Valpharma GROUP

VALPHARMA S.p.A.

VALPHARMA INTERNATIONAL S.p.A.

ERBA VITA GROUP S.p.A.

Agenda

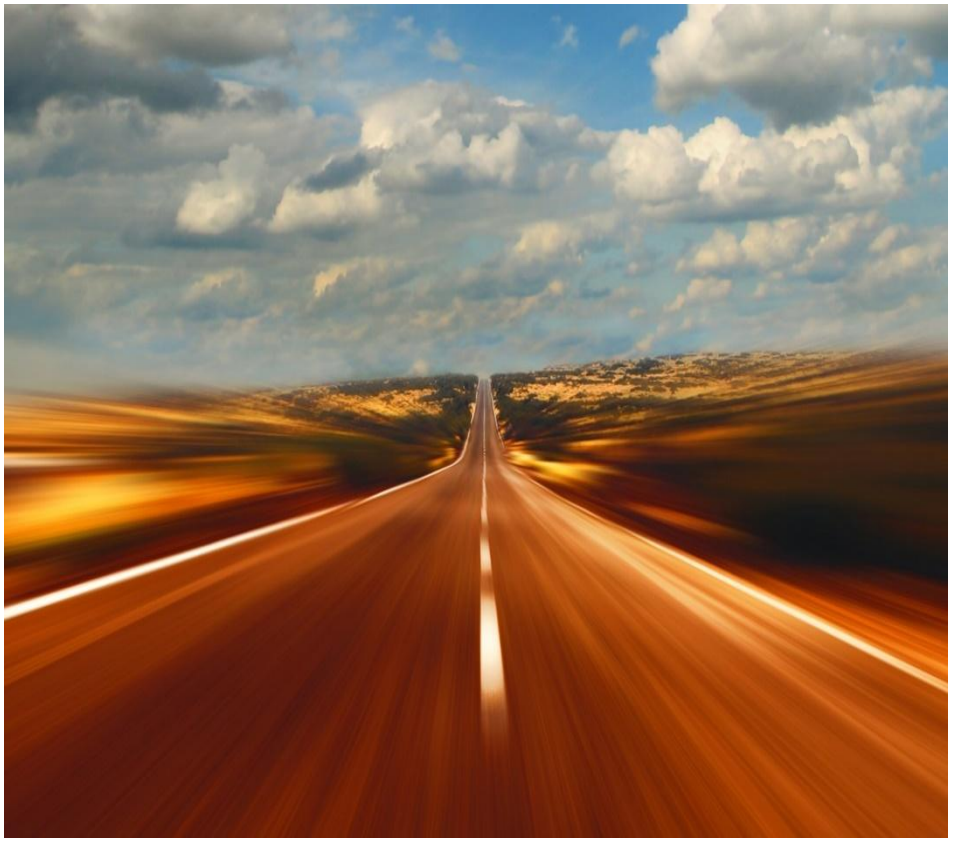
- Company presentation
- Innovation in Pharmaceutical activities_[**Products and Services**]
- Innovation lead by Sustainability_[Industrial and Operational impacts]
- Valpharma Green project_[Reason and Expectation]

WHO WE ARE

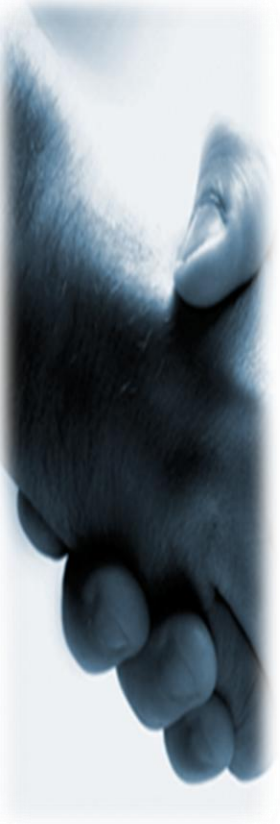
- A privately owned, European provider, specialized in development and supply of finished oral solid dosage forms;
- Innovative solutions for sustained release forms;
- A reliable partner with flexible manufacturing capabilities;
- Clinical and commercial demand for large volumes;
- PT RD group to develop together with our customers complex solid oral dosages;
- 10% of annual turnover invested in product development and technology innovation

OUR VISION

We contribute to the Health and Wellness of human being by pursuing and developing a sustainable business model in the pharmaceutical and nutraceutical sector, in relation to oral solid products with modified release and phytotherapeutic products.



