

**USA**

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**PRODUCT  
CATALOGUE**  
2025



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# 1. COMPANY PROFILE

Pharmathen is one of the leading developers of complex drug delivery systems and advanced formulations, leveraging proprietary in-house technologies to improve patient compliance and make high-quality, affordable medicines accessible to global markets.

Today, we proudly serve a broad network of more than 250 partners in over 90 countries across Europe, North America, South America, the Middle East, Asia, Australasia, and Southern Africa. Our diverse portfolio includes over 100 products, supported by one of the industry's most extensive and advanced pipelines of Long-Acting Injectables (LAI) and other complex dosage forms, such as peptides, sustained-release oral solids, and ophthalmic formulations. These are produced in our US FDA and EU-approved manufacturing facilities in Greece and through our global contract manufacturing network.

MANUFACTURING  
SITE SAPES RODOPI





Ranked among the top 50 pharmaceutical research companies in Europe, Pharmathen is also one of the largest private-sector investors in research and development in Greece, consistently investing close to €50 million annually. These continuous investments keep us at the forefront of innovation, enabling us to expand market access and strengthen partnerships worldwide, bringing more affordable, high-quality medicines to patients everywhere. We proudly employ more than 1,600 people representing over 24 nationalities across 9 locations. Our shared commitment to creativity, ethics, and reliability drives our vision of “making a difference in people’s lives.”

HEADQUARTERS  
MAROUSSI



## 2. PRODUCT PORTFOLIO - ANDAs

### a) Long Acting Injectables (proprietary technologies)

With the foundation of the three key in-house technologies these developments are geared to support the improvement and effectiveness of drug therapy and patient compliance.

PRODUCT (Reference drug)	PHARMACEUTICAL FORM & TECHNOLOGY	STRENGTHS	KEY INDICATION(S)	DEVELOPMENT STATUS
ARIPIPRAZOLE (Abilify Maintena®)	Long-acting Injectable Nanosuspension	300mg/vial 400mg/vial 300mg/syringe 400mg/syringe	Schizophrenia	Submitted
				Under development
ARIPIPRAZOLE LAUROXIL (Aristada™)	Long-acting Injectable Nanosuspension	441mg/syringe 662mg/syringe 882mg/syringe 1064mg/syringe	Schizophrenia	Under development
ARIPIPRAZOLE LAUROXIL INITIO (Aristada™)	Long-acting Injectable Nanosuspension	675mg/syringe	Schizophrenia	Under development
BUPRENORPHINE (Brixadi®)	Long-acting Injectable  In situ forming liquid crystalline gel (Fluid Crystal formulation technology)	WEEKLY: 8 mg/0.16 ml 16 mg/0.32ml 24 mg/0.48 ml 32 mg/0.64 ml	Moderate to severe opioid use disorder	Under development
		MONTHLY: 64 mg/0.18 ml 96 mg/0.27 ml 128 mg/0.36 ml		
BUPRENORPHINE (Sublocade®)	Long-acting Injectable  In situ forming solid implant	MONTHLY: 100 mg 300 mg	Moderate to severe opioid use disorder	Under development

PRODUCT (Reference DRUG)	PHARMACEUTICAL FORM & TECHNOLOGY	STRENGTHS	KEY INDICATION(S)	DEVELOPMENT STATUS
CABOTEGRAVIR (Apretude®)	Long-acting injectable Suspension	Single-dose vial of 600 mg/3 mL (200 mg/mL) of cabotegravir extended-release injectable suspension	HIV-1 PrEP	Under development
CABOTEGRAVIR RILPIVIRINE (Cabenuva)	Long-acting Injectable (2-drug co-packaged product) Suspension	400-mg/600-mg Kit: • single-dose vial of 400 mg/2 mL cabotegravir • single-dose vial of 600 mg/2 mL rilpivirine 600-mg/900-mg Kit: • single-dose vial of 600 mg/3 mL cabotegravir • single-dose vial of 900 mg/3 mL rilpivirine	Human immunodeficiency virus (HIV-1) infection	Under development
EXENATIDE (Bydureon BCise®)	Long-acting Injectable PLGA microparticles	2mg/auto-injector (BCise)	Improve glycemic control in adults with type 2 diabetes mellitus (Adjunct to diet and exercise)	Under development
LANREOTIDE (Somatuline Depot®)	Long-acting Injectable Nano-gel	60mg/syringe 90mg/syringe 120mg/syringe	Acromegaly; gastroenteropancreatic neuroendocrine tumors (GEP-NETs)	Commercialized

