs) to take on very specific manufacturing steps — either early in the synthetic process, or ones that involved challenging or hazardous chemistry and needed specialist capabilities. Fast forward a few decades to the present day, where an entire CDMO industry has been created to support the plethora of new projects as the trend towards outsourcing has continued. CDMOs’ capabilities have also evolved to be able to manufacture entire campaigns in large, multipurpose facilities.

After the end of the first wave of blockbusters, Big Pharma companies came under increasing pressure to reduce their costs, which ultimately filtered down to risking API product quality for a lower price from suppliers. This led to an inevitable migration to lower-cost CMOs such as those based in India and China. At the same time, the industry shifted from custom synthesis to toll manufacturing, and using a CMO for its skill or know-how in a specialist technology or developing a process was no longer required. CMOs were soon beginning to be seen as undifferentiated, and increasingly, the lowest-bidding supplier was awarded the business.

Again, fast forwarding to the present day, the now-evolved CDMO market has strengthened again for Western-based suppliers, which has coincided with a decrease in the amount of captive manufacturing in Big Pharma and the increase in the number of FDA [US Food and Drug Administration] and EMA [European Medicines Agency] approvals for small...
molecule new chemical entities (NCEs). Customers are also focused on high-quality API product rather than low costs.

The nature of the customer base for CDMOs has also seen an interesting shift, away from the traditional Big Pharma companies, to where the majority of new drugs in development are being developed by smaller and virtual companies. These smaller companies typically lack the manufacturing assets required to produce the quantities required for clinical or commercial supply, further tilting the balance to outsourcing.

Finally, the nature of the APIs and intermediates involved in the new wave of drugs in the pipeline has also seen dramatic changes: increased number of synthetic steps; the availability of key raw materials; the toxicities of the species produced; as well as the typical volume requirements of small molecule drugs have led to CDMOs needing to evolve and keep in step with these trends.

Come a long way

Q: How have CDMOs evolved to be able to deal with the various industry changes?

AM: The most successful CDMOs have had to invest in new technologies, facilities, containment capabilities, and staff expertise. CDMOs have moved a long way from the toll manufacturers of the late 1990s, and are once again considered experts rather than “capacity for hire.”

CDMOs have had to be increasingly attentive to their customers’ requirements, investing accordingly in appropriate capabilities, technologies, and capacity. Establishing in-house market intelligence groups has also proved important to monitor and measure industry trends and adapt to fulfill the markets’ needs.

Flexibility is key

Q: In the future, what might significantly impact CDMOs?

AM: The shift in the customer base and reacting to customers with new and different needs is key. Typically, these companies have little or no captive manufacturing, are less resourced in managing single or multiple outsourced suppliers, and are likely to have less experience in bringing a drug to market than Big Pharma. This means that those CDMOs in a position to offer integrated solutions over the lifecycle of a drug can benefit from strong, strategic partnerships with the growing number of smaller companies who are taking their products through the clinical pipeline and onto the market.

At the same time, it is imperative that CDMOs can offer a broad range of manufacturing chemistries and technologies, and have the ability and flexibility to manufacture clinical and commercial volumes. Historically, this meant volumes of hundreds of metric tonnes; but today, CDMOs also need to be able to cater for the growing number of niche volume APIs and drug products, requiring significantly lower volumes — even in the hundreds of kilograms. Flexibility is crucial for CDMOs to be able to respond to sudden changes in volumes that the customer has perhaps not forecast, either due to the need for additional clinical trials or sudden changes in the launch quantities or commercial supply.

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   Date: June, 2019

About the author

Alex Maw, Senior Director, Marketing and Communications, Cambrex

Title: The CDMO evolution

Date: August 2, 2019
Alex Maw, Senior Director, Marketing and Communications at Cambrex, shares her views on the Contract Development and Manufacturing Organization (CDMO) sector in this insightful interview.

Chemicals Knowledge Hub (CKH): How would you describe the pharmaceutical CDMO market at the moment?

Alex Maw (AM): No matter how you look at it, more people are taking more medicine. Many estimate the global pharmaceutical market to have exceeded $1 trillion, but often sales revenue can be misleading due to pricing fluctuations complicating the picture (e.g. recent launches of highly priced drugs, patent expiries for mature products and generic entry). Topline sales are usually an inadequate measure of consumption, which are vital data for CDMOs who sell MT or kg of white powder or sterile liquids shipped in drums and vials. Therefore, when you deconstruct the data for units (tablets, capsules, vials) it becomes obvious that the volumes are increasing, and consumers are reaching for the medicine cabinet.

In addition to this more medicine-focused consumer, patients are also demanding more research and development into safer, more efficacious treatments, as well as access to newly approved drugs. For example, we have seen a dramatic increase in orphan indication treatments that were once considered unprofitable for pharmaceutical companies to target.