VALUE TO OUR CUSTOMERS



Close collaboration;

Open and transparent dialogue with pharmaceutical industries all over the world, including the most important multinationals;

Consolidated business based on signed agreements (more than 500), with a combined manufacturing capacity of 1,6 billion solid oral doses/year;

and 300 products developed;

in 50 years of experience.

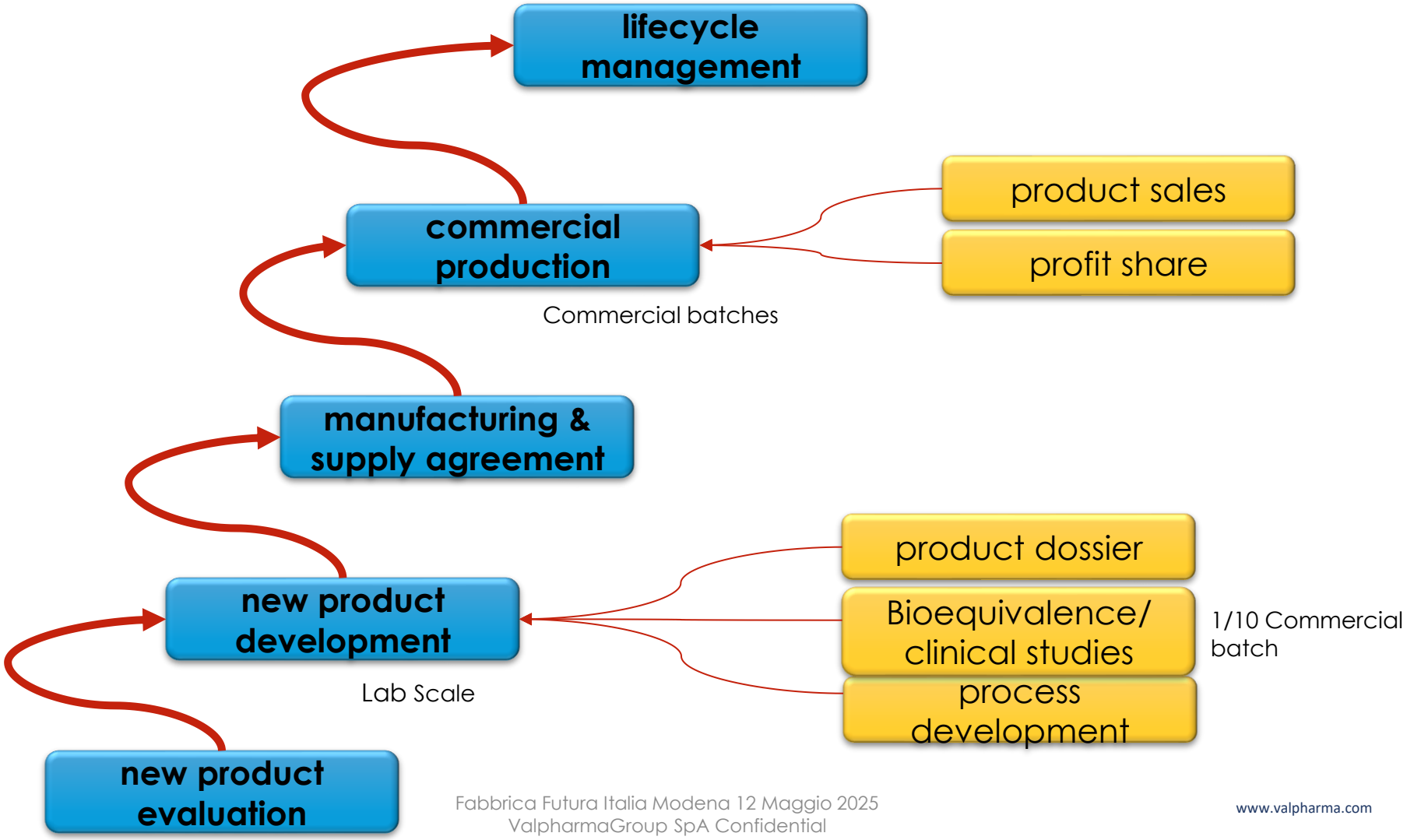
Sustainability RoadMap

to be re-evaluated within July 2025

Sustainability Business Practises

- **Ecovadis Ratings**: 52/100

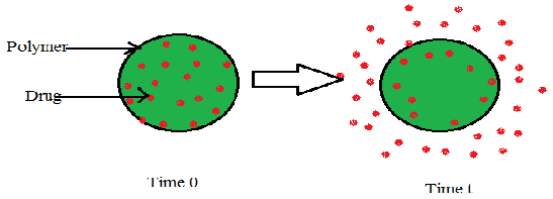
How We Operate



FORMULATION TECHNOLOGIES

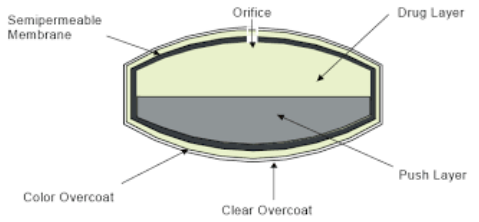
- Powder and granulates
  Amourphous spray dryed Nifedipine/PVP aggregate
  Enhance of Solubility/Taste masking of APIs by Hot Melt Extrusion

- Matrix tablets Delayed release achieved by excipients that physically create a barrier in the release of the API from the formulation.
  COMMERCIAL STAGE PRODUCTS:
  Gliclazide 30-60 mg Tablets
