Stason Pharmaceuticals, Inc.

Established 1994

High Containment Specialists

DEVELOPING PRODUCTS. BUILDING PARTNERSHIPS

March 2017

Milestones

1994	Established in California
1995-1999	3 ANDA's approved: captopril, selegiline and acyclovir
2000	Tech transfer of one ANDA to Standard in Taiwan, passed FDA inspection with zero deficiency; production area converted into high containment; began developing high-containment products, starting with mercaptopurine
2004	Expanded High Containment Manufacturing &facility in Irvine, CA.
2005	Expanded to Tokyo and Texas* Developed 1st NCE (oncology); Initiated internal oncology ANDA pipeline in addition to others
2006	High Containment Operations (HCO) expanded
2008	Initiated 2nd NCE ("CX3"); Launched the Brand Division
2010	Anastrozole approved in US and Canada; in-licensed a monoclonal antibody technology
2011	FDA granted CX3 the orphan drug status
2012	Letrozole approved in Canada
2013	Brand Div spin-off → KC Specialty Therapeutics; supplying a brand oncology product to Teva Canada
2014	Established Quinn Pharmaceuticals in Florida
2015	Bicalutamide approved; two Quinn products launched
2016	Acquired an NDA
2017	Launched an authorized generic; Aripiprazole ANDA approved

Headquarters

Irvine, California. USA

(Orange County)

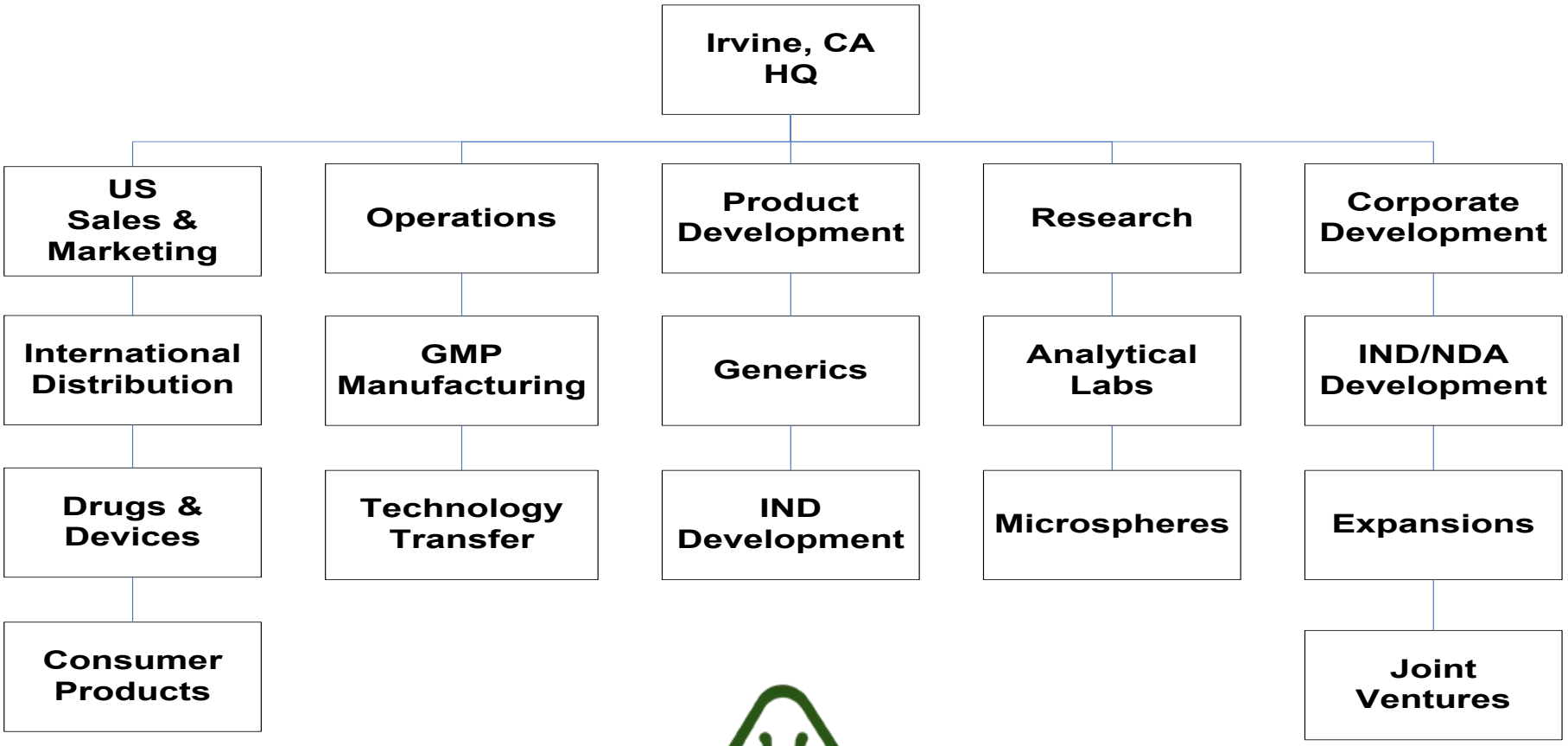
From John Wayne Airport (SNA): 20 min drive

