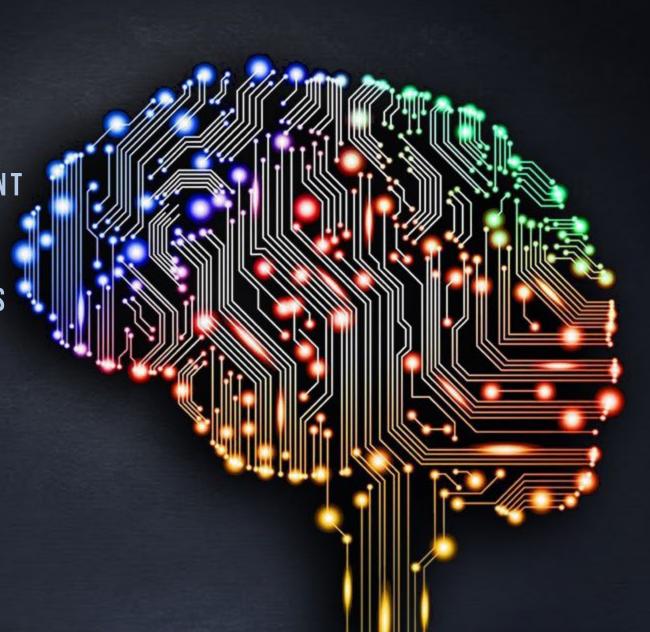
COGNOS

THE FIRST POTENTIAL TREATMENT
FOR ALZHEIMER'S DISEASE
UTILIZING BRAIN MICRODIALYSIS

INVESTOR PRESENTATION
COGNOS THERAPEUTICS, INC.



FORWARD LOOKING STATEMENTS



All statements, projections and estimates of future performance of the Cognos Therapeutics, Inc. (the "Company") or various elements of the Company's business contained in this presentation, other than those relating to historical facts, are "forward-looking statements." Forward-looking statements can generally be identified by their use of terms such as "may," "will," "should," "could," "aims," "seeks," "expects," "plans," "anticipates," "intends," "believes," "estimates," "predicts," "potential," "targets" and "continue," and similar terms and phrases, including references to assumptions. Forward-looking statements are not guarantees of future performance and are subject to a number of assumptions, risks and uncertainties, many of which are beyond the Company's control, which could cause actual results to differ materially from such statements. Investors should expect that anticipated events and circumstances may not occur, that unanticipated events and circumstances will occur and that actual results will likely vary from the forward-looking circumstances.

Factors that could cause the forward-looking statements or projections contained in this presentation or otherwise made by or on behalf of the Company to be incorrect or to differ materially from actual results. Forward-looking statements include, but are not limited to, statements about the Company's future strategic plans and future financial and operating results. Important factors that could cause actual results to differ materially from those presented or implied in the forward-looking statements include, among others: without limitation, (i) the ability of the Company to complete the development of its products in a timely manner, (ii) the demand for and timing of demand for such products, (iii) competition from other products and companies, (iv) the results of the Company's safety and efficacy studies, (v) the results of the regulatory approval process, (vi) the Company's sales and marketing capabilities, (vii) the Company's ability to sell its products profitably, (viii) the ability of the Company's third party suppliers to provide products and services in a reliable manner; (ix) availability of adequate debt and equity financing and (x) general business and economic conditions. There can be no assurance that the Company will be able to anticipate, respond to or adapt to changes in any factors affecting the Company's business and financial results. With the exception of the historical information contained in this presentation, the matters described herein contain forward-looking statements that involve risk and uncertainties that individually or jointly impact the matters herein described, including but not limited to financial projections, product demand and market acceptance, the effect of economic conditions, the impact of competitive products and pricing, governmental regulations, technological difficulties and/or other factors outside the control of the Company. These important factors and certain other factors that might affect the Company's financial and business results are discussed in this pr

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AT GLANCE

COGNOS THERAPEUTICS ("**COGNOS**") is a high technology medical company focused on creating advanced SINNAIS™ implantable pump devices for neurological indication intended to adjust the course of therapeutics for the treatment and mitigation of disease models where current technology does not provide an effective solution.

Our flagship product, **SINNAIS**TM, the first AI Implantable Smart Pump (AISP), is a fully implantable device designed to administer therapeutics metronomically directly to the central nervous system (CNS). By bypassing the blood-brain barrier (BBB), it has the potential to enable controlled, stable, and continuous drug delivery while providing biofeedback in real-time, improving potentially outcomes of Alzheimer's treatments by ensuring drugs effectively reach the brain.

COGNOS is also working on developing a Smart Drug Optical Sensor (SOS) which can collect important data from the disease target site and transmit that data to the cloud (big data, IA, and IoT) for further data analysis to customize drug dose (personalized medicine) and patient disease progression monitoring, which is intended to be part of the second generation SINNAIS™ pump − to bring a virtual physician concept to reality.