PRODUCT (Reference drug)	PHARMACEUTICAL FORM & TECHNOLOGY	STRENGTHS	KEY INDICATION(S)	DEVELOPMENT STATUS
LEUPROLIDE (Lupron Depot®)	Long-acting Injectable PLGA/PLA microparticles	Dual Chambered Syringe 3.75mg/syringe 7.5mg/syringe (1 month)	<ul style="list-style-type: none"> <li>• Endometriosis and uterine leiomyomata (Fibroids) (3.75mg)</li> <li>• Advanced prostatic cancer (7.5mg) (palliative treatment)</li> </ul>	Under development
		Dual Chambered Syringe 11.25mg/syringe 22.5mg/syringe 30mg/syringe (3 month)	<ul style="list-style-type: none"> <li>• Endometriosis and uterine leiomyomata (Fibroids) (11.25mg)</li> <li>• Advanced prostatic cancer (22.5mg and 30mg) palliative treatment</li> </ul>	Under development
		Dual Chambered Syringe 45mg/syringe (6 month)	Advanced prostatic cancer (palliative treatment)	Under development
NALTREXONE (Vivitrol®)	Long-acting Injectable PLGA microparticles	380mg/vial	Alcohol dependence; prevention of relapse to opioid dependence	Approved
OCTREOTIDE (Sandostatin® Lar Depot)	Long-acting Injectable PLGA microparticles	10mg/vial 20mg/vial 30mg/vial	<ul style="list-style-type: none"> <li>• Acromegaly</li> <li>• Severe diarrhea/flushing episodes (metastatic carcinoid tumors),</li> <li>• Profuse watery diarrhea (VIP-secreting tumors)</li> </ul>	Commercialized
PALIPERIDONE PALMITATE 1M (Invega Sustenna®)	Long-acting Injectable Nanosuspension	25mg/syringe 50mg/syringe 75mg/syringe 100mg/syringe 150mg/syringe	Schizophrenia	Submitted

PRODUCT (Reference drug)	PHARMACEUTICAL FORM & TECHNOLOGY	STRENGTHS	KEY INDICATION(S)	DEVELOPMENT STATUS
PALIPERIDONE PALMITATE 3M (Invega Trinza®)	Long-acting Injectable Nanosuspension	175mg/syringe 263mg/syringe 350mg/syringe 525mg/syringe	Schizophrenia	Under development
PALIPERIDONE 6M (Invega Hafyera™)	Long-acting Injectable Nanosuspension	700mg/syringe 1000mg/syringe	Schizophrenia	Under development
PASIREOTIDE (Signifor® Lar)	Long-acting Injectable PLGA microparticles	20mg/vial 40mg/vial 60mg/vial	Acromegaly	Under development
RISPERIDONE (Risperdal Consta®)	Long-acting Injectable PLGA microparticles	12.5mg/vial 25mg/vial 37.5mg/vial 50mg/vial	Schizophrenia	Commercialized
TRIAMCINOLONE ACETONIDE (Zilretta®)	Long-acting Injectable PLGA microparticles	32mg/vial	Osteoarthritis pain of the knee	Under development
TRIPTORELIN PAMOATE 3M (Trelstar®)	Long-acting Injectable Suspension	22.5 mg	Advanced prostate cancer (palliative treatment)	Under development



## b) All other Formulations

Driven by strong research, innovation and IP protection covering multiple therapeutic areas and market segments.