From Los Angeles Airport (LAX): 60 min drive

Office Locations

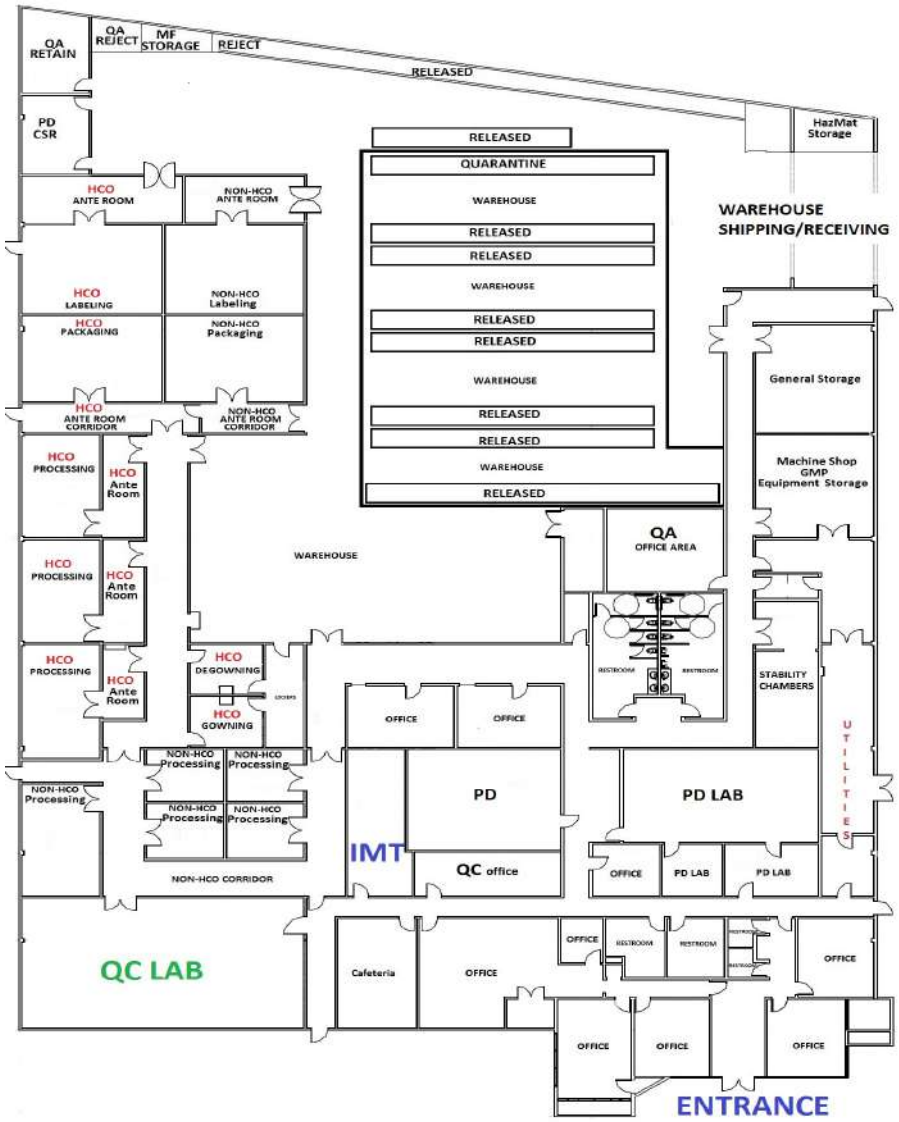
Location	Affiliates	Main Functions
California	Stason Pharmaceuticals	PD & Manufacturing
Kansas	KC Specialty Therapeutics	IND/NDA Development
Florida	Quinn Pharmaceuticals	Sales & Marketing
*Japan	Stason Pharma Japan	BD & Licensing

