CHEMELEON, INC.

Next-Generation, Instrument-Free, POC *In Vitro* Diagnostics

Brendan Walker, CEO | brendan@chemeleon.com | 917-727-7201 | chemeleon.com

COMPANY OVERVIEW

Chemeleon has developed the next generation of instrument-free, *in vitro* diagnostics that provide rapid, simple and affordable testing capabilities at the point-of-care (POC) for clinicians and at-home for laypeople. Chemeleon's proprietary, patented Binding-Induced Nanostructured Dynamic Surface (BINDS) assay provides on-the-spot diagnosis in minutes without the need for readers, instruments or training. This platform technology provides a truly decentralized testing solution that obviates the need for slow, complex and expensive laboratory-based analysis. Compatible with an array of chemical and biological sensors, this platform technology provides rapid testing capabilities for the detection of diseases, life-threatening conditions, drugs and viruses anywhere.

MARKET & COMMERCIALIZATION STRATEGY

The global *in vitro* diagnostics market is $80B+. Chemeleon will focus on upending the $29B POC diagnostics segment with the first major advancement in instrument-free, *in vitro* diagnostics since lateral flow assays. Chemeleon's initial focus is POC testing for the rapid detection and treatment of cerebrospinal fluid (CSF) leaks. Chemeleon will partner with domestic and international distributors with established brand recognition, marketing, sales, etc. in these channels. While pursuing this $670 million introductory market, Chemeleon will further monetize this platform technology by developing and out-licensing BINDS assays for larger, more complex markets (e.g., at-home tests for SARS-CoV-2) generating a diversified revenue stream to fund capital expenditures and other growth initiatives. After successfully commercializing this platform technology for several applications in healthcare, Chemeleon will engineer the BINDS assay to detect biological targets for industrial agriculture and veterinarian care as well as nonbiological targets such as drugs and pollutants for environmental analysis, food safety and law enforcement.

TECHNICAL & COMPETITIVE ADVANTAGE

Chemeleon's BINDS assay offers unprecedented diagnostic capabilities at a fraction of the standard cost, speed and complexity:

- Analyte and receptor-agnostic, capable of utilizing an array of biological receptors like antibodies and aptamers as well as biomimetic receptors like Molecularly Imprinted Polymers when biological receptors won't suffice due to their high molecular weight, limited stability and sensitivity to pH and temperature.
- The BINDS assay relies on the relative surface energy change from binding, enabling it to detect radically more analytes than *in vitro* diagnostics relying on capillary action (e.g., THC).
- The material itself is the transducer; no electronic reader is needed, significantly reducing costs (COGS < $1).

Today's standard of care for CSF leaks requires laboratory testing with a four to six-day turnaround before clinicians can administer care. Chemeleon's rapid, simple and accurate diagnostic provides clinicians with immediate and actionable insight at the POC, reducing the rate of meningitis by 87% while eliminating ~$16k in healthcare costs due to the extended hospital stay.

REGULATORY STRATEGY & INTELLECTUAL PROPERTY

Chemeleon will provide a submission for a Class II *in vitro* diagnostic device to the Neurology Review Panel at the Center for Devices and Radiological Health. As no predicate device exists for this novel technology, Chemeleon will submit a direct *De Novo* request to the FDA in 2022. Chemeleon will submit a request for a Breakthrough Device Designation to expedite regulatory clearance. Chemeleon's intellectual property portfolio comprises seven granted and 11 pending patents providing US protection and international protection throughout Australia, China, Canada, Japan and the 38 member states of the European Patent Convention.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2019	TechConnect Innovation Award
Q3/2021	Protype validation with non-clinical bench performance tests (TRL 4)
Q3/2021	Pre-Submission filing with FDA
2022	Direct *De Novo* submission anticipated for market clearance

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2013-2021	Seed-Bridge	Angel investor equity and convertible debt	$3.2MM
2017	NSF Phase I STTR	Date-rape drug sensor for ketamine in alcoholic beverages	$225K
2019	NIH Phase I SBIR	Cerebrospinal fluid leak diagnostic	$225K

USE OF PROCEEDS

Chemeleon will raise $10M in Series A funding and use $3.4M to finalize product development and attain FDA clearance, $1.7M to manufacture and stock inventory, $2.9M for sales and marketing, $1.2M for PP&E and $800K for general and administrative.

KEY TEAM MEMBERS

Brendan Walker (Co-Founder & CEO), BS from the US Military Academy and MBA from the Tuck School of Business at Dartmouth with 11+ years' experience building startups; **Min Hu** (CTO), BS from USTC and PhD from Notre Dame with extensive R&D experience in chemistry and sensor technology; **Jacob Trevino** (Principal Scientist), BS from Susquehanna University and PhD from Boston University with expertise in photonics and materials science; **Lilian Lamech** (Senior Scientist), BS from Denison University and PhD from University of Texas at Austin with expertise in nucleic acid biology and protein engineering.