Our mission is to develop and commercialize medical products that combine diagnostic, therapeutic, and sensing technologies with state-of-the-art drug delivery to advance healthcare through improved patient outcomes

\$24 Million

Incorporated in Delaware in 2020

INTELLECTUAL PROPERTY

(US & International)
Issued Patents 30+
Non-Provisional Patent Applications Pending 57

STRATEGIC COLLABORATORS



Developing proprietary bonding technique



Developing propriety piezoelectric micropump



severaping propriety prozestreame interspanie







Signed NDA and in discussion to do joint study for use of **SINNAIS**™ to deliver drugs to brain



Conducted a small study to demonstrate local delivery of a combination of Avastin® and CPT-11 which improves survival rate in mice





- Disruptive smart pump technology designed to offer metronomic drug delivery
 - A next generation piezoelectric micropump technology for precise, metronomic dosing
 - The only pump under development to deliver drug intraventricularly, thereby bypassing the blood-brain barrier (BBB)
 - Development of biosensor capability for a second-generation pump to provide cloud-enabled physician monitoring and precision dosing
- Technology may enable broad applicability across multiple indications and therapeutics
 - Potential for use with therapeutics employing immunotherapy/biologicals, small molecules, and gene therapy
- Technology validated through multiple small and large animal model studies
- Addressing large market opportunities in multiple neurological and other disease indications, including cancer, CAR-T cell and gene therapy.

- Delivery of approved drugs which offers a regulatory pathway that can lower risk and therefore gain engagement of drug companies
- Multiple potential milestones within ~24 months, including:
 - PMA submission to FDA for SINNAIS™ as a Class III pump indicated for infusion of Infumorph, potentially using FDA's 6-Year Rule which would allow PMA approval without conducting new human clinical trials
 - Investigational New Drug (IND) application submission for the initiation of Phase II human clinical trial of SINNAIS™ as a combination product for metronomic delivery of Biogen and Lilly FDA approved drugs for the treatment of Alzheimer's disease
 - CE-Mark submission in EU for SINNAIS™ as device alone based upon data with the first drug: methotrexate
- Strong intellectual property portfolio covering the pump design, smart pump delivery, and method of use
- Experienced management, board, and clinical advisors



ALZHEIMER'S - \$360 B ANNUALLY US

ALZHEIMER'S CURE STATUS

While there are several therapeutic treatments available to people with the disease, there is currently no cure.

ALZHEIMER'S PATIENTS

- ☐ 6.9 million US
- ☐ 50 million globally

ALZHEIMER'S COST CARE/MONTHLY, US

\$21,973 per patient
(Medicare)
\$6,772 per patient
(Medicaid)
\$28,745 per patient (Total)

ALZHIEMER'S COST, US

\$360 billion Annually (Direct & Indirect)







VALIDATION



BIOSENSOR

FEEDBACK TO

SINNAISTM.

ACTIVE

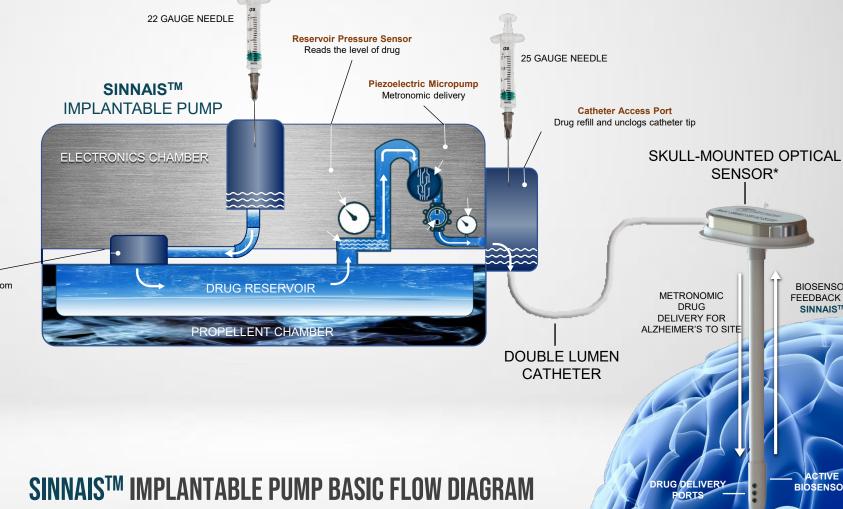
BIOSENSOR

THE DIFFERENCE: NOVEL DESIGN TO ADDRESS MULTIPLE CHALLENGES

Unique Features of SINNAIS™

- Inlet Safety Valve Prevents over pressurizing reservoir during refill
- Reservoir Pressure Sensor Reads the level of the drug
- Piezoelectric Micropump Metronomic delivery
- Catheter Access Port Drug refill and unclogs catheter tip

Inlet Safety Valve Prevents access drug pass-through from pump to patient body



*Skull-Mounted Optical Sensor is in development as part of the SINNAIS™ second-generation configuration. The current version of SINNAIS™ does not include this sensor. The size of the skull-mounted catheter that inserts into the brain is 7 cm, which is the approved industry standard."

