

### Archimica Corporate Presentation

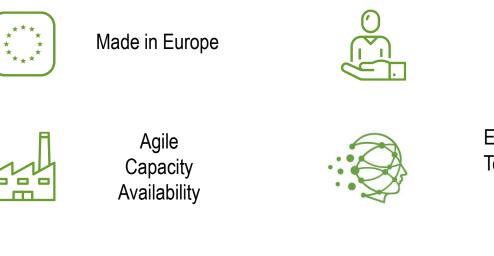
Strong. Steady. Focused on Technology.





### Archimica at a Glance - Strengths

Vast Experience with the Most Challenging Reagents, Reactions and Substance Classes Known.



Premium Client Attention

Experienced, flexible Technology Transfer, Development and Engineering Team



Highly Flexible Manufacturing and Development



### Profile

APIs/GMP Building Blocks - Process Development and Manufacturing. From Clinical to Large Commercial Scale for the Innovative and Generic Industry.

#### **Products**

APIS. Active Pharmaceutical Ingredients.

GMP/non-GMP Building Blocks.

#### Capacities

Typically: **1 to 600 mt annually.** Batch Size 25-2500 kg. synthesis steps 1-8.

Specifically: **2 to 300 mt annually.** Batch Size 50-1500 kg. Synthesis Steps 2-5.

Kilo lab **1-200 Kg annually** Batch size - 1 - 10 kg Synthesis steps 2-5

#### Portfolio

Products. Generic API Portfolio. Services. Custom Development and Manufacturing.

Broad Range of Substance/Therapeutic Classes.

#### **Regulatory/Quality**

Track Record of Successful Agency Inspections. FDA (2017), AIFA (2024).

#### Broad Scope.

Highly Flexible Permit. State-of-the-Art Environmental Protection.

### Technology/Differentiators

Small Molecules. Up to OEB4 Potency Level.

Vast Range of the Most Challenging Reagents and Reactions on Industrial Scale.

#### Company

Global Supply. More than 50 Countries Actively Supplied.

Backed by Prime Independent Investor.



### **Market Presence**

Customers are relying on Archimica's Products and Services for Quality Medicine Worldwide.

All Therapeutic Classes All Substance Classes (including Anticancer APIs)

7 Active Products24 Active Drug Master Files in 39 Countries200 Active CustomersSupplying more than 50 Countries Worldwide

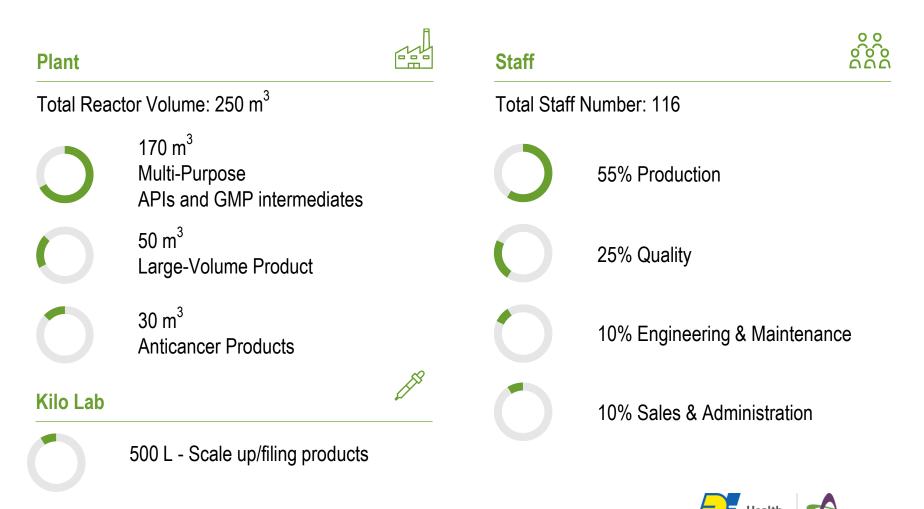
SAP™-ERP System





### **Site Overview**

Highly Flexible, Efficient, Experienced GMP Site - Located in Lodi, Italy, close to Milano



### **Manufacturing Overview**

Reactor Capacity Supported by a Vast Range of Sophisticated Ancillary Technology

#### **Reactor Capacity**



Highly Flexible Multi-Purpose Capacity. Various Materials of Construction. Stainless Steel - Glass Line - Glass - Hastelloy - Monel - Various.