CDMOs have been at the receiving end of this growth because it has caused an increased reliance on outsourcing for drug substance and finished drug product needs. Pharmaceutical companies are manufacturing less of their own products compared with 20 years ago and have been busy divesting or mothballing antiquated drug substance and drug product facilities that were tolling out the blockbusters of the past. There is now more money being invested with CDMOs for research, development and process efficiencies, as well as an uptick in the use of CROs for drug discovery and clinical trial needs because these companies are focused on offering the latest and greatest technology, and this removes a great deal of pressure from the drug manufacturer.

In terms of the nature of the products, small molecule drugs continue to dominate commercial products as well as account for the majority of R&D pipelines with more small molecules in clinical trials than ever before. The number of small molecule drugs approved in 2018 by the FDA is at a 20-year high and the industry is currently enjoying one of the most buoyant periods of venture capital funding for early-stage companies at any time in recent history.

At the same time, competition can be fierce. At the beginning, there were just a handful of small molecule CDMOs operating on the market in the early 1980s, but this number has drastically increased in today’s market. During the late 1990s and early 2000s, drug manufacturers started to migrate to low-cost countries for production as blockbusters began to fall off. However, this came with a cost, and in the last five years alone, there has been a strong return of business to the US and EU due to quality concerns and the customers' increasing preference of projects being located closer to home. Western-based CDMOs have started showing strong growth again and are benefiting by the surge of new products and clinical pipelines.
Large molecule drugs continually punch above their weight in terms of the numbers of headlines they generate, but their CDMO market is an order of magnitude smaller in terms of revenues and the number of commercial products available to manufacture. The competitive space is less crowded but outsourcing by Big Pharma is dominated by CDMOs who have a track record, access to the capital and can afford to build and maintain $150-200 million plants with exorbitant running costs (Lonza, Samsung and Celltrion for example).

To summarize, the ongoing high tide in new drug approvals and a robust clinical pipeline, coupled with the decline in captive manufacturing and increasing dominance of the pipeline by virtual and venture capital-funded companies, has led to a healthy and sustained period of growth for CDMOs.

CKH: The CDMO industry has been an attractive sector for M&A in recent years — Cambrex itself recently acquired Avista Pharma Solutions — what is driving this consolidation in the industry?

AM: The customer base for CDMOs has seen an interesting shift, moving away from just the traditional Big Pharma companies to included smaller or virtual companies. These smaller companies typically lack the manufacturing assets required to produce the quantities required for clinical or commercial supply and must outsource to be successful from a procurement and production perspective. The companies do not have the bandwidth to manage an army of suppliers across the different parts of the supply chain, which has led to the rise of the ‘full service CDMO’ model.

At Cambrex, we acquired Halo Pharma in 2018 and Avista Pharma Solutions in 2019 to add drug product manufacturing and analytical services to complement the existing drug substance expertise. Through these acquisitions, we have added hundreds of new customers, and now have the capabilities that allow us to offer our customers virtually all the services they need to develop and manufacture their small molecule therapeutics from start to finish.

As a CDMO, this allows our team to maintain the customer relationships over a broader range of the product lifecycle than in the past. We can get to know their process better, while improving delivery timelines through efficient transfer models. As they move along in their process, we can more easily shift resources across our network of facilities to accelerate development, manufacturing and testing services with a seamless experience for the customer.

Now we can work with early-stage customers who are focused on creating a broad pipeline of clinical candidates through to the large-scale drug substance and drug product customers that want to take advantage of our late stage or commercial manufacturing capabilities. This also allows us to grow with a customer as they move along the process themselves, or to step in at any point in the process to deliver that one-stop provider experience.

CKH: Largely as a result of M&A, one-stop shops are on the rise: how important is it to diversify your service offerings?

AM: The concept is certainly in vogue right now. If you look at the list of the recent M&A activity over the last three years including Cambrex/Halo/Avista, Lonza/Capsugel, Thermo/Pathenon and Catalent/Accucaps, we see a race toward offering more products and services to customers ‘under one brand’. It is common sense that using one CDMO for your drug substance, drug product and analytical service needs saves time and effort.

From the customer perspective, we can surmise that only a small handful of CDMOs (Cambrex, Patheon, Lonza and Catalent) are operating along a similar model, so there is a growing requirement to differentiate to the customer. For other CDMOs, reputations are based on the brand or fiscal strength, but for Cambrex we are building our reputation on expertise and the molecule type. We think of ourselves as the leading small molecule company — we are the only full service CDMO to be dedicated to small molecule drugs, whereas others have either discounted the small molecules business completely, or their activity is somewhat labouring under their heavy investments on the biologics CDMO market.

CKH: How do you choose which new technologies deserve investment?

AM: Most CDMOs know it is important to listen to their customers. Particularly those that have strategic relationships with large pharmaceutical companies and are uniquely privy to a first mover advantage on the new molecules that are coming down the pipeline — whether they require advanced chemistry, highly potent manufacturing, continuous flow chemistry, or cover new modalities such as cell therapies or oligonucleotides. This allows the CDMOs to make informed, often stepwise, investments into the next generation of technologies required.