DIFFERENTIATION COMPARISON & COMPETITION



CHALLENGES OF CURRENT PUMP TECHNOLOGY

All of the current commercially available pumps are based on technology and architecture that is more than three decades old and pose the following challenges:

- No intraventricular delivery Drug cannot bypass blood-brain barrier (BBB)
- No metronomic delivery
- Do not automatically respond to situational changes in the patient's condition
- Have a limited ability to receive delivery commands (no microprocessors)
- Crude dose delivery
- Cannot provide a metronomic delivery of drugs, which provides programmable scheduled dosing within a therapeutic range vs bolus injection.
- Are not able to provide real-time biofeedback and communication.
- Usually receive FDA approval for one size drug molecule
- Do not have connectivity to cloud
- Are not MRI-compatible
- Cannot meet many of the new safety regulatory requirements set by the FDA to deliver therapeutics to the brain.
- Due to crude dose size (1ml +) and not being able to provide information about level of toxicity after drug administered in brain, are not suitable to deliver drug to brain.

Source: MCRA (a leading CRO consulting company)
A Market Opportunity Assessment Key Findings, a report dated: 11/21/2022



INTRODUCING SINNAISTM

Metronomic drug delivery directly into the brain, bypassing the Blood-Brain-Barrier (BBB). Some key features/attributes include:

 SINNAISTM is believed to be the world's first implantable smart pump that delivers drugs locally and metronomically under development

• Intended to provide direct delivery of therapeutics into the brain ventricle, bypassing the blood-brain barrier

Potential to deliver neuroleptics locally to treat neurodegenerative diseases, such as Alzheimer's, Parkinson's, and MS



Precise programmable schedules

Micro-dose adjustment control based on a patient's reaction and tolerance

Enables delivery of multiple drugs*

- Secure high-level encrypted wireless communication through the cloud from anywhere in the world
- Refillable drug canister can be refilled





BENEFITS TO STAKEHOLDERS

The SINNAIS[™] implantable pump is expected to provide many key benefits across the healthcare spectrum to patients, healthcare providers, and drug manufacturing companies

FOR PATIENTS

- Improved quality of life and mobility
- Lower side effects
- Shorter hospital stays
- Lower health insurance premiums
- Lower hospitalization cost
- Increased postoperative longevity

FOR HEALTHCARE PROVIDERS

- Reduced costs
- Access to the patient's "Big Data" using Al to apply triage and better diagnostics

FOR PHARMACEUTICAL COMPANIES

- Converts a generic drug into a proprietary BRANDED drug
- Reduces cost of development for improved drug efficacy
- Increases the life of a drug's intellectual property
- Ability to adapt the system to various disease models and drugs

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^{*}SINNAIS™ piezoelectric micropump is made of titanium and silicon therefore the chemistry of material in pump does not interact with drugs regardless of drug biological chemistry or composition.

Microdialysis of Brain (CSF)

Technology Next Generation SINNAISTM for Alzheimer's **Treatment Additional Features Under Development:**

- Measures CSF Abeta levels in real-time
- Measures CSF p-Tau and total Tau levels in real-time
- Siphoning CSF capability
- Using proprietary biological filter to run CSF through filter and remove Abeta, pTau and other protein debris from CSF
- Real-time feedback on rates of Abeta clearance from the brain
- Customizes and optimizes dosage to patients' specific pharmacokinetic and pharmacodynamic needs - Personalized Medicine
- SMART Shunt and smart optical sensor (SOS) can monitor drug toxicity and concentration in real-time using a wireless connection to the cloud
- Can be refilled and recharged transcutaneously







The SINNAIS™ Implantable pump is expected to provide many key benefits across the healthcare spectrum to patients, healthcare providers, and drug manufacturing companies

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MEASURING CONCENTRATIONS OF AMYLOID BETA PROTEIN (A-BETA) IN CSF USING A **SKULL-MOUNTED OPTICAL SENSOR**

The Skull-Mounted Optical Sensor (SOS) is an implantable shunt that is the delivery point of the SINNAISTM' pump technology. The SOS is connected to the SINNAISTM via a doublelumen catheter which allows the therapeutic to be delivered directly to the disease site such as a tumor in the brain. In addition to being the delivery mechanism, the SOS also provides a proprietary biometric sensor that allows the attending physician to monitor the effectiveness of the therapeutic course so that the treatment can be adjusted, ensuring that the Maximum Effective Dose never exceeds the patient's Maximum Tolerable Dose threshold.

