



✚ Pharmathen

2023

**USA PRODUCT
CATALOGUE**



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1 Company Profile

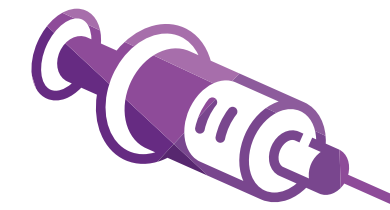
We are one of the leading complex drug delivery and formulation developers, using our key in-house technologies to support improved patient compliance. We service a broad partner network of 250+ customers in 90+ countries throughout Europe, North America, South America, Middle East, Asia, Australasia and Southern Africa.

Our portfolio consists of over 100 products, and today we are working on one of the most extensive and advanced pipelines of Long Acting Injectables (LAI) and other complex injectables, Sustained Release Oral Solid and Ophthalmic formulations, both Preserved and Preservative free, produced in our US-FDA and EU-approved manufacturing facilities.

We have fully validated to commercial scale multiple LAI in each of the three major LAI technology platforms (Microspheres, Nanosuspensions and Nano-Gels), and have registered these products with regulatory authorities in multiple countries globally. These platforms now support the enrichment of our pipeline with the addition of Long-Acting Therapeutic Technologies (LATT) which will target enhanced patient compliance for existing drug delivery therapies and methods, and support product Life Cycle Management (LCM) opportunities. In addition, through the utilization of these key technologies, we're offering B2B partnering solutions either for new drug candidates or your own LCM LATT candidates.

We proudly employ more than 1,300 people from over 22 different nationalities across 9 locations. Through our everyday activities and drug delivery advancements we remain committed to our vision "to make a difference in people's lives".





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	PHARMACEUTICAL FORM & TECHNOLOGY	STRENGTHS	THERAPEUTIC CATEGORY	DEVELOPMENT STATUS
ARIPIRAZOLE	Long-acting Injectable Nanosuspension	300mg/vial 400mg/vial 300mg/syringe 400mg/syringe	Treatment of schizophrenia	Clinical
ARIPIRAZOLE LAUROXIL	Long-acting Injectable Nanosuspension	441mg/syringe 662mg/syringe 882mg/syringe 1064mg/syringe	Treatment of schizophrenia	Formulation
BUPRENORPHINE	Long-acting Injectable In situ depot (based on PLGA)	100mg/syringe 300mg/syringe	Treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a transmucosal buprenorphine – containing product	Formulation
CABOTEGRAVIR RILPIVIRINE	Long-acting Injectable (2-drug co-packaged product) Suspension	400mg/600mg Kit: • single-dose vial of 400 mg/2mL cabotegravir • single-dose vial of 600mg/2 mL rilpivirine 600mg/900mg Kit: • single-dose vial of 600 mg/3 mL cabotegravir • single-dose vial of 900 mg/3 mL rilpivirine	Treatment of patients with human immunodeficiency virus (HIV-1) infection	Formulation
EXENATIDE	Long-acting Injectable PLGA microparticles	2mg/auto-injector (BCise)	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus	Formulation
LANREOTIDE	Long-acting Injectable Nano-gel	60mg/syringe 90mg/syringe 120mg/syringe	Long-term treatment of acromegaly; the treatment of patients with gastroenteropancreatic neuroendocrine tumors (GEP-NETs)	Commercial



PRODUCT	PHARMACEUTICAL FORM & TECHNOLOGY	STRENGTHS	THERAPEUTIC CATEGORY	DEVELOPMENT STATUS
LEUPROLIDE	Long-acting Injectable PLGA/PLA microparticle	Dual Chambered Syringe 3.75mg 7.5mg	Indicated for palliative treatment of advanced prostatic cancer, endometriosis and uterine leiomyomata (Fibroids).	Clinical
		Dual Chambered Syringe 11.25mg 22.5mg		
		Dual Chambered Syringe 30mg		
		Dual Chambered Syringe 45mg		Formulation
NALTREXONE	Long-acting Injectable PLGA microparticles	380mg/vial	Treatment of alcohol dependence; prevention of relapse to opioid dependence	Completed
PALIPERIDONE PALMITATE 1M	Long-acting Injectable Nanosuspension	25mg/syringe 50mg/syringe 75mg/syringe 100mg/syringe 150mg/syringe	Treatment of schizophrenia in adult patients	Completed
PALIPERIDONE PALMITATE 3M	Long-acting Injectable Nanosuspension	175mg/syringe 263mg/syringe 350mg/syringe 525mg/syringe	Maintenance treatment of schizophrenia in adult patients who are clinically stable on 1-monthly paliperidone palmitate injectable product	Clinical

PRODUCT	PHARMACEUTICAL FORM & TECHNOLOGY	STRENGTHS	THERAPEUTIC CATEGORY	DEVELOPMENT STATUS
PALIPERIDONE PALMITATE 6M	Long-acting Injectable Nanosuspension	700mg/syringe 1000mg/syringe	Indicated for the maintenance treatment of schizophrenia in adult patients who are clinically stable on 1-monthly or 3-monthly paliperidone palmitate injectable products	Formulation
PASIREOTIDE	Long-acting Injectable PLGA microparticles	20mg/vial 40mg/vial 60mg/vial	Treatment of patients with acromegaly who have had an inadequate response to surgery and/or for whom surgery is not an option (listed as an orphan indication in EU) Orphan indication in EU only: Treatment of adult patients with Cushing's disease for whom surgery is not an option or for whom surgery has failed	Formulation
RISPERIDONE	Long-acting Injectable PLGA microparticles	12.5mg/vial 25mg/vial 37.5mg/vial 50mg/vial	Acute and chronic schizophrenic psychoses treatment	Completed
TRIAMCINOLONE ACETONIDE	Long-acting Injectable PLGA microparticles	32mg/vial	An intra-articular injection for the management of osteoarthritis pain of the knee	Formulation