Aside from customer input, other CDMOs have invested in marketing intelligence teams, whose function is to routinely interpret the industry trends and assess the industry pipelines for the next opportunity. It is easy to scan industry headlines and monitor competitor trends, but this information is of no use if it is not being analyzed effectively to avoid the pitfalls of over-investing, investing too late or even investing too little in technology and capacity.

About the author

Alex Maw,
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First published: Chemicals Knowledge Hub
Title: A healthy time for CDMOs
Date: August 12, 2019
The pharmaceutical industry continues to grow and is estimated to be worth $1.5 trillion by 2021. One important driver is the trend towards outsourcing of development and manufacturing to contract development and manufacturing organizations (CDMOs). What sounds like good news for CDMOs also holds its own challenges — many of these companies are operating in a highly fragmented market that is currently undergoing a significant consolidation. At the same time, many of them are not fully prepared to exploit the maximum potential and willingness-to-pay in project pricing, which calls for new and innovative monetization strategies.

Since price is the single most powerful lever to increase a company’s profits, it is high time for CDMOs to reconsider their project pricing approach. Instead of clinging to traditional cost-plus pricing logic that usually lacks consistency, transparency and control, experts propose measures such as harmonizing costing methodologies, incorporating value-based pricing metrics, and systematically using internal project price benchmarks for developing a value-based price model.

CHEManager International asked executives and opinion leaders operating in this market to share their experience and advice.

CHEManager (CHE): How would you describe the current market situation for pharma CDMOs and which trends affecting your project pipeline do you see?

Alex Maw (AM): Until very recently, the majority of small molecules in the clinical pipeline were being developed by the larger, top 30 pharmaceutical companies. Today, however, data shows that this trend is strikingly different with approximately 65% of the current pipeline being developed by small and virtual pharma companies, many of which do not yet have revenue from commercial products and are backed by venture capital or private equity funding.

Instead of the traditional model where smaller, less capital-intensive companies would have typically looked to out-license their candidates halfway through the clinical trial process (usually stopping soon after phase II), the recent rise of drugs being tested in smaller patient cohorts, such as oncology or orphan diseases, has allowed the development of these molecules to stay at the original innovator.

This shift to smaller companies can bring additional changes or demands on the supplier base and the preference for working with CDMOs with end-to-end or integrated capabilities. Typically, these companies have limited resources in corporate functions such as procurement and supply chain management, and these roles are typically filled with people with other responsibilities. The benefits of using CDMOs that can manage more of the supply chain (drug substance, drug product, clinical and commercial supply) means a reduced set of CDMO partners to manage, fewer supplier agreements to negotiate, fewer people involved in decision-making, and can avoid multiple points of contact for each project.

Outsourcing adds value and reduces risk in development projects, but partners need to set up fair prizing models.
Cambrex made two recent acquisitions — Halo Pharma in 2018 and Avista Pharma Solutions in 2019 — adding drug product manufacturing and analytical services to the company’s expertise in drug substance, and broadening its capabilities to support small molecule drug developers looking for an integrated service provider. As well as new services, it allowed Cambrex to broaden the customer base and potential complementary customer service offerings.

About the author

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Title: The pharma CDMO challenge
Date: September 11, 2019
Key activity in 2019 thus far

In looking at key activity of deals or expansions in drug substance and drug product development and manufacturing announced thus far in 2019, several deals stand out in terms of the size of the investment. Chief among them is Cambrex’s announcement last month (August 2019) of the pending sale of the company for $2.4 billion (inclusive of Cambrex’s net debt) to an affiliate of Pemira, a private equity firm. The announced sale of the company follows two large-scale acquisitions by Cambrex. Last year (2018), Cambrex acquired Halo Pharma, a contract provider of drug product development and manufacturing services, for $425 million to provide Cambrex, a contract provider of small molecule active pharmaceutical ingredients (APIs) and intermediates, with drug product capabilities. Earlier this year (January 2019), Cambrex acquired Avista Pharma Solutions for $252 million to add early-stage development and analytical testing services to the company’s position in drug substance manufacturing. Completion of the sale to Permira is subject to customary closing conditions, including receipt of approval by Cambrex’s shareholders and customary regulatory approvals. Closing is expected to occur during the fourth quarter of 2019.

As Cambrex awaits its pending sale, it continues with several expansions announced or completed this year. Earlier this year (June 2019), the company added a new 600 sq. m. facility at its site in Karlskoga, Sweden for new laboratories for process and analytical development and a $6 million, 3,000 sq. m. logistics center. The Karlskoga site, which develops and manufactures small molecule APIs, had earlier expanded large-scale manufacturing capacity. In April 2019, Cambrex also opened a new 120 sq. m. quality control laboratory at its site in Paullo, Milan, Italy, which manufacturers generic and branded APIs.