KEY FEATURES

- The Intracranial Stem is custom-fitted to position the SOS directly adjacent to the desired delivery target
- A Cranial Pressure Sensor monitors the pressure of the therapeutic flow to ensure that excessive pressure levels are not exceeded
- All of the SOS's electronics are contained on a miniature Printed Circuit Board (PCB) Assembly in the top housing compartment
- An integrated sampling chamber is built into the stem of the SOS to allow for direct sampling and measure of fluids, such as the cerebro-spinal fluid located near a tumor site
- A pairing of a Fisheye and Reflective Lens in the **SOS** stem allows for active optical sensing of a variety of biometric measurements to be taken

SINNAISTM



OPTICAL CSF SAMPLING

COGNOS has developed a unique method for monitoring and measuring the concentration of a therapeutic in the target delivery area. An open flow chamber in the stem of the SOS allows for Cerebrospinal Fluid (CSF) to enter. By then using a focused LED light emitter in conjunction with a parabolic mirror and a photo detector, the exact concentration of the therapeutic to CSF volume can be determined. This allows the physician to be able to monitor and maintain Maximum Effective Dose and Maximum Tolerated Dose ranges in the sample chamber.





SINNAIS[™] offers one of the most advanced micro-pump technology in the industry today. Its unique design is a significant departure and advancement for controlled therapeutic drug delivery to the brain and central nervous system.

	DEVICE	METRONOMIC/ BIOFEEDBACK	DOSE RATE	UNCLOGGING CATHETER TIP	COMPATIBLE DRUGS	MRI COMPATIBILITY	MECHANISM OF OPERATION	ROUTE OF DELIVERY	POWER SOURCE
GINOS THERAPEUTICS INC.	SINNAIS™ Implantable Smart Pump*	YES	1ul	YES	Small Molecule and Biologics	MRI Safe	Piezoelectric Plus	Intraventricular	Battery Power
Medtronic	SynchroMed [™] II	NO	0.048-24 mL/day	NO	Infumorph®, Prialt®, Lioresal® chemo (pipeline)	MRI Conditional	Peristaltic Action	Intrathecal	Battery Power
Integra	Integra™ Reservoir	NO	2 mL volume	NO	Chemotherapy, Antimicrobials, Antineoplastic, Analgesic, etc.	MRI Safe	Gravity Drip	Intratumor	Gravity Power
Algorithm Sciences, Inc	Reprogrammable Prometra***	NO	0-28.8 mL/day	NO	Morphine, Baclofen Valproate	MRI Conditional	Valve-gate Action	Intrathecal	Battery Power
Pan Ther Ther apeutics	PTM-101*	NO	~1.5 mg/day	NO	Paclitaxel	MRI Safe	Diaphragm Action	Intratumor	Electrolysis Power
Massachusetts Institute of Technology	MiNDS Pump*	NO	N/A**	NO	I-dopa, Prozac, chemo (pipeline)	MRI Conditional	Diaphragm Action	Intrathecal	Diaphragm

^{*}Product is not yet on the market and subject to FDA approval

Source: MCRA (www.mcra.com) "Findings and Recommendations for Cognos Therapeutics, Inc SINNAIS™ ISP, dated: 12/2021
Technical Specification and data are shown in this table for SynchroMed II, Integra, MIT, MiNDS, and Flowonix pumps have been compiled from each company's website and the product brochures respectively

1 △

^{**}Dose rate for the MiNDs pump was not available on the MIT website

^{***} Algorithm Sciences acquired Flowonix in June 2023

CLINICAL VALIDATION OF SINNAIS



Source: MCRA (a Leading CRO Consulting Company)

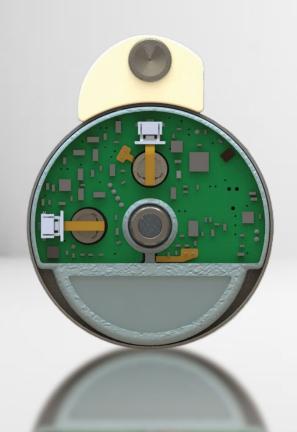
A Market Opportunity Assessment Key Findings, a report dated: 11/21/2022

THE DIFFERENCE: METRONOMIC DELIVERY



Metronomic delivery has been shown to minimize peak toxicity levels associated with current systemic delivery models. In addition to keeping therapeutic drug levels within acceptable ranges, metronomic delivery has also been shown to provide longer efficacy of the therapeutic in the beneficial therapeutic range.

The chart below shows that metronomic delivery allowed a therapeutic to stay within acceptable toxicity ranges while also maintaining the targeted therapeutic range set by the physician. This study was based on delivering the standard dosage amount of methotrexate (MTX) for treating Glioblastoma multiforme (GBM). The Bolus injection below represents the current gold standard of delivery with implantable pumps.





DEVELOPMENT

HISTORY

COGNOS pursued a strategic path of *in vivo* research in animal studies utilizing supporting clinical data that were generated from Dr. Shinoura's clinical work that was conducted in 2008 demonstrating that local delivery improves the incidences of cure in patients with Glioblastoma Multiform (GBM).