Temperature Range: -20 to 160°C. Pressure Range: 10 mbar to 6 bar. Reactor Volume Range: 50 to 10.000 liters.

### **Centrifuges/Filters**



Filters: Filter Presses - Filter Dryers - Pressure Filters Centrifuges: Vertical Axis Top Discharge - Vertical Axis Bottom Discharge - Horizontal Axis Peeler

#### Dryers



Fluid Bed - Agitated Vacuum Pan -Vacuum Horizontal Agitated -Vacuum Double Cone - Planex<sup>™</sup> - Tray

#### Kilo Lab

Capable of handling: 1 to 10kg batch size Three stages of manufacturing -Glass Radley reactors ; SS reactors -Filtration & drying -Powder processing

### **Ancillary Equipment**



Sieves - Ultra Filters -Ion Exchange Chromatography Columns



### **Multi-Purpose Capabilities - Broad and Flexible**

Seamless from 100 gm to 100 mt-Scale - APIs and GMP Intermediates.

Scale	1-10 kg	>10-250 kg〉	> 1-5 mt	<b>5-20 mt</b>	<b>&gt; 5-100 mt</b>	<b>&gt; 10-100 mt</b>	0,1-100 mt			
Plant	F5	> F2B	> F5B	F6B	> F7	F2A	F3B Drying			
Reactor Size	0,05-0,1 m <sup>3</sup>	0,2-0,8 m <sup>3</sup>	3,0-4,9 m <sup>3</sup>	3,4-10 m <sup>3</sup>	0,7-6,6 m <sup>3</sup>	0,8-9,7 m <sup>3</sup>	0,1-1 m <sup>3</sup>			
Temperature Range	-20/120°C	-20/160°C -10/145°C								
Equipment	Reactors Distillation Pressure Filters		Fluid Bed, Double Cone Various							
Construction Materials	Stainless Steel Glass Line	Stainless Steel Hastelloy Monel	Stainless Steel Glass Line							
Volume Total: 170 m <sup>3</sup>	0,25 m³	2,75 m <sup>3</sup>	15 m <sup>3</sup>	20 m <sup>3</sup>	60 m <sup>3</sup>	72 m <sup>3</sup>	Volume Total 5,5 m <sup>3</sup>			



### **Therapeutic Areas and Substance Classes**

Supporting Active Pharmaceutical Ingredient Supply for All Applications.

Nitroimidazoles

**Phtalazines** 

Purine Analogues

Pyrrole Derivates

Nucleoside Analogues

Organometallic Complexes

Phospholipids, deacylated

#### **Therapeutic Areas**

Anthrachinones Benzodiazepinones Benzophenones Dibenzazepines Fluorouracils Heterocyclic Acidic Acids Heterotricyclics

### **Substance Classes**

Anti-Alzheimer, Cognition Enhancers Antiacidics, Antiulcers Antiarrhythmics Anticancers, Cytostatics Anticonvulsants Antidepressives/Anti-Epileptics Anti-Bipolar Disorders Antihistaminics, Antiallergics Antihypertensives/Vasodilators Antiinfectives Antiinflammatories Antiobesities Immunosuppressives Sucrose Sulfates/Complexes Sulfanilamides Sulfonamides Tetrazoles, Mono/Bicyclic Ureas





### **Reactions, Reagents and Solvents**

Practically unlimited capability to perform/use the most challenging reactions, reagents and solvents on small, medium and large industrial scale under GMP - a few examples.