B ALL OTHER FORMULATIONS



B. All other Formulations

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



PRODUCT	PHARMACEUTICAL FORM & TECHNOLOGY	STRENGTHS	DEVELOPMENT STATUS
APREPITANT	Hard capsules	40mg 80mg 125mg	Commercial
APREPITANT	Injectable emulsion, for intravenous use	130 mg in single-dose vial	Formulation
BIMATOPROST	Eye drops, solution	0.1mg/ml 0.3mg/ml	Formulation
BRINZOLAMIDE	Eye drops, suspension	10mg/ml	*Commercial
BRINZOLAMIDE BRIMONIDINE	Eye drops, suspension	2mg/ml 10mg/ml	Completed
BRINZOLAMIDE TIMOLOL	Eye drops, suspension	5mg/ml 10mg/ml	Scaling Up
CASPOFUNGIN	Powder for concentrate for solution for infusion	50mg 70mg	*Commercial

* These products are commercialized in other regulated markets, like EU.



PRODUCT	PHARMACEUTICAL FORM & TECHNOLOGY	STRENGTHS	DEVELOPMENT STATUS
CYCLOSPORINE PRESERVATIVE FREE in multi-dose vial	Ophthalmic emulsion	0.5mg/ml	Formulation
DIMETHYL FUMARATE	Delayed-release capsules	120mg 240mg	Completed
DULAGLUTIDE	Injection, for subcutaneous use	<ul style="list-style-type: none"> Injection: 0.75 mg/0.5 mL solution in a single-dose pen Injection: 1.5 mg/0.5 mL solution in a single-dose pen 	Formulation
FERRIC CARBOXYMALTOSE	Solution for injection/infusion	100mg/2ml 500mg/10ml 750mg/15ml 1.000mg/20ml	Formulation
FERUMOXYTOL	Injection for Intravenous (IV) use	30mg/ml (510 mg of elemental iron in 17 mL)	Formulation
IRON SUCROSE	Injection, for intravenous use	50mg/2.5ml, 100mg/5ml or 200mg/10ml (20mg/ml) in single-dose vials	Formulation

* These products are commercialized in other regulated markets, like EU.



PRODUCT	PHARMACEUTICAL FORM & TECHNOLOGY	STRENGTHS	DEVELOPMENT STATUS
ISOTRETINOIN	Capsules	10mg 20mg 30mg 40mg	*Commercial
LIFITEGRAST	Ophthalmic solution	50mg/ml	Formulation
LIRAGLUTIDE	Solution for injection in pre-filled pen	6mg/ml	Formulation
NUSINERSEN	Solution for injection	12mg/5ml (2.4mg/ml)	Formulation
PALIPERIDONE	Prolonged-release tablets	1.5mg 3mg 6mg 9mg 12mg	Completed
PARICALCITOL	Solution for injection	2mcg/ml 5mcg/ml 4mcg/2ml 10mcg/2ml	*Commercial

* These products are commercialized in other regulated markets, like EU.



PRODUCT	PHARMACEUTICAL FORM & TECHNOLOGY	STRENGTHS	DEVELOPMENT STATUS
QUETIAPINE	Prolonged-release film-coated tablets	50mg, 150mg 200mg, 300mg 400mg and 600mg*	*Commercial
RALOXIFENE	F.C. Tablets	60mg	*Commercial
RIFAXIMIN	Tablets	200mg 550mg	Formulation
TACROLIMUS	Extended-release capsules	0.5mg, 1mg, 5mg	*Commercial
TAPENTADOL	Extended-release oral tablets	50mg, 100mg, 150mg, 200mg, 250mg	Formulation
SEMAGLUTIDE	Injection, for subcutaneous use	Multi use/single dose pen: 0.25mg, 0.5mg & 1mg (1.34mg/mL) & 2mg (2.68mg/mL) Multi use/dual dose pen: 0.25mg & 0.5mg (0.68mg/mL & 1.34mg/mL)	Formulation

* These products are commercialized in other regulated markets, like EU.



PRODUCT	PHARMACEUTICAL FORM & TECHNOLOGY	STRENGTHS	DEVELOPMENT STATUS
SEMAGLUTIDE	Injection, for subcutaneous use	Pre-filled, single-dose pen that delivers doses of 0.25 mg, 0.5 mg, 1 mg, 1.7 mg or 2.4 mg	Formulation
SEMAGLUTIDE	Tablets	3 mg 7 mg 14 mg	Formulation
VALGANCICLOVIR	Tablets	450mg	*Commercial
VORICONAZOLE	Lyophilized powder for injection	200mg	*Commercial
VORICONAZOLE	Tablets	50mg 200mg	*Commercial

* These products are commercialized in other regulated markets, like EU.





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 container	0.3mg/ml 0.1mg/ml
BIMATOPROST TIMOLOL PRESERVATIVE FREE	Eye drops solution multi-dose container	0.3mg/ml 5mg/ml
BRIMONIDINE PRESERVATIVE FREE	Eye drops solution multi-dose container	2mg/ml
BRIMONIDINE TIMOLOL PRESERVATIVE FREE	Eye drops solution multi-dose container	2mg/ml 5mg/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



PRODUCT	PHARMACEUTICAL FORM	STRENGTHS
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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We embrace science and innovation





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