Company Divisions



STASON

Irvine Facility



Manufacturing:

- Facility Area: 37,000 sq. ft
- cGMP Clean Rooms: 8,750 sq. ft
- High Containment Level (<0.03µg/m3)
- Warehouse : 12,500 sq. ft

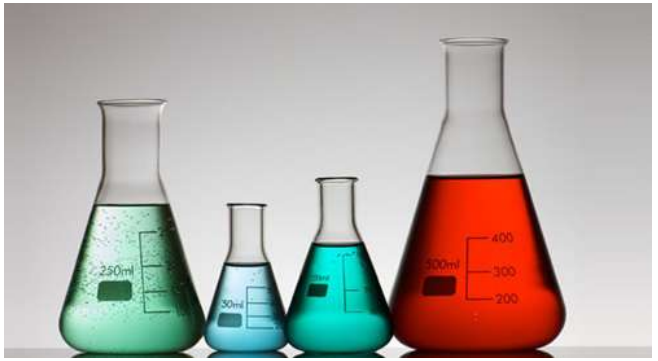
Total Number of Employees: 60

Annual Capacities:

- Tablets: 400 million
- Capsules: 200 million

Capabilities

- **High-Containment Operations**
  - Cytotoxics
  - Immunosuppressants
- **Finished Oral Solid Dosage Forms**
- **Clinical Supply & Commercial Manufacturing**
  - FDA & Health Canada Inspected Facility
- **Process Development**
  - Formulation
  - Method Development and Validation
  - Process Optimization, Global Site Transfer & Scale-Up
- **Analytical Testing**
  - QC Testing
  - Stability Studies
- **Packaging**
- Co-Development
- Contract Manufacturing
- Regulatory
- Project Management
- Distribution & Marketing



Portfolio

Oncology

Approved:	Anastrozole (US & Canada)
	Bicalutamide
	Letrozole (Canada)
	Purinethol NDA US Canada*
	Temozolomide *
In Development:	1UO** (IND) Phase I/II
	APA* (IND) Phase III
	ARS* (IND) Phase III
	Capecitabine
	Cyclophosphamide *
	Dasatinib
	Erlotinib
	Imatinib **(submitted, paragraph IV)
	Methotrexate **
	Nilutamide*

Other Categories

Approved:	Acyclovir
	Bisacodyl*
	Calcium Acetate*
	Captopril
	Carbinoxamine*
	Cyproheptadine
	Glycopyrrolate
	Mefenamic Acid*
	Repaglinide **
	Selegiline
	Aripiprazole (paragraph IV)
In Development:	CK9 (NADA): pre-clinical
	CX3** (IND) Phase I
	LOX** (505b2) injection
	Sorafenib **
	Methotrexate **

* Contracted ** Partnered

Regulatory Compliance

- July 2000 – FDA Pre-Approval Inspection (PAI)
- March 2001 – GMP Inspection
- February 2003 – PAI
- 2004-2005 – HCO Facility Expansion
- April 2006 – PAI
- October 2006 – GMP
- January 2008 – PAI
- June 2008 – PAI
- February 2009 – PAI
- December 2009 – PAI
- August 2010 – GMP
- March 2011 – PAI
- July 2012 – GMP (zero deficiency)
- February 2013 – GMP (zero deficiency)
- December 2013 – PAI
- January 2015 – PAI
- February 2016 – GMP

Experience:

- Regulatory submissions and approvals (US & Canada)
- Successful international tech transfers
- Products (owned, licensed, co-developed):
  US: 23 ANDAs, 2 INDs (out-licensed)
  Canada: 2 ANDS's approved; 1 NDS approved
- Japan Accreditation of Foreign Drug Manufacturer: AG30400487

Global Experience