Movers and shakers: Deals and expansions of CMOs/CDMOs

Which CDMOs and CMOs are making the mark in terms of deal-making and expansions and what manufacturing sectors are seeing the greatest activity?

About the author

Steven Klosk, President and Chief Executive Officer, Cambrex
Over the last five years, data has shown a resurgence in the overall pipeline for small molecules (Table 1), with a historically strong growing pipeline now being fuelled by more preclinical candidates and Phase I starts than ever before. Currently more than 7,600 small molecule drugs have been launched or are in development, an increase of 40% on five years ago.

The data also shows that the number of phase transitions — that is, the number of small molecules successfully moving between clinical phases — hit a record high of 520 in 2018. This suggests that the industry continues to invest in small molecule drugs, with new opportunities in previously untreatable indications, such as oncology and orphan diseases. Furthermore, there is a growing trend for smaller and virtual companies to advance projects further through the clinical pipeline than they typically would have done before. They now account for a record 65% of clinical projects (Figure 1).

Another positive indicator is the large amount of venture capital funding available, including investment for early-stage life science companies, which are developing the majority of new chemical and molecular entities (NCEs, NMEs).

It was estimated in 2018 that over $60 billion was raised during initial public offerings, follow-on funding, private investment in public equity, venture capital and other sources of fundraising investment for the biotech industry. Of this, a record $20 billion was attributed to venture capital funding for new start-ups and early-stage companies with molecules in development.

These trends are expected to continue throughout the remainder of 2019 and 2020. The increasing tide of investment into a pharmaceutical industry has boosted both small molecule and biologics R&D.
In addition, the increasing numbers of small molecules being used in specialist care settings, such as oncology and orphan indications, involve clinical trials with fewer patients. This in turn means that fewer resources, in terms of capital, people and material, are required for lengthy, late-stage clinical studies, allowing smaller pharma companies and start-ups to stay longer in the development of their assets.

**Out-licensing later**

Historically, the high costs of clinical trials meant that projects were out-licensed during the clinical phases, with only the large companies having access to the funds for late-stage development and approval. As the clinical pipeline continues to focus on smaller patient cohorts, which typically require fewer resources, smaller and virtual companies can now manage late-stage trials and, in some situations, even launch and commercialise their assets.

This trend can be seen in recent FDA drug approvals. For example, a drug developed for use in a specialist care setting may only require a relatively small sales force to be deployed in a targeted manner, compared with the much larger number of sales reps required in a primary care setting to make daily calls to physicians.

**Orphan drug approvals**

A total of 42 NCE drugs were approved during 2018, well above the overall average of 25-35/year in recent years. This included an increased number of smaller pharmaceutical companies launching orphan products.

The latest analysis of API volumes for these recent approvals shows a continued trend towards peaks at about one tonne. These data are based on peak volume forecasts for newly approved commercial products, as well as drugs in Phase III, estimated using epidemiology and patient market share.

Taking the broader commercial market into account too, analysis of pharmaceutical consumption data for all small molecule prescription drugs — without over-the-counter and commodity products — in the seven major markets (US, UK, France, Germany, Spain, Italy and Japan) shows a total market volume of 3,500 tonnes/year of API, with growth of 100-200 tonnes/year. This reflects a combination of continued growth for both the larger 100 tonnes+ high-prevalence disease therapies and the more targeted therapies in the 10-20 tonnes range.

**Outsourcing opportunities**

There is currently a large and growing $25-35 billion/year small molecule API market, characterised by a growing reliance upon outsourcing, particularly by small and virtual pharma companies. Despite the growth in biologics and cell-based therapies, the small molecule drug substance market continues to be attractive to companies like Cambrex.

With the industry currently experiencing a renewed focus on quality, rather than the cost-buying behaviour seen during the 2000s, customers are showing a preference, once again, for working with Western CDMOs. This, coupled with the fact that the sector continues to exhibit a robust and growing clinical pipeline, with strong movement between development phases and an FDA approval rate that is the highest since the 1990s, the industry is in rude health.

**The oncology scene**

In recent years, many investments by CDMOs have been focused on building or expanding facilities to safely handle highly potent small molecules. An accurate measure of the high potency pipeline can only be made through a bottom-up study and looking at each molecule in turn, which is an expensive and time-consuming exercise.

To make some meaningful observations, the numbers of small molecules being developed for or used in oncology indications can be used as a proxy for the high potency pipeline with some level of comfort. Whilst not all of the drugs in the oncology pipeline are highly potent, the vast majority of highly potent drugs are being developed in oncology.

Cambrex recently commissioned its own study and, using two independent consultants, assessed 38 of the 290 small molecules from the top 30 pharmaceutical companies in clinical trials within oncology indications. As expected, the results were mixed and showed that consensus in classification is very difficult. One data set showed that 97% of products are highly potent (occupational exposure limits (OEL) <1 µg/m³), the other that less than 20% were.