  Nifedipine 30-60 mg Tablets
  Pentoxifylline 400 mg Tablets



- Capsules and Stickpacks containing Pellets Microspheres containing Active Principle, then retarded by coating with low solubility polymers.
  COMMERCIAL STAGE PRODUCTS:
  Diltiazem HCl 200-300mg Capsules
  Isosorbide-5-mononitrate 50-80 mg Capsules
  Mesalazine 1500mg Sticks
  Esomeprazole Mg Trihydrate 20-40 mg Capsules (stage: RD- BE completed)

- *OROS (Osmotic Release Oral System) tablets By-layer tablets with 0-order kinetics controlled by an osmotic system.*
  COMMERCIAL STAGE PRODUCTS
  Nifedipine 30-60 mg Tablets OROS
  Oxybutynin 7.5-15 mg Tablets OROS (stage: RD)
  Doxazosin Etexilate Mesylate 4-8 mg Tablets OROS (Stage RD)
  Methylphenidate HCl 18-27-36-54 mg Tablets OROS (stage: RD)



FORMULATION TECHNOLOGIES

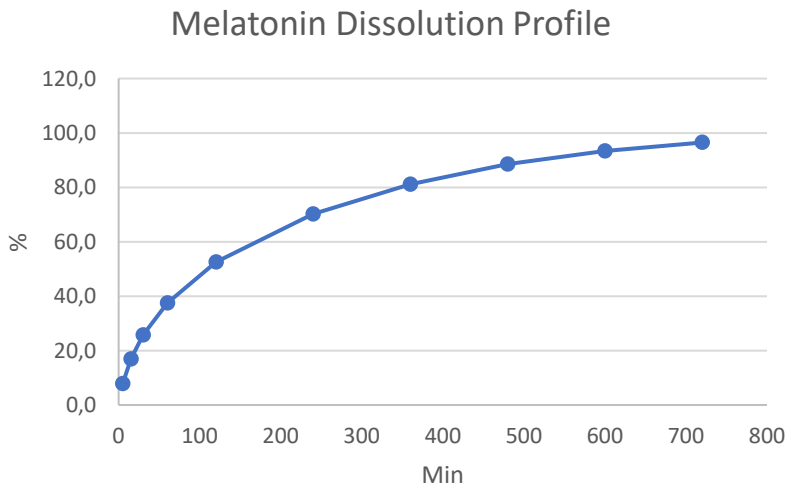
- MUPS tablets (Multiple Unite Pellets System)
  Pellets inserted into tablets.
  COMMERCIAL STAGE PRODUCTS
  Esomeprazole Mg Dihydrate 20-40 mg Tablets MUPS
  Theophyllinea 200-300 mg Tablets MUPS