HUMAN (20 subjects)



(30 mice)

2009*

COGNOS

LC



SMALL ANIMAL 2 (30 mice)





DATE

TYPE

TE 2008

2000

2010*

COGNOS

2011*

2020

COGNOS

BY

PURPOSE

Prove viability of convection enhanced delivery (CED) to the brain for treating LC

* Dr. Nobusada Shinoura

Prove viability of local delivery of Genentech's Avastin for the treatment of

Prove viability of local delivery of Velcade for the

treatment of glioma

COGNOS

Prove the viability of the MBP to deliver MTX to the brain and to provide a relevant sampling of cerebrospinal fluid (CSF)

Prove viability of **SINNAIS™** to deliver MTX to the brain in micro-dose levels that could be controlled and monitored remotely

METHOD

20 patient study using an extremal pump and a catheter to deliver Methotrexate directly into the brain

An Alzet mini-osmotic pump was implanted in a group of mice with LC for local delivery of Avastin with a second group receiving same-dose systemic delivery and third control group with no treatment

An Alzet mini-osmotic pump was implanted in a group of mice with gliomas for local delivery of Velcade with a second group receiving same-dose systemic delivery and a third control group with no treatment

Test pigs had the SINNAIS™ and catheter implanted over a course of four studies where both contrast dye and MTX were metronomically delivered and CSF sampling was performed

9 sheep (Group 1 (3), Group 2 (6)) were implanted with the SINNAIS™ pump and an Ommaya reservoir where MTX was then delivered at various micro-dose levels and intervals over both an 8-week term for group one and 12-week term for group two

RESULT

The study showed that patients who received local delivery survived significantly longer than those who did not

The study showed that the mice who received local delivery had survival rates 20% longer than those receiving systemic delivery

The study showed that the mice who received local delivery had longer survival rates then those receiving systemic delivery

The studies showed that the pump delivered therapeutics that were well tolerated, and wireless communication through animal skin was successful confirming the antenna in **SINNAIS**TM receiving signals successfully

The study showed that the test animals tolerated the pump and therapeutic; and that control and monitoring of the pump could be done remotely

Dr. Nobusada Shinoura is a neurosurgeon based in Tokyo, Japan, affiliated with Komagome Metropolitan Hospital. His
2008 clinical work demonstrated that the use of local delivery of chemotherapy significantly improves patients' quality of
life post-operation using local delivery of chemotherapy improves significantly

- Study conducted by Pharmaco-Kinesis Corporation (Cognos pre-spin-off)

Dr. Wu checks communication

protocols between the SINNAISTM

pump and several smartphones

being used in the trial.

VALIDATION STUDIES - SHEEP MODEL





- Validate the pump's ability to deliver metronomic dosing of a therapeutic to the brain in a large animal model
- Test the ability of the pump's wireless data and system control to allow for remote dose adjustment (metronomic delivery) and the flow delivery data to be received and monitored

1ST PILOT STUDY

- Three animal non-GLP (Good Laboratory Practices) studies using sheep
- Eight-week survival study
- Studied verified:
 - Wireless communication
 - Pump delivery capabilities
 - Ability to safely refill the implanted pump

2ND PILOT STUDY

- Six animal non-GLP study using sheep
- Twelve-week survival study
- Study verified:
 - Metronomic pumping at microdose levels
 - Delivery of Methotrexate (MTX) to the brain
 - Durability and biocompatibility of the pump



SINNAISTM pump is connected to catheter prior to implantation in a test animal.



An Omamya reservoir connected to the **SINNAIS™** pump is implanted in the test animal's brain.



The research team monitors the SINNAISTM pump's function after the implantation.

RESULTS

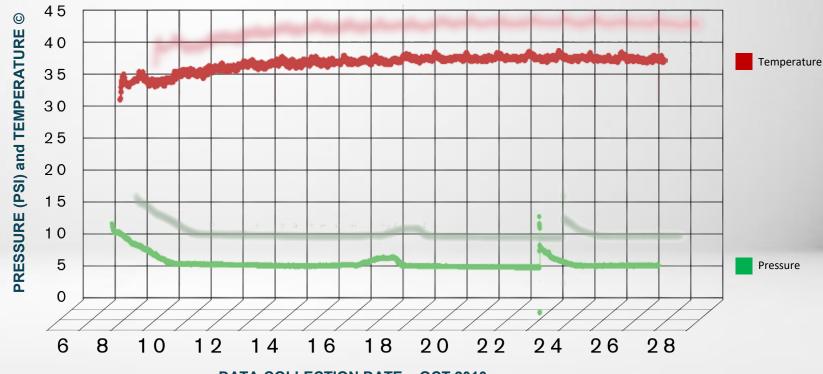
- Provided insight to continue to refine the pump's accuracy and biocompatibility in providing adjustable, controlled micro-dose delivery of a therapeutic
- Provided insight to develop the protocols for control of the system, CSF sampling, and data monitoring via wireless communication to a remote computer or an app-enabled smartphone





The chart below displays a sample of pressure and temperature readings taken from a test animal during the second phase of the large animal trial. As shown in the graph, both pressure and temperature remain extremely stable, indicating the pump's ability to provide consistent metronomic delivery without any adverse effects on the test subject.

