Syngene
Putting Science to Work

A Complete Nonclinical GLP Safety Tox Package to a successful IND submission in Six Months

For a first-in-class small molecule against a novel target, all non-GLP and GLP safety toxicology, bioanalysis, eCTD-ready reports, and SEND datasets were delivered in 6 months as one integrated programme.

Client
Artelo Biosciences, Inc.

Compound
ART26.12, the first selective FABP5 inhibitor to enter clinical trial

Scope
PK, non-GLP tox and GLP safety tox studies genotoxicology, analytical and bioanalytical validation, eCTD and SEND data sets

The Client

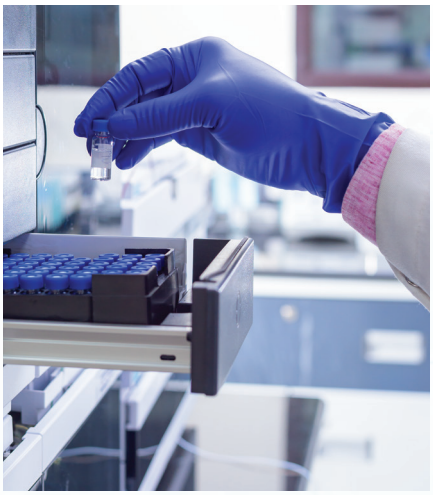
Artelo Biosciences, Inc. is a clinical-stage pharmaceutical company dedicated to the development and commercialization of proprietary therapeutics that modulate lipid-signaling pathways. Artelo has portfolio of broadly applicable product candidates designed to address significant unmet needs across anorexia, cancer, anxiety, dermatologic conditions, pain and inflammation.

The Challenge

An Investigational New Drug (IND) application to the US FDA is a complex, high-stakes milestone. Delays in IND-enabling studies, fragmented data compilation and regulatory formatting errors can push timelines back by months shifting capital plans and delaying first-in-human (FIH) trials.

ART26.12 is the lead compound in Artelo's proprietary Fatty Acid Binding Protein (FABP) platform and the first selective FABP5 inhibitor with a promising mechanism of action for the management of painful neuropathies.

Following due diligence and a review of Syngene' s Safety Assessment capabilities, Artelo was prepared to place the entire nonclinical package with Syngene provided that the non-GLP and GLP safety toxicology program, including the eCTD and SEND datasets, to be completed within six months. That single constraint defined the program.



Syngene
Putting Science to Work

The Solution

A nonclinical package is conventionally run in sequence analytical and bioanalytical set-up and validations first, safety tox in concurrent, regulatory datasets compiled at the end. Syngene' s safety assessment team organized the program around dependency rather than department: only the work that genuinely had to wait was sequenced, and everything else ran concurrently across three synchronized tracks under a single project management structure.

Track 1

Pharmacokinetics, non-GLP tox & Safety

PharmacologyPharmacokinetic, non-GLP tox and safety pharmacology assessments ran alongside rather than in sequential, so neither track waited on the other.,

Three Synchronous Tracks, One Program

Track 2

GLP Toxicology & Genetic Toxicology

GLP *In vivo* tox together with genotoxicology, supported by in-house analytical and bioanalytical validation work under a GLP quality system.

Track 3

Regulatory Data & Submission Readiness

eCTD-ready summary tables and SEND datasets built alongside the QA audited reports rather than final report removing the compilation lag that typically sits between the last report and the filing.

The Six-Month Program at a Glance

The three tracks ran concurrently across the six-month window, with study reports, bioanalysis and regulatory datasets progressing in step rather than in sequence.

SL	NonGLP and GLP Safety Tox Studies	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26
1	nonGLP MTD/DRF Rat and Dog Tox Studies																										
2	HPLC analytical method development & validation for in vivo dose confirmation analysis																										
3	LCMS/MS bioanalytical method validation – rat plasma																										
4	LCMS/MS bioanalytical method validation – non-rodent plasma																										
5	28-day repeat dose tox study with TK & 14-day recovery – rats																										
6	In vivo micronucleus test in rat																										
7	HPLC analytical method developmednt and validation – in vitro studies																										
8	In vitro Ames test																										
9	In vitro chromosomal aberration test																										
10	28-day repeat dose tox study with TK & 14-day recovery – Dog																										
11	CNS safety pharmacology – rat																										
12	Respiratory safety pharmacology – rat																										
13	Cardiovascular telemetry study – dog																										
14	In vitro hERG assay																										
15	eCTD summary table and SEND Data Sets																										

Syngene
Putting Science to Work

The Outcome

Delivered ahead of schedule. Filed on time. Approved by the FDA.