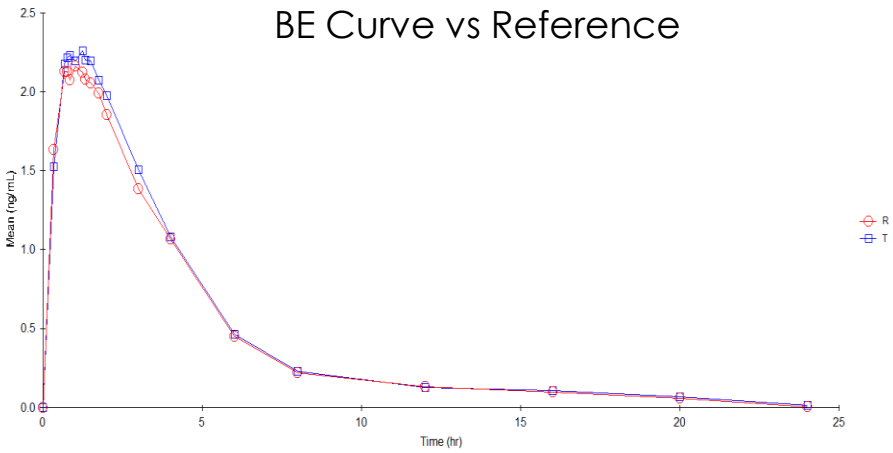
- Orally Disintegrating Tablets
  ODTs be considered solid oral preparations that disintegrate rapidly in the oral cavity, with an in-vitro disintegration time of approximately 30 seconds or less,

- Multi-layer tablets
  Tablets having several layers, able to give the same formulation several degrees of release (immediate + delayed, faster delay + slower delay, etc.).

Melatonin 2 mg tablet ER

- Melatonin ER tablet (Matrix Tablets)
- Unmet need
  - Monotherapy for the short-term treatment of primary insomnia characterized by poor quality of sleep in patients who are aged 55 or over.
    Dose: 2 mg once daily, 1-2 hours before bedtime and after food. This dosage may be continued for up to thirteen weeks.
    Modified-release melatonin causes the blood concentration over time to more closely mimic a naturally occurring melatonin profile.





Valpharma International S.p.A.

Valpharma International S.p.A. grass-root plant with enlarged capacity, surface 45‘000 m^2 employs today approx. 200 staff and offers large spaces for further expansion and technology specialization

Valpharma International offers for Pharmaceutical Products :

- Powders,
- Granules,
- Tablets,
- Film-coated tablets,
- Pellets for hard gelatine capsules
- Blister‘s Packaging line.

Valpharma San Marino Plant

- Valpharma San Marino Plant employs 136 people and operates on a surface of 6‘000 m^2. Valpharma produces and offers:

- Powders
- Granules
- Tablets
- Film-coated tablets
- Pellets which can be filled into hard gelatine capsules

Regulatory & Compliance

International Authorizations issued to Valpharma Group

Valpharma Group can reach its partners and clients everywhere, to meet all requests and needs, always working with **certification regulators and the authorization of worldwide health authorities.**