PUMP INLET PRESSURE AND TEMPERATURE READINGS FROM TEST ANIMAL 2

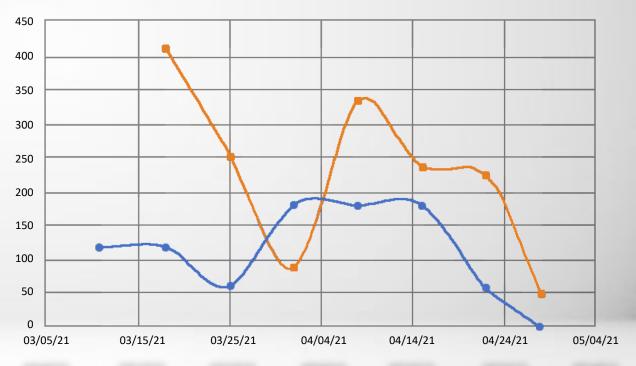


VALIDATION METRONOMIC DELIVERY – SHEEP MODEL



- Sheep 90-0 (38D2) produced a sufficient quantity of CSF. The chart shows that the MTX concentration level in CSF samples tracked well with the changes in the delivery rate.
- Sheep 134-R (FB90) generally produced a sufficient quantity of CSF except on 04/08/21 and 04/15/21. We received a smaller quantity of CSF on those two days. FB90 was set to deliver about half the rate of 38D2 so we expected to find the MTX concentration level to be about half of 38D2.
- The data supports the metronomic pump's successful delivery of MTX into the ventricle CSF at different rates and, following a lag, and taking into account dilution/ADME (absorption, distribution, metabolism, and excretion), the CSF MTX concentration is rate responsive.
- The data shows the implanted SINNAIS™ pump is working *in vivo* and the delivered drug concentration is responsive to changes in pump rate.

MTX Concentration in CSF Samples from **Sheep 90-0 Compared with Delivery Rate**



metronomic pump's strokes/hr given into sheep 90-O's ventricle. The pump rate was wirelessly changed over time to develop a MTX protocol to identify the maximum tolerated dose for a future GLP study

micromolar (mM) concentration of MTX in the CSF at that specific time/day in sheep 90-0

MICRODIALYSIS OF THE BRAIN



THE FIRST POTENTIAL TREATMENT FOR ALZHEIMER'S DISEASE USING SINNAIS BASED ON AMYLOID HYPOTHESIS (R. TANZI)

DR. RUDOLPH TANZI'S PROPOSAL FOR HOW THE SINNAIS PUMP CAN BE EMPLOYED TO SAFELY PREVENT ALZHEIMER'S DISEASE:

THE PROBLEM: DECADES-LONG BUILD-UP OF BETA-AMYLOID AND NEED FOR BETTER THERAPIES

- Brain imaging, fluid biomarker and post-mortem studies over the past four decades of research have shown that excess deposition of beta-amyloid in the brain is the initial trigger of Alzheimer's disease.
- Beta-amyloid leads to neurofibrillary tangles, synapse loss, and cell death. These pathological events lead to neuroinflammation and exponentially more cell death resulting in dementia.
- Recently approved anti-amyloid Alzheimer's Drugs: The faster beta-amyloid is produced, the sooner Alzheimer's develops to advance stage.
- Recently approved anti-amyloid immunotherapies remove amyloid but are very costly and have safety issues.
- Safety issues (*ARIA) are largely due to binding of amyloid immunotherapy antibodies to cerebral blood vessel amyloid leading to edema and micro-hemorrhage.



THE FIRST POTENTIAL TREATMENT FOR ALZHEIMER'S DISEASE USING SINNAIS BASED ON AMYLOID HYPOTHESIS (R. TANZI)

DR. RUDOLPH TANZI PROPOSES A METHOD BY WHICH THE SINNAIS PUMP CAN SAFELY PREVENT ALZHEIMER'S DISEASE:

THE OPPORTUNITY: STOP THE BUILD-UP OF BETA-AMYLOID DECADES BEFORE ALZHEIMER'S SYMPTOMS

- Plasma and CSF biomarkers (*Aβ42:40, Ptau-217) indicate Alzheimer's neuropathology decades before symptoms appear
- · We believe that by curbing the buildup of cerebral Abeta, we can halt the pathological cascade and nip Alzheimer's in the bud
- Recently approved anti-amyloid immunotherapies (Legembi and Kisunla) can be used to clear amyloid
- Antibodies that clear beta-amyloid are best delivered directly to the brain; this would also avoid binding to blood vessel amyloid that leads to ARIA-related side effects brain swelling and hemorrhage.
- The SINNAIS[™] pump can be used to deliver anti-amyloid antibodies into the brain, avoiding sides effects.
- As amyloid is cleared, the pump can also measure the rate of Abeta removal in the brain guiding administration of the appropriate dose for each patient.
- The SINNAIS[™] pump can be used to cleanse the CSF of exported Abeta to prevent further cerebral amyloid buildup.
- Since Abeta has normal roles in the brain (e.g. host defense, synaptic regulation), the SINNAIS[™] pump can be employed to deliver drugs that reduce Abeta production, e.g. Dr. Tanzi's gamma secretase modulators, to reduce cerebral Abeta levels to a normal levels but not eliminating it completely. ______

We propose the first solution for preventing Alzheimer's disease by managing amyloid beta levels over the lifetime of patients



THREE PHASE HUMAN CLINICAL TRIALS USING SINNAIS TO PROOF DR. TANZI'S HYPOTHESIS

ANTICIPATED CLINICAL PATH AND STRATEGY

PHASE I.

Use SINNAIS[™] to deliver newly approved amyloid immunotherapies (Leqembi, Kisunla) and/or Dr. Tanzi's gamma secretase modulator and/or drug combinations delivering directly to the brain and assess efficacy of treatment using SINNAIS[™] versus systemic delivery. *Length of study (6-12 months)*

PHASE II.

Use SINNAIS[™] to deliver the immunotherapy or drug directly to the site of pathology, measure concentrations of amyloid beta protein (Abeta) administer the appropriate dose of immunotherapy or drugs to reduce Abeta levels, remove Abeta from CSF, and maintain Abeta levels at a therapeutic range to curb the progression of the disease.

Length of study (12 months)

PHASE III.

Conduct Phase III procedure to population of patient over long-term to obtain data for submission of investigative new drug (IND) to FDA to approval of insurance code accepting the outcome of the three-phase trial to be accepted as mainstream viable solution as standard care.

Length of study (12-18 months)



DEVELOPMENT PHASE AND MILESTONE.

Milestone 1

Proof of Concept for SINNAIS™ Filtering System

 Development has started – 50% completed (Collaboration with Sandia National Lab)

*6 Month

Milestone 2

Proof of Concept for Measuring Concentration of Beta-Amyloid

- Assess CSF from Alzheimer's disease patients
- Technology for measuring protein proof-of-concept has been completed

*12 Month

Milestone 3

Functional Prototype of SINNAIS[™] for Alzheimer's

*12 Month

Milestone 4

First-in-Man Research Human Clinical Trial

*Month of 15 – Start of human Clinical Trial





FDA & REGULATORY STRATEGY

COMBINED REGULATORY FDA AND EU APPROVAL STRATEGY



U.S.

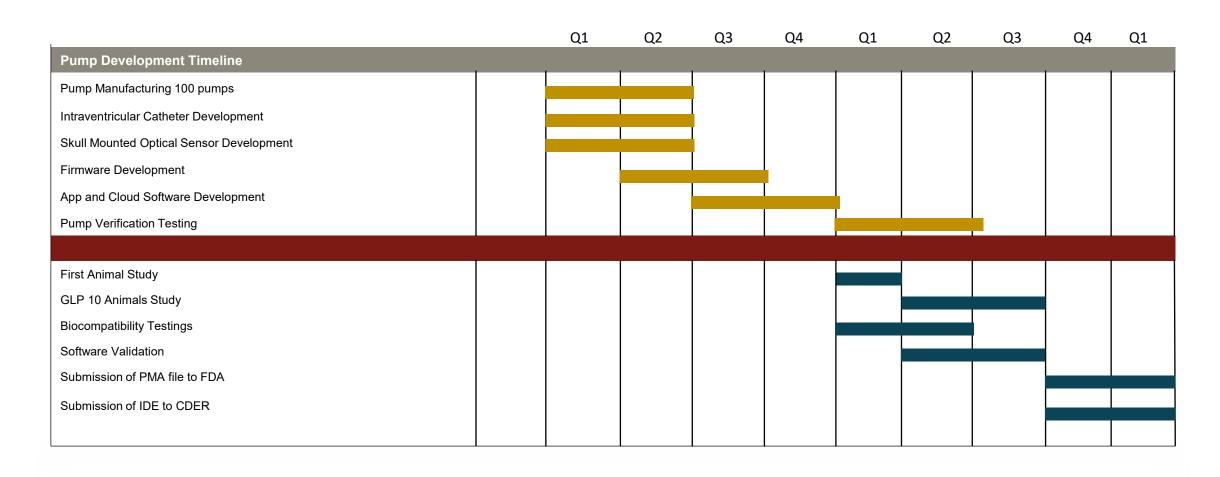
- Q4 2021 Filed pre-submission with FDA for PMA submission for SINNAISTM
- Q1 2022 Received FDA's written pre-sub feedback, which will inform application for SINNAIS™
- ~24 Months* Submit PMA application to FDA approval for SINNAIS™ as a Class III pump indicated for infusion of Infumorph, potentially using FDA's 6-year Rule which would allow PMA approval without conducting new human clinical trials as a device alone (from Device Center (CDRH) and Drug Center (CDER)
 - Initiate Phase II human clinical trial of SINNAIS™ the following quarter as a combination product for metronomic delivery of FDA Biogen and Lilly AD approved for treatment of AD under IND from CDER
- ~24 Months* CE-Mark submission for SINNAIS™ as device alone based upon data with the first drug: methotrexate.