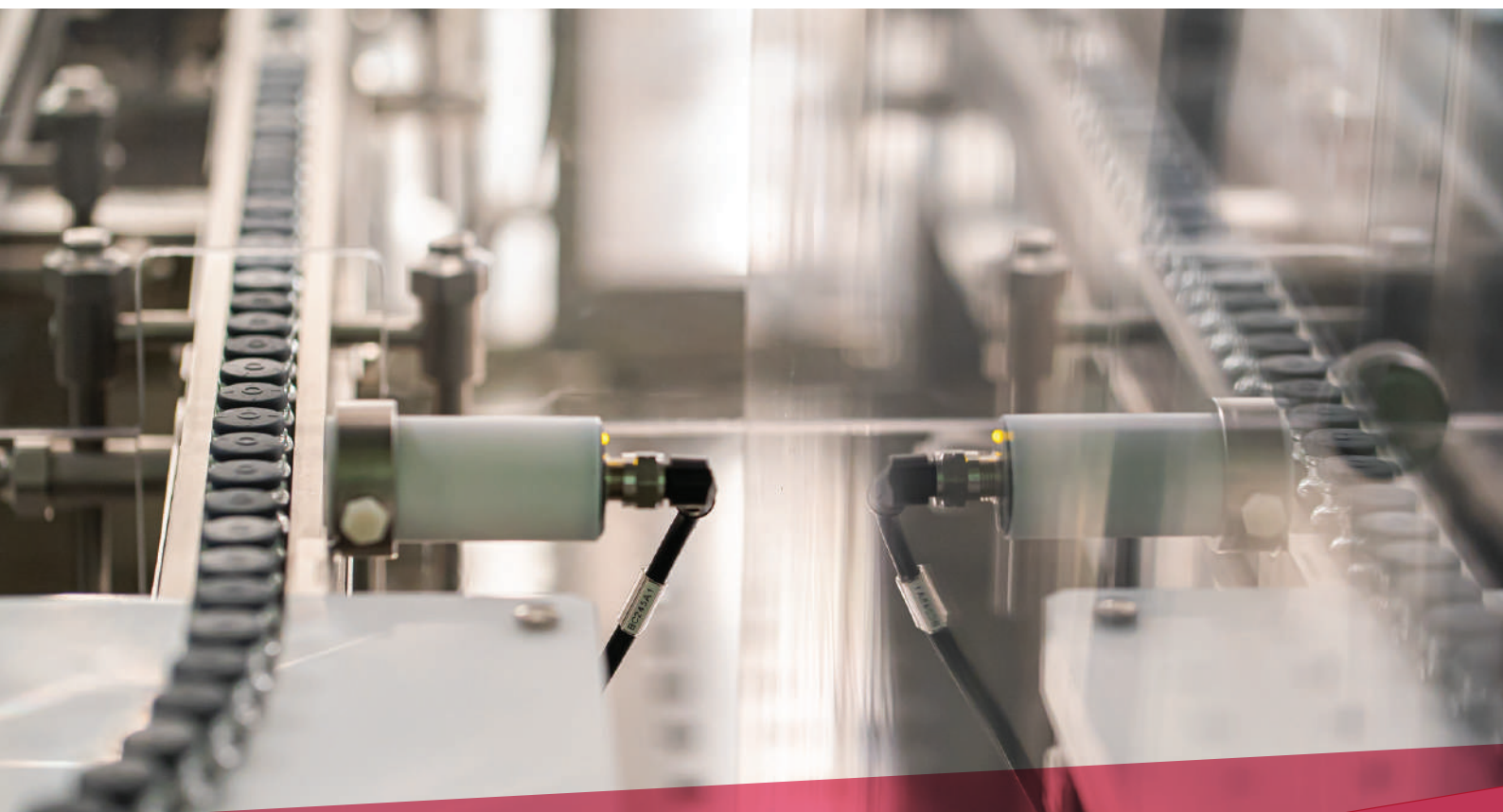
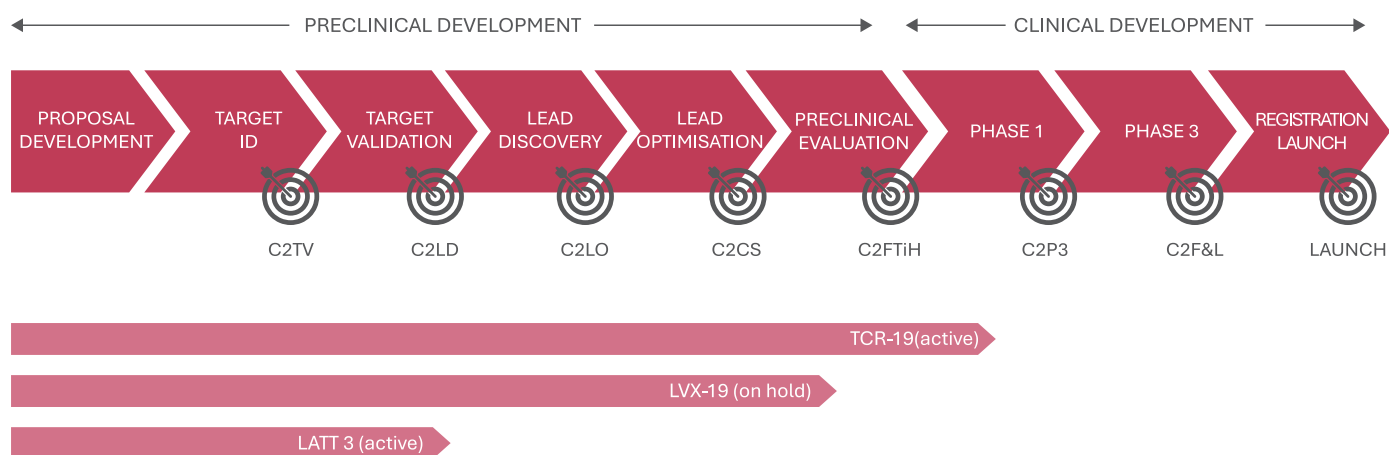
PRODUCT (Reference drug)	PHARMACEUTICAL FORM	STRENGTHS	DEVELOPMENT STATUS
APREPITANT (Emend®)	Capsules	40mg, 80mg, 125mg	Commercialized
BRINZOLAMIDE (Azopt®)	Ophthalmic suspension	10mg/ml	Commercialized
BRINZOLAMIDE BRIMONIDINE (Simbrinza®)	Ophthalmic suspension	2mg/ml 10mg/ml	Approved
DIMETHY FUMARATE (Tecfidera®)	Delayed-release capsules	120mg 240mg	Commercialized
FINERENONE (Kerendia®)	FC Tablets	10mg 20mg	Under development
IRON SUCROSE (Venofer®)	Injection	50mg/2.5ml, 100mg/5ml or 200mg/10ml (20mg/ml) in single-dose vials	Under development
INCLISIRAN (Leqvio®)	Solution for injection	284 mg/1.5 ml	Under development
LIRAGLUTIDE (Victoza®- Saxenda®)	Solution for injection in pre-filled pen	6mg/ml	Under development
LINACLOTIDE (Linzess®)	Hard capsules	72 mcg 145 mcg 290 mcg	Under development

