

2018 Full-Time Equivalent (FTE): Drug Substance – Small Molecule, API

15 Dedicated Research and Business Intelligence Team Members

MARKET SEGMENTS

Preclinical Trials

Drug Substance

Small Molecule, API

+ Biologics

Drug Product

+ Small Molecule

+ Sterile Injectables

Pharmaceutical Excipients

OEM Pharmaceutical Equipment

+ Drug Product

+ Biologics

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Shanghai – Shenzhen



Supplier Business Story

POINT(S) OF CONTACT

Board-Level

CORPORATE PROFILE / BUSINESS STORY

We are an embedded CDMO in the drug substance small molecule API outsourcing space offering both clinical and commercial scale manufacturing of APIs and HPAPIs. We have facilities in Europe, and are interested in selling into both Europe and North America.



Ideal Supplier Business Offering

	RESPONSIBLE ROLE	PARAMETERS CATEGORY	PARAMETERS
1	Chief Executive Officer / President, General Manager	Project Definitions	<p>Looking for API projects in Phases II-b, III and commercial from innovator or generic pharmaceutical outsourcing departments.</p> <p>We are also looking for commercial advanced intermediate projects from other CDMOs who are looking for partnerships or innovator / generic companies' outsourcing departments.</p>
2	Chief Scientific Officer, Plant Manager	Chemistry / Technical Barriers	<p>Looking for hormone (estrogen) manufacturing capability, controlled substances (II-III) manufacturing and encapsulation of powders, granules, HPAPIs, non-cytotoxic HPAPIs and combinations with 2- to 12-step chemical synthesis.</p> <p>[Customers want to see where you're spending money now to promote capital avoidance in the later stages.]</p>
3	Chief Executive Officer / President, General Manager	Project Type Prioritization / Focus <i>(based on experience)</i>	Plant Capabilities: Custom synthesis, catalytic hydrogenation, high pressure preparative LC, HPAPI handling; continuous improvement to reduce steps and/or costs without impacting the chemistry of the API.
4	Chief Commercial Officer, Sales Director	Minimum Project Size <i>(based on department)</i> <i>[Profitability is important for a small CDMO]</i>	<ol style="list-style-type: none"> 1. Tech transfer from a competing API CDMO: 6 months at \$900,000 2. 10 kilos for a Phase IIa clinical batch: \$15,000 per kilo (HPAPI) 3. 2nd supply capacity guarantee: \$1 million
5	Chief Executive Officer / President, General Manager	Ideal Project Specifications <i>(for consideration)</i>	<ol style="list-style-type: none"> 1. 500 kilos of late-phase finished API for innovator corporations selling at \$5,000 per kilo across 10 batches in 1 year: \$2.5 million 2. 5,000 kilos of commercial HPAPI for a generic company selling at \$1,500 per kilo across 50 batches in 1 year: \$7.5 million 3. 5,000 kilos of commercial finished API for an innovator HPAPI company selling at \$10,000 per kilo across 50 batches in 1 year: \$50 million



Research & Lead Generation by Phase

POINT(S) OF CONTACT

PARAMETERS CATEGORY

PARAMETERS

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Chief Commercial Officer, Sales Director

Geographic Target Area (Prospect) [With 50 states, this client expanded a sales territory]

Specific focus on 12 HPAPIs manufactured in the USA that closely align with our capabilities.

A total of 48 companies sell drug products in the USA, which require the 12 HPAPIs of interest.

In-house manufacturing: 13 out of 48

Outsourced/procured APIs from CDMOs: 21 out of 48

Both in-house manufacture and CDMO procurement: 14 out of 48

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Chief Financial Officer, Compliance

Risk Assessment; Historical Success & Therapeutic Approval

PRODUCT	NUMBER OF MANUFACTURERS	WAC DOLLARS (USD MILLION)	KILOS SOLD (2016)
All 12 HPAPIs	48	\$404.80	17.41
Acitretin	8	\$77.83	83.98
Nilutamide	2	\$20.68	17.99
Probenecid/Colchicine	2	\$8.39	4,091.82
Ulipristal Acetate	2	\$1.15	1.32



Buyers' Molecule Specification & Compatibility — 12 HPAPIs of interest (3 OF 8 COMPANIES SHOWN)