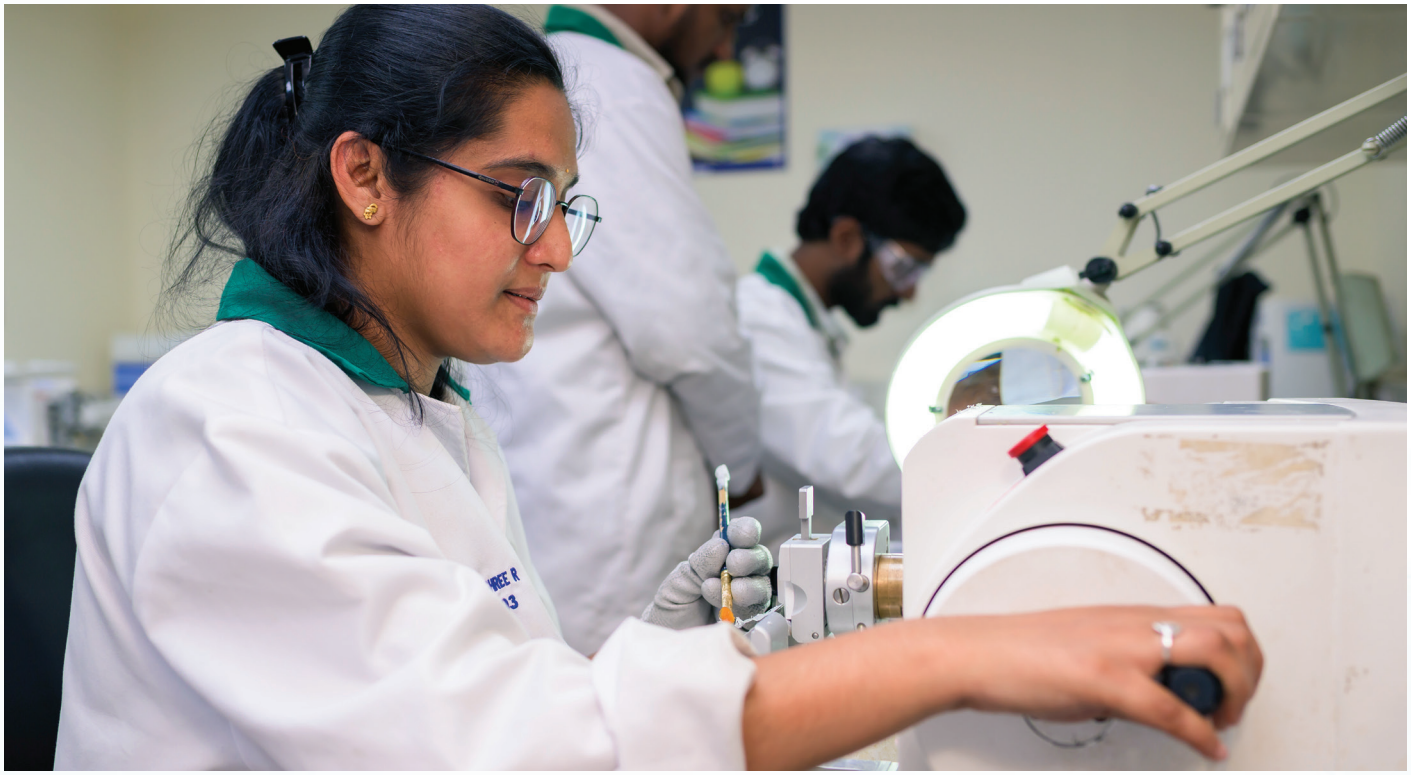
The complete non-clinical package was delivered within the six-month window, with study reports reaching the client well ahead of the expected submission date. Artelo pointed to four things in particular: the depth of Syngene' s toxicology expertise, the turnaround itself, the speed of response whenever a query or a change arose, and the quality of the reports. Close coordination between the scientific and project management teams kept updates timely and the program moving smoothly throughout.

That head start supported the timely filing of the Investigational New Drug (IND) application for ART26.12, for the treatment of chemotherapy-induced peripheral neuropathy (CIPN). FDA clearance of the IND enabled the Company to initiate its first-in-human Phase 1 single ascending dose study — the milestone the entire six-month program was built around.

> "Syngene' s scientific expertise, responsiveness and partnership-driven approach were instrumental in advancing our IND program. From delivering a high-quality GLP safety tox package to providing rapid support during FDA review, the team consistently demonstrated the agility and commitment needed to keep our program on track. Throughout the engagement, Syngene acted as a true extension of our team, helping us successfully progress toward clinical development."
>
> — Artelo Biosciences, Inc.

Bringing the Same Approach to Your Program

The six-month result did not come from compressing studies. It came from running toxicology, bioanalysis and regulatory data generation as one integrated program, from building the eCTD and SEND deliverables during the studies rather than after them, and from a single accountable team owning the package end to end. Sponsors working to a fixed IND date get the same program design, the same in-house scientific bench and the same project management discipline that kept ART26.12 on schedule.



For more information, contact bdc@syngeneintl.com
www.syngeneintl.com

Scan the QR code to learn more

Stay Connected