In either case, however, the small molecule oncology pipeline is growing at about twice the rate of other indications. It now accounts for 38% of preclinical and 35% of clinical small molecules respectively.

Recent oncology approvals account for one third of FDA approvals and, as of 2019, there were 252 oncology drugs on the market or in registration. Analysis shows that the market is approaching $53 billion/year in revenue and 920 tonnes/year in volume, with a typical commercial API volume per molecule of around five tonnes.

Most CDMOs have built capacity assuming that all oncology drugs are highly potent and have OELs of <1 µg/m³, with a large proportion having OELs of <1 µg/m³. However, OEL assessments have a tendency to be relaxed over time as more toxicology data become available.

This ultimately means that products are migrated to lower-containment equipment and can be manufactured more
cost-effectively. Given the complexity of handling such products and the preference for Western suppliers, this is very much an area of interest for CDMOs and an opportunity to provide an integrated high-potency drug substance and drug product offering.

**Conclusion**

There is a strong commercial market for small molecule drugs, with more patients than ever taking more tablets for a widening range of health conditions. There is also a track record of strong approval history in this sector, which helps fuel the interest in and development of new small molecule products.

The industry is currently witnessing the strongest, most dynamic pipeline in the history of small molecule drug development, with more than ever entering clinical trials and more transitioning to the next clinical phase. For CDMOs with the right assets, a flexible approach to business, and an integrated offering to respond to the dynamic nature of customers and projects, the future continues to look bright.

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**About the author**

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**First published**: Speciality Chemicals
**Title**: Small molecule CDMO market in good health
**Date**: September/October, 2019
Although it may be true that much has changed since the first early chemical blockbusters, the popularity of small molecule drugs endures even to this day. As the global population continues to show little signs of slowing down, now more than ever we live in a medicine-focused society, and small molecules are at the cornerstone of it all. Existing in today’s small molecule market requires flexibility and foresight as the trends shift and demand for outsourcing grows. Big Pharma is increasingly reducing its large investments into captive manufacturing facilities that age rapidly and are hard to maintain, whilst new small or virtual pharma companies lack the resources to dedicate to building or managing their own internal capabilities.

Cambrex, a contract manufacturing and development organization (CDMO) headquartered in the US with locations across North America and Europe, is committed to meeting these needs. The company provides pharmaceutical products, expertise, and technologies that accelerate small molecule therapeutics and has been in the business for nearly 40 years. Through recent strategic growth initiatives and the acquisitions of Halo Pharma and Avista Pharma Solutions, Cambrex now offers services and expertise from preclinical development, through to clinical Phase 1, Phase 2, and Phase 3 and into commercial-scale manufacturing for drug products.

Throughout the past five years, the executive team has been focused on making Cambrex THE small molecule provider of choice, and features locations in Europe (including Estonia, Sweden, UK, Germany, and Italy), Canada, and the US. Headquartered in NJ, with NC, IA, MA, and CO locations, the company employs more than 2,000 people and had 2018 net revenue of $532 million.

Drug Development & Delivery recently interviewed Stephan Haitz, President, CDMO Sales and Marketing at Cambrex, to discuss the biggest trends in the small molecule outsourcing market.

Drug Development & Delivery (DD&D): What has the past year looked like for Cambrex?

Stephan Haitz (SH): The past year has been active. Our team has focused in on a strategic transformation and expansion of capabilities across the full small molecule lifecycle to better serve customers. In 2018, we acquired Halo Pharma to expand formulation development and drug product GMP manufacturing, and in January 2019, we acquired Avista Pharma Solutions for early-stage development and analytical services to support our existing drug substance and drug product expertise. These two acquisitions have allowed us to broaden and diversify our service offering in what is our continued mission to become the leading small molecule company.

Not only did these investments significantly increase the customer base and funnel of projects, we are now able to partner with customers at any point or breadth across the whole lifecycle of small molecule drugs, from preclinical development through to commercial launch.

Cambrex providing big value in the small molecule outsourcing market
**DD&D: What was the driver for the acquisitions, and how is integration going?**

**SH:** These investments were critical additions to our well-established active pharmaceutical ingredient (API) expertise to evolve with the industry and stay in step with customers who continue to seek more from their CDMO partner. The integration of Halo and Avista into Cambrex has allowed us to structure the business into three key offerings for our customers: The drug substance offering incorporates the majority of the legacy Cambrex API business, including the development and manufacturing of innovator APIs; the scale-up and technical transfer of projects and analytical development; and specialist capabilities, such as handling of controlled and highly potent substances, continuous flow chemistry, biocatalysis, and solid-state science.

The drug product offering features expertise in formulation and development of conventional dosage forms, including oral solids, liquids, creams, sterile and non-sterile ointments; as well as specialist capabilities, including developing and manufacturing highly complex and difficult-to-produce formulations, products for pediatric indications, and controlled substances.