### **Reagents/Reactions**

#### 1-500 mt/a

 $SO_3 \cdot Py$  (sulfur trioxide/pyridine) CISO<sub>3</sub>H (chlorosulfonic acid) CrO<sub>3</sub> (chromium trioxide) Ac<sub>2</sub>O (acetic anhydride) HOAc (acetic acid) Py (pyridine) AlCl<sub>3</sub> (aluminium chloride) POCl<sub>3</sub> (phosphorous oxychloride)

#### 1-100 mt/a

NH<sub>2</sub>OH (hydroxylamine) NaOCN (sodium cyanate) Natural source materials (lecithin, aloine)

### $N_2H_4$ (hydrazine) NH<sub>3</sub> (ammonia) HCHO (acetaldehyde) HCOOH (formic acid) HF/HCI/HBr (hydrogen halides) KCN (potassium cyanide) CH<sub>3</sub>N (trimethylamine) F<sub>2</sub>/Cl<sub>2/</sub>Br<sub>2</sub> (halogen gases) H<sub>2</sub> (hydrogen) CH<sub>2</sub>O (ethylene oxide)

**Dess-Martin Periodinane** 

R-SO<sub>2</sub>CI (sulfonyl chlorides)

Ag/Au/Cu-salts (precious metals)

Styrene oxide







1-500 mt/a
Dimethylacetamide
Ethanol
Acetone
Cyclohexane
Isopropanol
Methanol

#### 1-100 mt/a

Methylene chloride 1,2-Dichloropropane Tetrachloromethane Dimethylformamide



### **Generic API Portfolio**

Archimica Continuous API Supply Worldwide.

**Active Pharmaceutical Ingredients (APIs)** 

Anticancer Cytarabine (nucleoside analogue) - CEP Hydroxyurea (modified urea) - CEP

Antirheumatic Diacerein (anthraquinone) - CEP

Antipsychotic Mianserin (tetracyclic) – CEP ongoing Oxcarbazepine (dibenzazepine)

Antiacidic/Antiulcer Sucralfate (saccharose sulfate)

Antiinfective Sulfathiazole (sulfonamide)





### **Generic API Portfolio**

Archimica Continuous API Supply Worldwide.

**Products on Request - Active Pharmaceutical Ingredients (APIs)** 

More than additional 20 Active Pharmaceutical Ingredients (APIs) available from Archimica's Experience - including Customer-Specific Development - a selection

Bromfenac – EUDMF/USDMF Capecitabine – EUDMF/USDMF Citicoline – EUDMF Dihydralazine sulfate – EUDMF Disopyramide – EUDMF Hydralazine hydrochloride – EUDMF/USDMF Lithium Carbonate – EUDMF/USDMF Pirenzepine Dihydrochloride - EUDMF/USDMF Sulfapyridine – EUDMF/USDMF Thenfadil – EUDMF





## **Quality System, Inspections, Certificates**

Sucessfully Inspected and Accepted Worldwide.





### **Infrastructure - Operating Permits**

Integrated Responsibility for Environment, Health and Safety.

**Environment & Health** 



Residual Thermal Oxidizer. All Waste Gas Streams.

Wastewater Treatment on Site. Backed by External Partners.

Solvent Recovery. Backed by Flexible Tank Farms. Safety



IPPC-based Authorization. Integrated Pollution Prevention and Control. Highly flexible and broad permit for all technologies, reagents and solvents.

Compliance with IED Directive 2010/75/UE. Best Available Technology.

Compliance with Directive 105/15 2012/18/EU. Seveso Directive. Prevention and Control of On-Shore Major Accident Hazards involving Dangerous Substances.



## History

Archimica's Evolution - 77 Years of Continuity of Supply into the World's Pharmaceutical Market.

1947	>	1984	>	2008	>	2012	>	2016	>	2019	>	2023
Foundation of Istituto Chemioterapico Italiano (I.C.I.)	Т	Foundation of Prime European herapeuticals p.A (Euticals)		Mandarin Capital Partners becomes Majority		Clessidra, an Italian Financial Fund becom Majority		AMRI acquires Euticals Group	l	via acquires odi Site, it becomes Archimica		PI HEALTH SCIENCES Acquires chimica S.p.A
	0.			Euticals Shareholder		Euticals Shareholde	er			LIVIA I NTERNATIONAL VENTURES & I NVESTMENT ACTIVITIES	F	Health Sciences

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