



# 2018 Full-Time Equivalent (FTE): Drug Product – Small Molecule

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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New York – Raleigh – Chicago

San Diego – San Francisco

Dallas – London – Frankfurt

Shanghai – Shenzhen



# Supplier Business Story

## POINT(S) OF CONTACT

Board-Level

## CORPORATE PROFILE / BUSINESS STORY

We are a CDMO in the drug product outsourcing space offering formulation, manufacturing, and filling of small molecule compounds. Our single northeast US location offers tablets, capsules, creams and ointments. We are currently looking for projects from domestic and overseas innovators or generic pharma companies.



## Ideal Supplier Business Offering

	RESPONSIBLE ROLE	PARAMETERS CATEGORY	PARAMETERS																				
1	Chief Executive Officer / President, General Manager	Project Definitions	Looking for projects in Phases I, II-a, II-b and III, into batches from innovator or generic pharmaceutical outsourcing departments																				
2	Chief Scientific Officer, Plant Manager	Chemistry / Technical Barriers	Looking for hormones (estrogen) manufacturing capability, controlled substances (II-III) manufacturing and encapsulation of powders, granules, tablets, HPAPI and combinations																				
3	Chief Executive Officer / President, General Manager	Project Type Prioritization / Focus <i>(based on experience)</i>	Plant Capabilities: Tablets, Capsules, Creams, Ointments																				
4	Chief Commercial Officer, Sales Director	Minimum Project Size (based on department) <i>[Profitability is important for a small CDMO]</i>	<table border="1"> <thead> <tr> <th>INITIAL</th> <th>ONE OFFER</th> <th>REGISTRATION BATCH</th> <th>REGISTRATION BATCH</th> </tr> </thead> <tbody> <tr> <td>Lab / Analytical: \$50K</td> <td>\$50K</td> <td></td> <td></td> </tr> <tr> <td>Lab R&amp;D Only: \$100K</td> <td>\$100K</td> <td></td> <td></td> </tr> <tr> <td>Lab Process Development Outside + Research Batch + Process Validation</td> <td></td> <td>\$700K</td> <td>\$1M</td> </tr> <tr> <td>Ointment &amp; Cream, Semi-Solid</td> <td></td> <td>\$500K</td> <td>\$700K</td> </tr> </tbody> </table>	INITIAL	ONE OFFER	REGISTRATION BATCH	REGISTRATION BATCH	Lab / Analytical: \$50K	\$50K			Lab R&D Only: \$100K	\$100K			Lab Process Development Outside + Research Batch + Process Validation		\$700K	\$1M	Ointment & Cream, Semi-Solid		\$500K	\$700K
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5	Chief Executive Officer / President, General Manager	Ideal Project Specifications <i>(for consideration)</i>	<b>1. SOLID ORAL DOSE – TABLETING   36 MONTHS</b> Raw material testing, Dry / Wet Granulation, Method Transfer, Validation, Solubility Enhancement <table border="1"> <tbody> <tr> <td><b>UNITS</b></td> <td>1 to 2 million tablets / year</td> </tr> <tr> <td><b>VOLUME</b></td> <td>25 batches / year</td> </tr> <tr> <td><b>VALUE</b></td> <td>\$1.5 million / year</td> </tr> </tbody> </table>	<b>UNITS</b>	1 to 2 million tablets / year	<b>VOLUME</b>	25 batches / year	<b>VALUE</b>	\$1.5 million / year														
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<b>2. SEMI-SOLID DOSE (CLINICAL SCALE) – CREAM   60 MONTHS</b> <b>UNITS</b> 50,000 tubes / year <b>VOLUME</b> 25 batches / year <b>VALUE</b> \$1 million / year																							
<b>3. ANALYTICAL TESTING – ROBUST CLINICAL PHASE II/III TESTING PROJECT   6 MONTHS</b> Method Transfer, Validation, Stability Testing, Release Testing <table border="1"> <tbody> <tr> <td><b>VALUE</b></td> <td>\$0.5 million / year</td> </tr> </tbody> </table>	<b>VALUE</b>	\$0.5 million / year																					
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## Research & Lead Generation by Phase

### POINT(S) OF CONTACT

### PARAMETERS CATEGORY

### PARAMETERS

6

Chief Commercial Officer, Sales Director

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

Specific focus on 35 companies in Massachusetts that closely align with our capabilities.

The 35 companies have a total of 166 products in the development pipeline with another 71 products marketed.