Finally, with extensive analytical capabilities, such as solid-state chemistry, microbiology testing, cleanroom services, and material characterization added to our portfolio, we can support drug substance and drug product projects, or provide these as standalone services.

Following the integration of the two businesses into our global network, customer response has been extremely positive. We are now a truly world-class CDMO and will continue building on our platform of services and technologies.

**DD&D: How is Cambrex preparing for this future?**

**SH:** As Big Pharma moves away from its reliance on a handful of blockbuster drugs to more specialized products serving smaller patient groups, they are faced with the prospect of trying to keep their large manufacturing facilities occupied or looking to divest or mothball old plants. We have seen these larger players outsourcing more of their projects in order to harness new manufacturing technologies that they currently do not have, as well as the small or virtual Pharma companies who lack any commercial manufacturing capability.

**About the author**

Stephan Haitz, President, CDMO Sales and Marketing, Cambrex

**First published:** Drug Development & Delivery

**Title:** Cambrex: providing big value in the small molecule outsourcing market

**Date:** October, 2019
Expert Insight & Awards

Matt Kehrli
Chemist

Chelsea Fritz
Advanced Scientist II
What are your company’s major accomplishments over the past year?

In 2018, Cambrex diversified its business with two acquisitions, Halo Pharma and Avista Pharma Solutions. Prior to these acquisitions, Cambrex had been wholly focused on providing customers with development and manufacturing of APIs and advanced intermediates for branded and generic pharmaceuticals.

Both acquisitions have expanded Cambrex into new markets, while maintaining our focus on small molecule therapeutics.

Both the new drug product and early-stage development and analytical testing services offerings complement our existing capabilities and expertise. The businesses were a natural fit and bring a wider customer base and increase the opportunities for us to offer a wide range of services to new and existing customers. Avista provides services for preclinical and early clinical stage small molecule therapeutics, and Halo adds formulation and drug product development and manufacturing capabilities. The combination of both, alongside the existing Cambrex capabilities, under one brand, allows an integrated offering and the potential to feed and expand the clinical and commercial manufacturing pipelines.

In addition to the acquisitions, Cambrex has also continued its investment at our manufacturing sites to ensure the company meets the demands of the industry. 2018 saw numerous investments at our US facilities in High Point, NC, and Charles City, IA, including the purchase of a new 45,000 sq. ft. building adjacent to the current one in High Point, allowing the site to expand its clinical supply and process development capacity.

What do you want your company to be known for?

Both acquisitions have been undertaken to continue Cambrex’s commitment to providing best-in-class services to meet the needs of our global pharmaceutical, biotech and generic customers. The company’s goal is to be the leading global small molecule CDMO offering clients end-to-end solutions.

Our network of 12 facilities across North America and Europe now offers customers the opportunity to access services from early-stage discovery through to clinical and commercial manufacturing of drug substance and drug products, either as an integrated solution or in standalone activities.

What are the most pressing challenges the industry faces and what are some possible solutions?

The pharma industry continues to evolve, and we see a healthy clinical pipeline as well as a high number of FDA approvals for small molecules. However, the nature of the molecules has changed. Commercial products are no longer the blockbusters that require hundreds of metric tons of API annually; and the drug substance’s requirement may be under a ton to meet an orphan drug demand, or could be highly potent so requires contained manufacture. As a CDMO, we must recognize these changing needs and adapt accordingly to be able to offer the most suitable solutions in terms of capacity, expertise and technologies to customers.
Customers change too: Alongside the multinational pharmaceutical companies, are the small and virtual companies that are investing more, and progressing products further down the clinical pipeline. The needs of each are different, but have some commonality in that they are looking to reduce the burden of managing complex supply chains and work with a smaller number of strategic outsourcing partners and suppliers. This has led to the consolidation in the service sector, and has been pivotal in the strategic decisions Cambrex has made to invest in technologies, specific manufacturing capabilities and capacity, and acquisitions to broaden our service offering.

What areas of innovation or technology development within the company or in the industry generally are you most excited about?

As a company we have made a number of investments over the last two years in continuous flow capabilities at both development and commercial scale, to match industry demand. The advantages that continuous flow has for chemical synthesis include both safety and efficiency, and there are a number of examples of pharmaceutical companies looking to leverage the technology for process improvements in clinical-phase development.

Cambrex identified a need for continuous process development capabilities within the CDMO industry and took the decision to develop a continuous flow Center of Excellence at its High Point, NC facility. A number of continuous flow reactor platforms have been installed at the site and process development work carried out can now be seamlessly transferred to any site within the Cambrex global network for commercial manufacture.

Another recent investment in this area has been made at our Milan, Italy, site which develops and manufactures intermediates and generic APIs under GMP conditions. A new flow chemistry platform has been installed in a recently completed R&D laboratory to assist in the efficient development of new products.