AIFA Italia

ANVISA Brazil

MHLW Japan

Ministry of Health Care Russia

United Arab Emirates

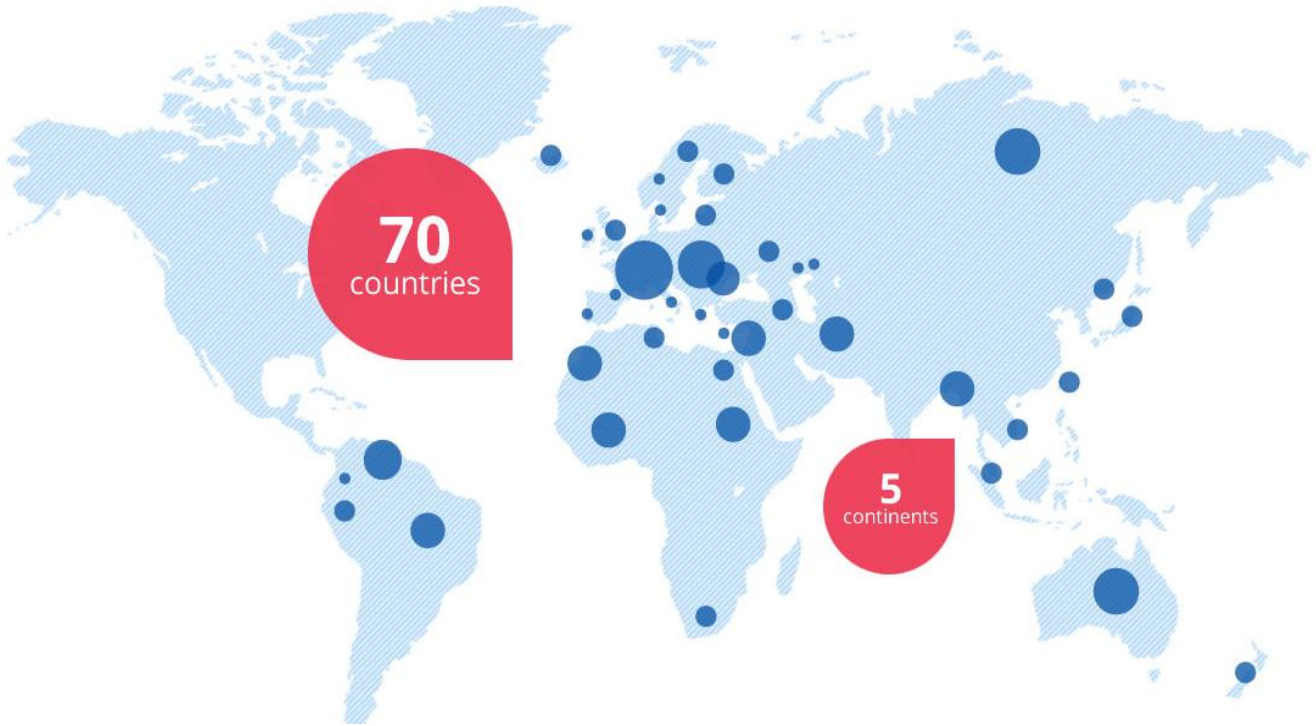
NMPA China

Iranian Health Authority

F.D.A. Taiwan

Ivory Coast Health Authority

Worldwide footprint



Valpharma's modified release products were granted marketing authorizations by many national authorities and are sold with success in 5 continents and in more than **70 countries**.

www.valpharma.com

Innovation by product:

a) Me too: develop of new generic drug product identifing challenging products in term of Delivery Technologies or Equipment to avoid clones (Cmax; Tmax; T1/2)

b) Me better: identify niche or needs (patient side) to improve the originator:
Dose Regimen
Taste
Tolerability
Side Effects (nausea; dizziness; peak effect; etc)
Swallow

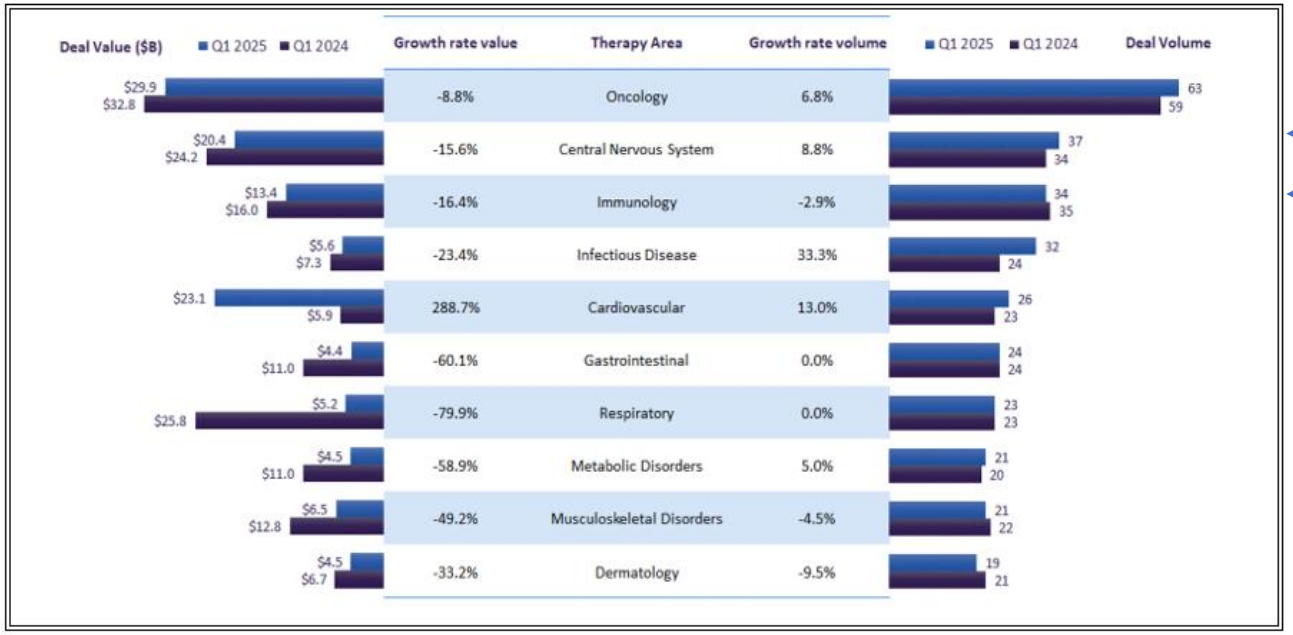
e) Life Cycle Management to constantly monitor new regulatory requirements mostly at supply aspects to avoid any commercial discontinuity (impurities; organic solvent reduction; reduce of water; new packaging solution)