PRODUCT (Reference drug)	PHARMACEUTICAL FORM	STRENGTHS	DEVELOPMENT STATUS
NUSINERSEN (Spinraza®)	Injection	12mg/5ml (2.4mg/ml)	Under development
PALIPERIDONE (Invega®)	Prolonged-release tablets	1.5mg, 3mg, 6mg, 9mg, 12mg	Submitted
PATISIRAN (Onpattro®)	Solution for injection	10mg base/5 ml	Under development
RIFAXIMIN (Xifaxan®)	Tablets	200mg 550mg	Under development
SEMAGLUTIDE (Ozempic®)	Injection, for subcutaneous use	Single dose: 0.25mg, 0.5mg, 1mg, 2mg, Dual dose: 0.25mg, 0.5mg 0.68mg/mL, 1.34mg/ml	Under development
SEMAGLUTIDE (Wegovy®)	Injection, for subcutaneous use	0.25mg, 0.5mg, 1mg, 1.7mg, 2.4mg solution for injection in pre-filled pen-dispos- able autoinjector  0.25mg, 0.5mg, 1mg, 1.7mg, 2.4mg solution for injection in pre-filled pen-Flex Touch	Under development
SEMAGLUTIDE (Rybelsus®)	Tablets	3 mg 7 mg 14 mg	Under development
TACROLIMUS SR (Envarsus®)	Prolonged-release tablets	0.75mg 1.0mg 4mg	Under development

# 3. PRODUCT PORTFOLIO - 505(B)(2)S

## a) Long-Acting Therapeutic Technologies

Pharmathen is leveraging its expertise in Long-Acting Injection formulation technologies to develop a novel portfolio of non-generic products – our Long-Acting Therapeutic Technologies (“LATT”) program. The aim is to reformulate existing medicines currently in various dosage forms into Long Acting Injectables, serving unmet patient needs. We are currently developing a carefully selected basket of LATT products across multiple therapeutic areas, and plan to expand this portfolio in further therapeutic areas in the near future.





## b) Preservative-free Ophthalmics in multi-dose vials

Supporting the advancement in the eye-care market and treatments, through improved patient convenience and tolerance. The entire portfolio is currently commercialized in other regulated markets like EU.

PRODUCT	PHARMACEUTICAL FORM	STRENGTHS
BIMATOPROST PRESERVATIVE FREE	Eye drops solution multi-dose bottle	0.3mg/ml 0.1mg/ml
BIMATOPROST TIMOLOL PRESERVATIVE FREE	Eye drops solution multi-dose bottle	0.3mg/ml 5mg/ml
BRIMONIDINE PRESERVATIVE FREE	Eye drops solution multi-dose container	2mg/ml
BRINZOLAMIDE PRESERVATIVE FREE	Eye drops suspension multi-dose container	10mg/ml
CHLORAMPHENICOL PRESERVATIVE FREE	Eye drops solution multi-dose container	5mg/ml
DEXAMETHASONE PRESERVATIVE FREE	Eye drops solution multi-dose container	1mg/ml
DORZOLAMIDE/ TIMOLOL PRESERVATIVE FREE	Eye drops solution multi-dose container	5mg/ml 20mg/ml
DORZOLAMIDE PRESERVATIVE FREE	Eye drops solution multi- dose container	20mg/ml
LATANOPROST PRESERVATIVE FREE	Eye drops solution multi-dose container	0.05mg/ml
LATANOPROST TIMOLOL PRESERVATIVE FREE	Eye drops solution multi-dose container	0.05mg/ml 5mg/ml
TIMOLOL PRESERVATIVE FREE	Eye drops solution multi-dose container	2.5mg/ml 5mg/ml
TRAVOPROST PRESERVATIVE FREE	Eye drops solution multi-dose container	30mcg/ml 40mcg/ml
TRAVOPROST & TIMOLOL PRESERVATIVE FREE	Eye drops solution multi-dose container	40mcg/ml 5mg/ml

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