About the author

Shawn Cavanagh, President and Chief Operating Officer, Cambrex

Date: April 30, 2019
What are your company’s major accomplishments over the past year?

With the completion of the acquisition of Avista Pharma Solutions for early-phase API support and Halo Pharma for drug product supply, Cambrex can now service the entire continuum of the pharmaceutical market. Avista provided services for preclinical and early clinical stage small molecule therapeutics, while Halo added formulation development and drug product manufacturing capabilities. The combination of both, alongside the existing Cambrex small molecule drug substance capabilities, allows the company to offer an integrated solution, with the potential to feed the clinical and commercial manufacturing pipelines.

With our new and diverse set of services, customers have the choice of selecting the appropriate offerings. For companies who may not have the time or resource to manage multiple service providers, they also have the option of benefitting from an integrated approach to maintain a project and product with Cambrex throughout its entire lifecycle. That is a service offer that few other companies in our space can provide.

What areas of innovation or technology development within the company or in the industry are you most excited about?

Although continuous flow has been utilised in a variety of industries for over a century, the pharmaceutical industry has been slow to adopt this technology for historical and regulatory reasons.

The strategic initiative taken by Cambrex to develop a continuous flow Centre of Excellence in High Point, NC, aims to strategically fill the shortfall of continuous flow process development capabilities within the CDMO industry supporting pharmaceutical companies. As a result, we now have several continuous flow projects under way with pharma customers of varying sizes. We have the benefit of a dedicated engineering group at our High Point facility, focused on continuous flow projects with the aim of developing those for scale-up to our commercial drug substance facilities in the US and Europe. That, coupled with our existing commercial continuous flow nitration capabilities in Europe, creates an interesting and attractive offering to the market.

What are some of your company’s goals for the next 12 months?

Cambrex now employs over 2,000 people, operating in 13 locations across Europe and North America, with the company offering three distinct capabilities: Drug Substance, Drug Product and Analytical Services. The acquisitions mentioned above have allowed us to expand our services and evolve the business with a broader customer base. As we continue to integrate these services into a single company, and align functions together over the next 12 months, we will aim to make it simpler for customers to work with us and leverage the expertise we have across all aspects of small molecule drug development.
How would you describe your company’s culture?

In a word, transparent. Cambrex employees understand the importance of transparency and being able to advise our customers up front what we can deliver and what is outside of our realm. We are also always striving for process improvement and operational excellence. Project teams are empowered to continually be looking for ways to enhance the offering to our customers, whether that be strengthening process robustness, reducing manufacturing costs, or increasing throughput. Our teams throughout the organisation are focused on delivering meaningful gains to our customers.

What do you find most rewarding about working in the industry?

The ability to change the quality of life for someone I may never meet. As a young chemical engineer, I never imagined I would have the opportunity to impact global health in the ways that I now am able to. It has been incredibly rewarding to be a part of the supply chain for several drugs that since launch have changed the global landscape of medicine and quality of life for so many people. I truly look forward to the next one.

What advice would you give to younger professionals?

Stick with your passion. Being a part of the pharmaceutical industry can be incredibly rewarding. Your passion and dedication may lead to the launch of a drug that can save millions of lives including those of family and friends. In the end, that global change in quality of life is what it is all about.

About the author

Joe Nettleton, President, Drug Substance, Cambrex

Date: November 7, 2019
Award winning

Cambrex recognized at 2019 CMO Leadership Awards

Cambrex was recognized across five categories in the annual CMO (Contract Manufacturing Organization) Leadership Awards, which were announced at a ceremony in New York, in March 2019.

Cambrex received CMO awards for five consecutive years, and this year, has been recognized in the following categories: Compatibility, Service, Expertise, Quality and Reliability; and were noted for four individual attribute awards for Accessible Senior Management, Reputation, Right First Time, and Strength of Science.

“Cambrex is once again honored to be recognized as a leading supplier to the pharmaceutical industry,” commented Steven Klosk, President and Chief Executive Officer at Cambrex.

He added, “With our recent acquisitions of Halo Pharma and Avista Pharma Solutions, we have created a leading, fully integrated small molecule CDMO across the entire drug lifecycle offering more products and services to our customers. Being the recipient of a 2019 Leadership Award is a testament to the hard work of all our employees across the entire company.”

Established in 2011, the CMO Leadership Awards recognize top outsourcing partners, determined by feedback from sponsor companies who outsource manufacturing. The awards are presented by Life Science Leader magazine and Industry Standard Research.

When asked by The Medicine Maker, “What’s the luckiest break of your career?”, Steven commented: “Joining Cambrex early in my career, because the experiences I have had and the people I have shared my time with have given me 28 years of steady personal and professional growth. In addition, building a strong team of experts within Cambrex has ensured our success.”