c) Repurposing Develop new formulation using well known Active Pharmaceutical Ingredient to treat new pathologies; (by partner or co-development)

Innovation by product_ therapeutic trends in M&A

GlobalData.

Figure 12: Top 10 Therapy Area M&A Review

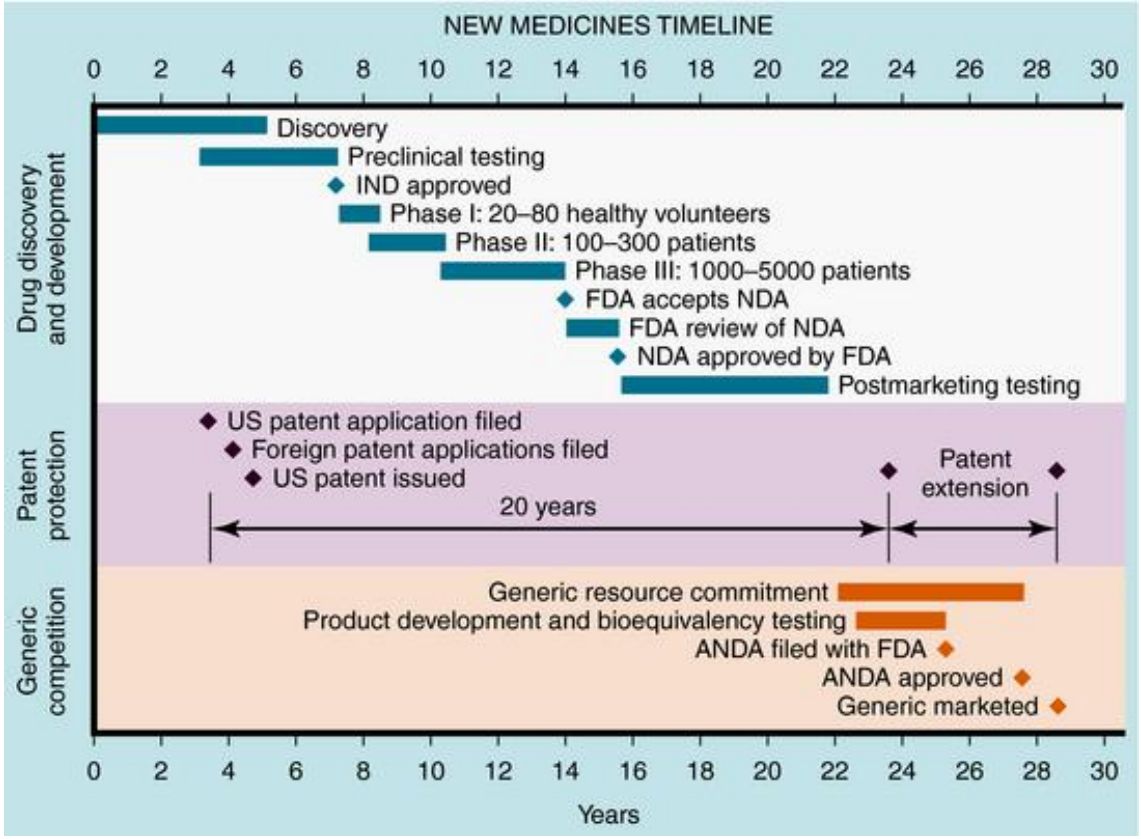


Deal Value ($B) Q1 2025	Deal Value ($B) Q1 2024	Growth rate value	Therapy Area	Growth rate volume	Deal Volume Q1 2025	Deal Volume Q1 2024
$29.9	$32.8	-8.8%	Oncology	6.8%	63	59
$20.4	$24.2	-15.6%	Central Nervous System	8.8%	37	34