After SINNAIS™ receives CE-Mark in EU market, SINNAIS™ will be allowed to be used with any approved drug in the European market without requiring to go through additional regulatory approvals.





SINNAISTM ~24 MONTHS PRODUCT DEVELOPMENT TIMELINE



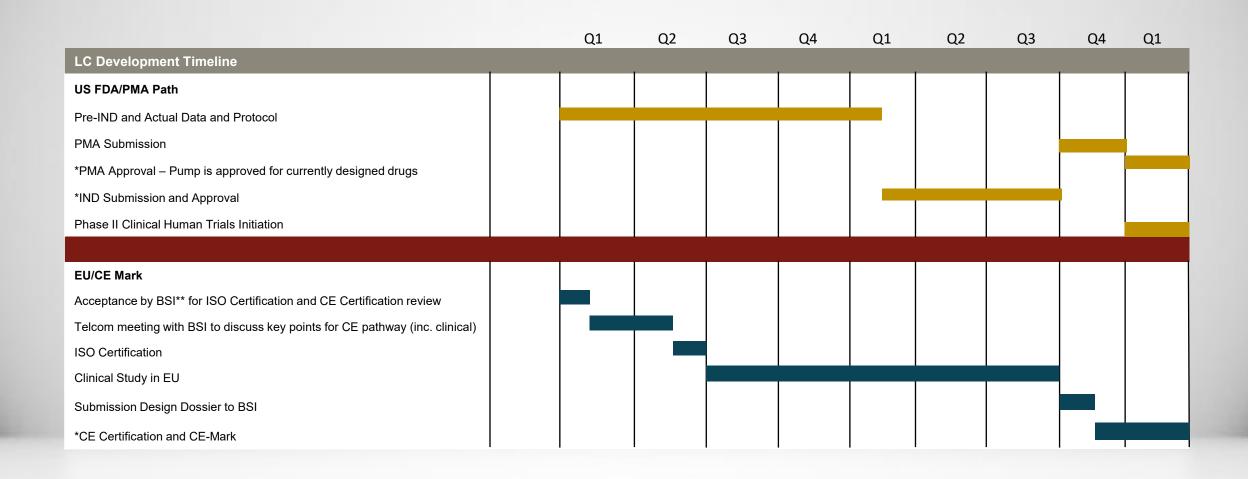


^{*} Expected timing of FDA decision for PMA and IND submissions.

^{**} BSI is a European medical device regulatory agency that issues CE-Marks for products in the EU. BSI performs a similar role to the FDA in the U.S.

^{***} Expected development timeline from closing of a business combination

SINNAIS™ ~24 MONTHS FDA/EU CE-MARK REGULATORY MILESTONE & TIMELINE





^{*} Expected timing of FDA decision for PMA and IND submissions, and CE-mark in E.U.

^{**} BSI is a European medical device regulatory agency that issues CE-Marks for products in the EU. BSI performs a similar role to the FDA in the U.S.

^{***} Expected development timeline from closing

INTELLECTUAL



cognos has always pursued an aggressive strategy of identifying and protecting its Intellectual Property assets through global patent protection



COGNOS IP Portfolio by the Numbers:

ISSUED - Over 30 Patents issued in the U.S. and Internationally

PENDING – 57 Patent Applications pending in the U.S. and Internationally

IP PORTFOLIO COVERS



- Implantable pump for detection of spine issues
- Implantable piezoelectric pump for delivery of therapeutics to the spine
- A method for Cerebral Microdialysis to treat neurological disease

IP PORTFOLIO

- Implantable piezoelectric pump for delivery of biological response modifiers
- Artificial Tooth Medicating device for local delivery of therapeutics
- An implantable magnetic breather pump for local delivery of bevacizumab into a brain tumor

- A method for creation and manufacture of a hermetic seal for use in an implantable metronomic drug pump
- Creation of a MRI compatible drug pump with overpressure protection
- Method for the intratumoral delivery of Bortezomib
- Development of a Magnetic Breather Pump for tumor treatment
- An implantable pump for the local delivery of intrathecal chemotherapy for Leptomeningeal Carcinomatosis
- Development of a Multipurpose Cerebrospinal Fluid Sensor
- Development of a Skull-Mounted Drug And Pressure Sensor

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