POINT(S) OF CONTACT

COMPANY PRODUCT KILOS SOLD (2016) WAC DOLLARS (2016, USD MILLION) API CLASS API TYPE

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Chief Marketing Officer

GSK	Acitretin	2.93	\$7.33	Chemical	High Potency Non Cytotoxic
Mylan	Acitretin	13.676	\$8.15	Chemical	High Potency Non Cytotoxic
Teva	Acitretin	32.932	\$36.45	Chemical	High Potency Non Cytotoxic



Leads Generated – 529 Leads from 48 Companies (6 OF 529 SHOWN)

POINT(S) OF CONTACT

COMPANY FIRST LAST CONTACT TITLE PHONE NUMBER EMAIL

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Chief Marketing Officer

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Mylan	Adi	Kleinman	Senior Director, Global API Sourcing	+1 724-514-1800	adi.kleinman@mylanlabs.com
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Teva	Michael	Cunnane	Senior Director, Global Procurement	+1 201-307-6900	michael.cunnane@tevapharm.com



Worldwide Competitors with Similar Capabilities, Equipment & Ability to Deliver on Specification

POINT(S) OF CONTACT

10 Chief Marketing Officer

COMPANY

LOCATION

THREAT LEVEL*

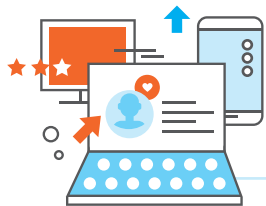
Abbvie CMO	Michigan, USA	★
Alcami	Wisconsin, USA	↔
AMPAC Fine Chemicals	California, USA	★
Albany Molecular Research Inc. (AMRI)	New York, USA	↗
Avara	Avalon, UK	★
Cambrex	New Jersey, USA	↗
Corden Pharma	Colorado, USA	★
Evonik	Indiana, USA	↔
Fareva	Haute Loire, France	★
Fabbrica Italiana Sintetici (FIS)	Montecchio Maggiore, Italy	★
GSK CMO	Cork, Ireland	↔
Helsinn	Biasca, SUI	↔
Hovione	New Jersey, USA	★
Johnson Matthey	New Jersey, USA	★
Thermo Fisher / Patheon	South Carolina, USA	↗
Pfizer CenterOne	Michigan, USA	↗
SAFC/Merck KGaA	Missouri, USA	↗
Siegfried	Nantong, China	↗
Teva Tapi	Missouri, USA	↗

*THREAT LEVELS KEY

★ **HIGH**
Similar / same offering; direct competitor

↔ **MEDIUM**
Compatible equipment; larger scale; indirect competitor

↗ **LOW**
Larger scale equipment; aspirational competitor



Brand Awareness Through Strategic Content Subject Matter (FOCUSED ON BUYER NEEDS)

HIGH POTENT COMPOUNDS

Outsourcing Provides Advantages to Sponsor Companies
(Placed in *Pharma's Almanac Q4 October 1, 2015*)

The complexity of drug compounds is increasing as pharmaceutical companies seek new classes of drug substances. Two particular aspects are challenging the production capabilities of many manufacturers: poor solubility and very high potency.

CYTOTOXIC

Propagating a Full Spectrum of Services for ADC Development and Manufacture
(Placed in *Pharma's Almanac Q2 June 5, 2017*)

These complex drugs consist of three components — an antibody conjugated using linker chemistry to a small molecule, highly potent payload. This design enables targeted delivery of a cytotoxic agent to the site of interest.

CONTAINMENT

Designing Effective Drug Formulations: Keys to Successful Proof of Concept Services
(Placed in *Pharma's Almanac Q4 October 1, 2016*)

Trademarked BREVI-BATCH® is a processing platform for solid dose mini-scale R&D formulation development targets batch sizes of 100 – 500 grams. In addition, the equipment is small enough to allow processing of highly potent compounds under containment conditions.

SPRAY DRY

Accelerating Approval and Reducing Costs of Spray Dried Drugs Through Development by Design (DbD)
(Placed in *Pharma's Almanac Q3 August 1, 2016*)

Spray drying, hot melt extrusion and coprecipitation are the three most commonly used techniques for the manufacturing of amorphous solid dispersions (ASDs).