$13.4	$16.0	-16.4%	Immunology	-2.9%	34	35
$5.6	$7.3	-23.4%	Infectious Disease	33.3%	32	24
$23.1	$5.9	288.7%	Cardiovascular	13.0%	26	23
$4.4	$11.0	-60.1%	Gastrointestinal	0.0%	24	24
$5.2	$25.8	-79.9%	Respiratory	0.0%	23	23
$4.5	$11.0	-58.9%	Metabolic Disorders	5.0%	21	20
$6.5	$12.8	-49.2%	Musculoskeletal Disorders	-4.5%	21	22
$4.5	$6.7	-33.2%	Dermatology	-9.5%	19	21

Global M&A and licensing deals are influencing access to new therapies

This slide extracted on : 27 May 2025

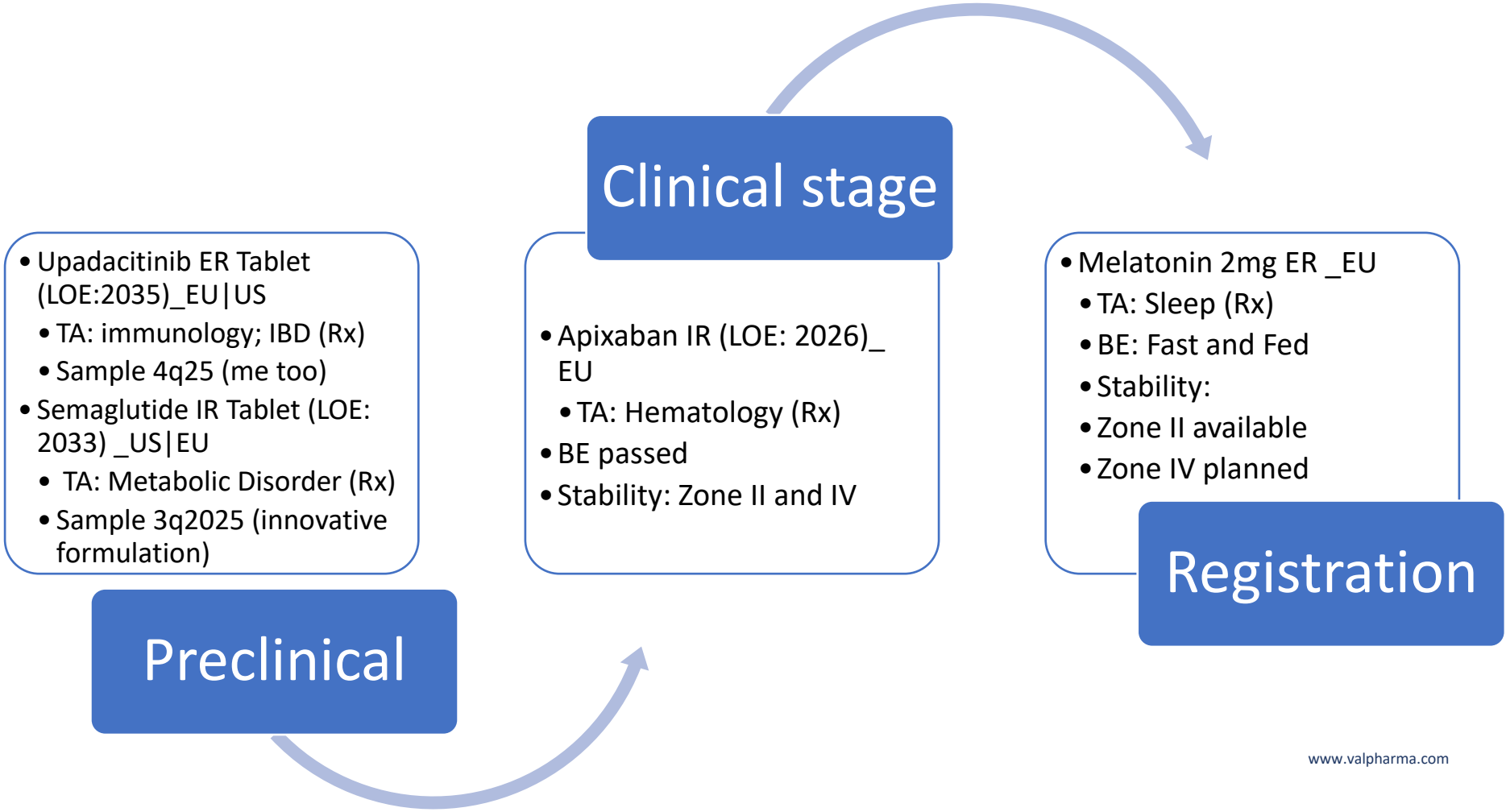
Innovation by product_generic & innovators