Steven Klosk recognized in industry Power List 2019

Breakthroughs at the bench, novel technologies and groundbreaking policies and regulation have helped the pharma industry grow from strength to strength.


Cambrex President and Chief Executive Officer, Steven Klosk, was recognized in the Business Captains category of The Medicine Maker Power List in 2019.
Award winning

Cambrex Wins CPhI Pharma Award for API Development

Cambrex won the ‘Excellence in Pharma: API Development’ category at the annual CPhI Pharma Awards, which took place at a Gala Dinner at CPhI Worldwide in Frankfurt on November 5th. This marks the third time that Cambrex has won the category in the past four years, having previously won in 2016 and 2017. The company was also judged ‘highly commended’ in the same category in 2018.

The winning entry, for the company’s crystallization screening and process development service, highlighted a peptide crystallization project bridging the gap between the laboratory and manufacturing plant, providing a controlled, robust and scalable crystallization process.

Cambrex’s advanced expertise and innovative approach to peptide crystallization allowed for the delivery of a robust, scalable and transferable process affording effective isolation and batch-to-batch consistency and reducing the cost of the purification and manufacturing process. The development also resulted in a crystalline solid form of the peptide, which showed enhanced physical properties and allowed for improvements to be made in downstream processing.

“We thank the judges and our industry peers for this unprecedented third API Development award,” commented Hayley Reece, Executive Director, Technical Services at Cambrex Edinburgh. She added, “This project was undertaken at our Edinburgh site, which is a world leader in providing solid-form development services for drug substance and drug product and where we recently announced a strategic expansion, to enable us to serve more customers in the solid-state screening and crystallization process development market.”

Established in 2004, the CPhI Pharma Awards are among the most prestigious recognitions within the pharmaceutical industry. The awards celebrate thinkers and creators breaking new ground and strongly advocate companies committed to driving the industry forward.
Cambrex Webinars

Alongside our contributions to these thought leadership articles for industry publications, you can watch our experts’ informative, educational webinars online.

Kayla Thomas
Associate Scientist

Salah-Eddine Riahi
Material Handler
Pediatric dosage form development: Challenges and opportunities

The global pediatric dosage form market is expected to reach $110 billion in 2019 — a 5% year on year growth from 2016. With a five-fold increase in drug approvals over the last 20 years, pediatric drug developments offer advantages to younger patients — and to the sponsor pharma companies through extended exclusivity for their marketed product.

This market, which requires different oral dosage forms from adults due to differences in swallowing abilities, taste preferences and dosage requirements, presents great growth opportunities and is expected to remain at this rate until 2021.

**This Cambrex webinar:**
- Provides an overview of the pediatric market and presents potential growth areas
- Considers the challenges and opportunities of pediatric formulations
- Reviews several pediatric formulation dosage forms including liquid dosage forms and solid dosage forms (mini-tablets, orodispersible tablets (ODT) and chewable formulation)
- Concludes with an overview of the regulatory considerations for new pediatric formulations.

**Contributor**

Dr Anthony Qu  
Vice President, Scientific Affairs, Cambrex

**Date:** May 8, 2019

Watch now
De-risking the solid form landscape of an API:
How predictable stability and solubility can minimize development timelines and cost

The market for solid-state services (including salt, polymorph and crystallization screening) is worth around $150 million and there is a growing trend from pharmaceutical companies to outsource much of this activity to CDMOs such as Cambrex.

De-risking the solid form landscape of an API early in development is of utmost importance to ensure its success as a viable drug candidate. Entrusting your project to an outsourced supplier requires careful consideration. Our Edinburgh site is a world leader in providing solid-form development services for drug substance and drug product.

This Cambrex webinar:
• Discusses how predictable stability and solubility can minimize development timelines and cost
• Provides an introduction and overview of the solid-state market
• Discusses the importance of de-risking the solid-state landscape of an API
• Considers two examples of typical issues faced during development of an API
• Provides a brief overview of hydrates, and why understanding their formation is so critical.

Contributors
Dr David Pearson
Chief Scientific Officer,
Cambrex Edinburgh

Date: September 19, 2019

Watch now
As we enter a new decade, the next 12 months represent another opportunity for investment and growth. Having expanded operations beyond small molecule API development and manufacturing into the drug product segment, we are investing in our sites, capabilities and people to maintain our leading position as the small molecule company.

We have doubled the cGMP liquid filling capacity at our Mirabel Québec facility. Edinburgh’s strategic expansion, increase in headcount and investment in new equipment in Europe will enable us to serve more customers in the solid-state screening market. The new 6,500 sq. ft. facility at our site in Karlskoga, incorporating labs for process and analytical development, is also now complete.

This will help us with our strategy of providing best-in-class services to meet the needs of our global pharmaceutical, biotech and generic customers.

These are exciting times. As always, we will do our best at Cambrex to serve you, our customers, by being the experts you enjoy working with.

Shawn Cavanagh
President and Chief Operating Officer