PHASE I 69  
PHASE II 70  
PHASE III 23  
PENDING APPROVAL 4  
MARKETED 71

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Chief Financial Officer, Compliance

Risk Assessment; Historical Success & Therapeutic Approval

COMPANY	R&D SPENDING (USD MILLION)	SALES (USD MILLION)	R&D INTENSITY (%)
Top 10 Biopharma	\$70,500	\$404,800	17.41
Albireo Pharma	\$5.63	\$5.10	110.49
Amgen	\$4,006.00	\$20,944.00	19.13
Eisai Co., Ltd	\$1,060.25	\$4,749.83	22.32
Retrophin Inc	\$50.43	\$99.89	50.48



## Buyers' Molecule Specification & Compatibility

(3 OF 35 MASSACHUSETTS COMPANIES SHOWN)

### POINT(S) OF CONTACT

### COMPANY

### PRODUCT

### THERAPEUTIC CATEGORY

### PHASE OF COMPANY INVOLVEMENT

### ROUTE OF ADMINISTRATION

### CHEMICAL / BIOLOGICAL CLASS

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Chief Marketing Officer

Acetylon	ACY 1215	Oncology	Phase II	Oral	Hydroxamic Acids, Pyrimidines
Allena	ALTU 237	Genitourinary Disorders	Phase I	Oral	--
Amgen	AMG 009	Respiratory	Phase I	Oral	Phenylacetates, Sulfonamides



## Leads Generated – 251 Leads from 35 Companies

(6 OF 251 SHOWN)

### POINT(S) OF CONTACT

### COMPANY

### FIRST

### LAST

### CONTACT TITLE

### PHONE NUMBER

### EMAIL

9

Chief Marketing Officer

Acetylon	Robert	Markelewicz	Senior Medical Director	+1 617-245-1300	rmarkelewicz@acetylon.com
Acetylon	Sue	Fischer	Associated Vice President, Clinical Operations	+1 617-245-1300	sfischer@acetylon.com
Allena	Annamaria	Kausz	Vice President, Clinical Development	+1 617-467-4577	akausz@allenapharma.com
Allena	Hugh	Wight	Vice President, Technical Operations	+1 617-467-4577	hwight@allenapharma.com
Amgen	Venkat	Yepuri	Head, Global Strategic Sourcing, Chief Procurement Officer	+1 805-447-1000	vyepuri@amgen.com
Amgen	Christina	Camacho	Senior Manager, Contract Manufacturing	+1 805-447-1000	ccamacho@amgen.com



## North American Competitors with Similar Capabilities, Equipment & Ability to Deliver on Specification

### POINT(S) OF CONTACT

10 Chief Marketing Officer

### COMPANY

### LOCATION

### THREAT LEVEL\*

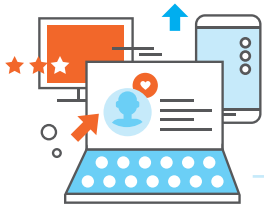
Aenova Group	Florida, USA	↗
Alcami	North Carolina, USA	★
Albany Molecular Research Inc. (AMRI)	Massachusetts, USA	↗
BioDuro	California, USA	★
Catalent/Accucaps/Pharmatek	New Jersey, USA	↗
CMIC	Massachusetts, USA	★
Contract Pharmaceuticals Limited	Massachusetts, USA	★
Corden Pharma	Colorado, USA	
CoreRx	Florida, USA	★
Famar	Ontario, Canada	↔
Halo Pharma	New Jersey, USA	↔
Lonza (Capsugel, Xcelience, Bend Research)	Florida, USA	↔
Mayne Pharma / Metrics Contract Services	North Carolina, USA	★
Mylan / Confab / DPT	Quebec, Canada	↔
Pharmaceutics International, Inc. (Pii)	Maryland, USA	↗
Piramal	New York, USA	↗
Siegfried	Pennsylvania, USA	↗
Thermo Fisher / Patheon	North Carolina, USA	↗
UPM Pharmaceuticals	Tennessee, USA	★
Wellspring	Ontario, Canada	↔

#### \*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)

### SLOW-RELEASE TABLET TECHNOLOGY

*Energizing Client Portfolios with Patient-Friendly Dosage Forms (Placed in Pharma's Almanac Q1 March 8, 2017)*

Patient noncompliance costs the pharmaceutical industry approximately \$564 billion annually. Despite the fact that patients typically prefer oral administration, one of the biggest contributors to medical nonadherence is dysphagia, or the inability to swallow traditional tablets and capsules.

### SERIALIZATION MANUFACTURING

*Rigorous Integration in a Scalable Development and Manufacturing Enterprise to Support Continued Growth of Biopharmaceuticals (Placed in Pharma's Almanac Q2 April 1, 2016)*

Over the last several years, Alcami has produced millions of parenteral fills in its small- and large-molecule sterile parenteral product manufacturing facilities that also support lyophilized products, suspensions, emulsions and terminal vial sterilization.

### ENTERIC CAPSULES

*Expanding the Commercial Options for Preparation of Amorphous Solid Dispersions (Placed in Pharma's Almanac Q1 March 8, 2017)*

A wide variety of approved polymer excipients are available for the formulation of ASDs. The specific polymer and preparation method are dictated by the characteristics of the API and the desired properties of the formulated product, including the dose and form (tablet, capsule, etc.).

### PROOF OF CONCEPT

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

Increasing API complexity has created a need for innovative formulation solutions. To rapidly reach the formulation proof of concept stage, pharmaceutical companies frequently rely on outsourcing partners with extensive formulation development experience. Because the goal is commercialization, however, many sponsors prefer to work with contract development and manufacturing organizations (CDMOs) that can readily scale those proven formulations.