Efficiency in project development to meet stringent deadline and make available dossier at DAY=0

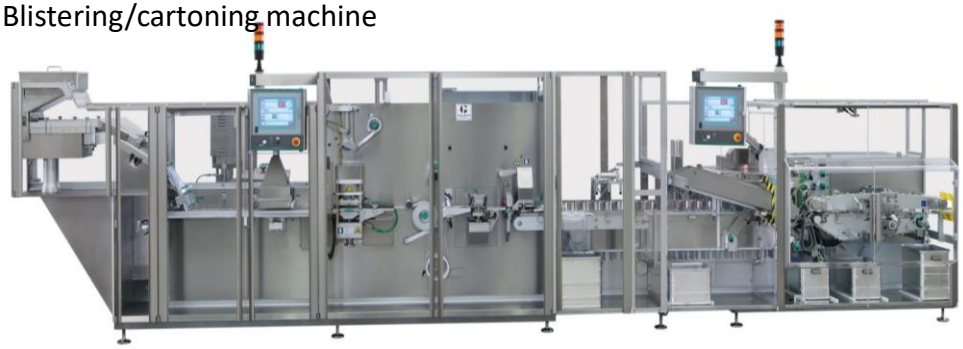
Drug Development, Regulation, and Prescription Writing | Basicmedical Key

Current Gx Product Pipeline



Innovation as capabilities extension

Blistering/cartoning machine



Labelling Machine

Casepacker

Approx 3 mln € of direct investment to establish new production line:

Cost of Packaging line: 1,9 million euros

Cost of Packaging department : 1 million euros

Demand to reduce supply chain (for state of the art technologies) is one of the main driver of sustainability topics in Pharmaceutical;

New packaging line: Project_Milestones

Main Milestones:

▪ End of line installation:	June 2022	(Completed)
▪ End of line packaging validation :	June 2023	(Completed)
▪ AIFA line inspection and authorization:	Mar 2025	(Completed)
▪ **Start of supply within**	**Q32025**	**(Planned)**

Valpharma has planned to start commercial packaging supply within q3 2025

confidential

Innovation in Industrial Operation
_ Valpharma **Green** project

Innovation in Industrial Operation
_ Valpharma **Green** project

Reason to **change**

- Obtain maximal **Environmental Sustainabilty**
- Value local **Energy provider**
- **Reduce Emission of Gas** driving greenhouse effect
- Adopt **Efficiency and Containment approach** of energy **maintenance costs** and maintenance
- **Improve** quality of Electrical Energy

Innovation in Industrial Operation
_ Valpharma **Green** project

Risultati attesi

	ANTE	POST	RISULTATO
Gas Naturale [TEP]	1.246	370	- 876
Energia Elettrica prelevata da rete [TEP]	804	724	- 80
Energia Elettrica autoprodotta da FV [TEP]	0	314	+ 314
Consumo Totale [TEP]	2.050	1.408	- 642
CO_2 emessa [ton]	4.636	3.241	- 1.395
Reflui conferiti [ton]	2.073	145	- 1.928

Innovation in Industrial Operation _ Valpharma **Green** project

Total amount investment	8.0 mln €
Subsidized finance	3 mln €
Expected saving	1,5 mln €

Partner: MIMIT; Invitalia; Unicredit; Banca Intesa;
Industrial partner: SGR

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