

### **Forward-Looking Statement**

This presentation contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including those relating to the Company's product development, clinical and regulatory timelines, market opportunity, cash flow and other statements that are predictive in nature, that depend upon or refer to future events or conditions. All statements other than statements of historical fact are statements that could be forward-looking statements. Forward-looking statements include words such as "expects," "anticipates," "intends," "plans," "could," "believes," "estimates" and similar expressions. These statements involve known and unknown risks, uncertainties and other factors which may cause actual results to be materially different from any future results expressed or implied by the forward-looking statements. Forward-looking statements are subject to a number of risks and uncertainties, including, but not limited to, our ability to obtain additional capital to meet our liquidity needs on acceptable terms, or at all, including the additional capital which will be necessary to complete the clinical trials of our product candidates; our ability to successfully complete research and further development and commercialization of our product candidates; the uncertainties inherent in clinical testing; the timing, cost and uncertainty of obtaining regulatory approvals; our ability to protect the Company's intellectual property; the loss of any executive officers or key personnel or consultants; competition; changes in the regulatory landscape or the imposition of regulations that affect the Company's products; and the other factors listed under "Risk Factors" in our filings with the SEC, including Forms 10-K, 10-Q and 8-K. Investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this release. Except as may be required by law, the Company does not undertake any obligation to release publicly any revisions to such forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. Matinas BioPharma's product candidates are all in a development stage and are not available for sale or use.



### **Company Overview**

#### **MAT9001**

#### **Cardiovascular and Metabolic Conditions**

- Potential best-in-class drug focused on multibillion-dollar market
- Head to head data demonstrating superiority against market leading drug, Vascepa®
- Key additional head to head data vs. Vascepa® expected in 2020.
- **Clear differentiation** from currently approved prescription omega-3 products

Founded: 2013

#### **MAT2203**

#### Oral, Non-toxic Delivery of Amphotericin B

- **Broad spectrum antifungal agent** with 50+ years of robust efficacy; Current use significantly limited by IV administration and significant renal toxicity
- **LNC Platform** technology provides for oral, targeted, non-toxic delivery to infected tissues
- Financially supported by the National Institutes of Health
- **EnACT** study set to **enroll patients** in September 2019



# **Key Milestones Position Company for Near-Term Value-Driving Events**

November 2018



Positive REDUCE-IT data pivotal to relaunching development program for MAT9001, a potential best-in-class prescription-only omega-3

December 2018



Assembled world class Scientific Advisory Board to guide clinical development strategy of MAT9001

February 2019



Bolstered team with cardiovascular expert, James J. Ferguson III, M.D. as Chief Medical Officer to lead clinical development of MAT9001

**March 2019** 



Closed \$32MM financing led by fundamental institutional investors to fund MAT9001 through key data

September 2019



Start NIH-funded phase 1/2 EnACT study of MAT2203 in Cryptococcal Meningitis. Data expected in 1H 2021. Cohort updates throughout 2020

January 2020

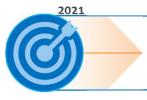


Begin enrolling MAT9001 head-to-head study vs Vascepa (n=70). Data expected to read out in Q4 2020

Mid 2020



Expected end of phase 2 meeting with FDA for MAT9001. Expected to discuss Phase 3 program design.



Expected start of two phase 3 programs for MAT9001 in patients with SHTG and HTG. Data expected in late 2022





# MAT9001 - Potential Best-in-class prescription-only Omega-3 fatty acid

#### **Demonstrated Superiority Versus Vascepa® in a Head-To-Head Study**

Recent Events in Cardiovascular Space Provide New Opportunity for MAT9001

November 2018: Positive CV outcomes data for Vascepa®

**January 2019: Updated ADA Guidelines** 

**August 2019: AHA Scientific Advisory** 

**August 2019: Updated ESC Lipid Guidelines** 

**Clear clinical development pathway** 

505(b)(2) - initial indication in patients with severe hypertriglyceridemia (≥500 mg/dL)

**Outcomes trial not required for approval** 

Eligible for **NCE** 



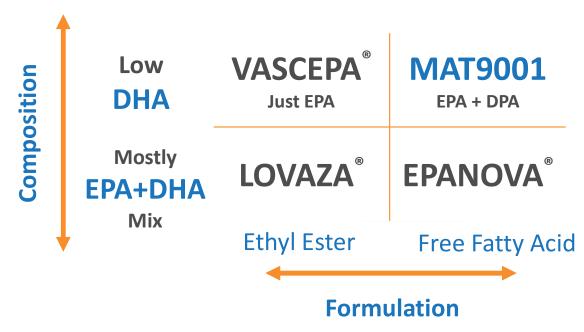
## MAT9001 - Unique Prescription-Only Omega-3 Fatty Acid

MAT9001 Specifically Designed to Treat Hypertriglyceridemia and Dyslipidemia

# **Differentiating Features**

Uniquely engineered omega-3 composition; highly bioavailable

**DPA - Highest potency** and unique MOA

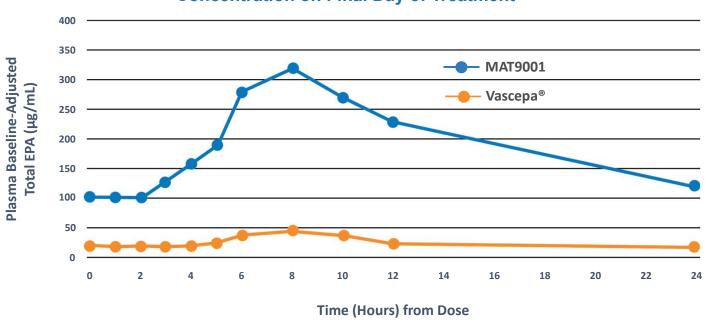




# Substantially Higher Blood Levels of EPA with MAT9001 Over Vascepa®

#### **Potential Implications for Future CV Outcomes**

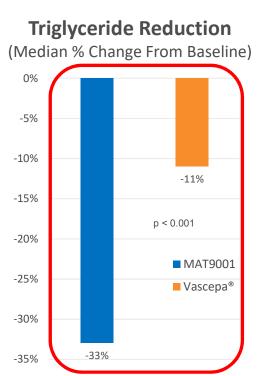
# Mean Plasma Baseline-Adjusted Total EPA Concentration on Final Day of Treatment<sup>1</sup>



