



Company Overview

Experts in continuous flow technology, Continuity Pharma (Continuity) leverages innovative chemistry and flow technology to improve drug manufacturing quality and safety, while reducing costs for the pharmaceutical industry by designing efficient manufacturing processes for small molecule therapeutics, key starting materials, and targeted nucleic acid delivery vehicles.

Problem or Market Opportunity

The pharma industry is plagued with shortages – especially for active pharmaceutical ingredients (API) & key starting materials. In this \$361.7B and growing industry, the number of drugs on the FDA shortage list is larger than it has ever been, placing patients at risk, every single day. Domestic production of the critical ingredients needed using modern technology is key to reducing these shortages.

Technical & Competitive Advantage

Continuity Pharma brings expertise in developing and optimizing chemical reaction pathways of API and key starting materials. Applying our protected IP, we offer a broad array of services from route discovery, through process optimization, pilot scale manufacturing, tech transfer and flow process manufacturing system design. Whether customers are seeking an end-to-end solution or leveraging experts in any step of the API manufacturing process, Continuity is the leading national expert with which to partner.

Implementation of Continuity’s modern continuous flow capabilities generates significant savings for manufacturers. Janssen Pharmaceuticals demonstrated that their switch from traditional batch processing to a modern continuous process yielded 50% reduction in operating costs, 33% reduction in waste, 80% reduction in manufacturing time, and a 66% reduction in time from testing to release.* Additionally, when comparing the manufacturing of lorazepam using a batch process versus manufacturing the same product using Continuity’s continuous manufacturing process, we demonstrated both a 200% boost in yield and a 6000% increase in manufacturing rate with flow, while producing in 2 hours with continuous flow what required a five 12-hour day campaign in batch.

Regulatory Strategy & Intellectual Property

Continuity holds licenses for several continuous manufacturing processes and the rights to composition of matter and process patents. Continuity also has a portfolio of mapped chemical reactions most frequently used in the pharmaceutical industry. As a member of the FDA Emerging Technology team, Continuity has direct access to FDA when there are questions concerning application of existing rules to novel technologies.

Key Milestones

Q/YYYY	Objective	Milestone Description
Q3/2018	Novel chemistry for a high potency (HP) API	1 HP API pathway developed using flow chemistry
Q1/2020	Novel chemistry for a novel HP drug candidate	1 NCE pathway developed using flow chemistry
Q3/2022	Plug & play model for flow manufacturing system	4 API from a single manufacturing rig, critically clean and switch between API in < 2 hours
Q1/2024	Commercial scaleup of flow manufacturing process for HP API	1 HP API manufacturing rig produces US annual supply within 1-week

Capitalization History

Year	Grant or Equity Type	Description	Amount
2020-2022	Grant	DARPA DP2 SBIR grant, 2 years	\$1M
2020	Grant	Indiana Economic Development Commission via Elevate	150,000
Q4 2022-current, operations have been funded by contract research generated revenue			

Current Round, Terms, and Use of Proceeds

While Continuity is not seeking funding at this time, they are seeking strategic partnerships and customers.

Key Team Members and Advisors

Nancy Hathaway | CEO

Nancy is an experienced entrepreneur with a demonstrated history of working in the research industry to move innovations from bench to bedside.

David Thompson | CTO

David has extensive experience in developing novel compounds and processes for the betterment of patients. He is a professor in Organic and Biomolecular Chemistry at Purdue University and is an internationally recognized expert in continuous manufacturing.

* Kuehn S., Janssen Embraces Continuous Manufacturing for Prezista. *Pharmaceutical Manufacturing* (2015); MacDonald G., Janssen working on other continuous processes post US FDA OK for Prezista. *inpharmatechnologist.com* (2016).