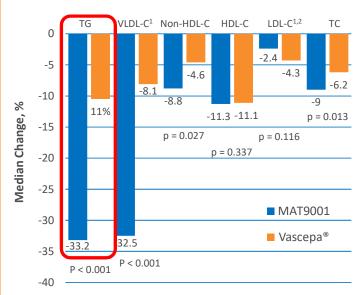


#### Demonstrated Superiority of MAT9001 Over Vascepa® in a Head-to-Head Study

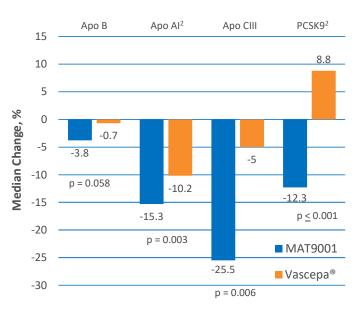
# Significant Reductions in Triglycerides, VLDL, Non-HDL-C, Total Cholesterol, ApoAI and ApoCIII Additional Significant Reductions in PCSK9







# Median % Changes from Pre-Treatment for Apolipoproteins and PCSK9





<sup>1:</sup> Some values were not calculated because the TG concentration pre- or post-treatment was >400 mg/dL

<sup>2:</sup> Response variable was not normally distributed (Shapiro-Wilk p<0.01), analysis was completed using ANCOVA after rank transformation for between treatment comparisons

#### Omega-3 U.S. Market Could Reach \$10 Billion+ with 70 Million+ Patients



(icosapent ethyl)

- Approved for SHTG in 2012
- Est. 2019 Sales: ~\$400+ million
- REDUCE-IT AdCom scheduled for November 14, 2019
- Generic entry in 2029
- NCE expires 2020



- Phospholipid and OM3 from Krill
- Total omega-3 less than 400 mg/capsule
- Phase 3 data in SHTG expected late 2019 and early 2020



- Approved in SHTG 2014; unlaunched
- NCE expires 2019
- Data from 13,000+ patient STRENGTH outcome trial expected ~2020



- Approved in SHTG 2004
- 2013 sales: \$1.1 billion
- IP expired
- Generic entry in 2013



## Strong Evidence for Omega-3 class continues to build...

#### **Updated ADA "Standards of Medical Care in Diabetes" – 2019**

Based on findings from the Reduction of Cardiovascular Events with Icosapent Ethyl – Intervention Trial (REDUCE-IT), an additional recommendation has been officially added to the section "Treatment of Other Lipoprotein Fractions or Targets". The new recommendation reads as follows:

"In patients with ASCVD or other cardiac risk factors on a statin with controlled LDL-C, but elevated triglycerides (135-499 mg/dL), the addition of icosapent ethyl should be considered to reduce cardiovascular risk."

**Diabetes Care** 2019;42(Suppl. 1):S1–S2 https://doi.org/10.2337/dc19-SINT01

Level of evidence A



# Strong Evidence for Omega-3 class continues to build...

#### **AHA Scientific Advisory – 2019**

"The use of n-3 FA (4 g/d) for improving atherosclerotic cardiovascular disease risk in patients with hypertriglyceridemia is supported by a 25% reduction in major adverse cardiovascular events in REDUCE-IT (Reduction of Cardiovascular Events With EPA Intervention Trial), a randomized placebocontrolled trial of EPA-only in high-risk patients treated with a statin."

"We conclude that prescription n-3 FAs (EPA+DHA or EPA-only) at a dose of 4 g/d (>3 g/d total EPA+DHA) are an effective and safe option for reducing triglycerides as monotherapy or as an adjunct to other lipid-lowering agents."

Skulas-Ray AC et al *Circulation*. 2019;140 DOI: 10.1161/CIR.00000000000000709



### **Strong Evidence for Omega-3 class continues to build...**

#### 2019 ESC/EAS Guidelines for the management of dyslipidemias

#### Recommendations for drug treatment of patients with hypertriglyceridaemia

Recommendations	Class	Level <sup>b</sup>
Statin treatment is recommended as the first drug of choice to reduce CVD risk in high-risk individuals with hypertriglyceridaemia [TG levels > 2.3 mmol/L (>200 mg/dL)].	1	В
In high-risk (or above) patients with TG levels between 1.5—5.6 mmo/L (135—499 mg/dL) despite statin treatment, n-3 PUFAs (icosapent ethyl 2×2 g/day) should be considered in combination with a statin. <sup>194</sup>	lla	B :
In primary prevention patients who are at LDL-C goal with TG levels >2.3 mmol/L (>200 mg/dL), fenofibrate or bezafibrate may be considered in combination with statins. 305-307,356	ПР	В
In high-risk patients who are at LDL-C goal with TG levels >2.3 mmoVL (>200 mg/dL), fenofibrate or bezafibrate may be considered in combination with statins. 305-307,356	ШЬ	с

#### **Cardiovascular Risk Categories**

Very High-Risk	People with any of the following:  Documented ASCVD, either clinical or unequivocal on imaging.  Documented ASCVD includes previous ACS (MI or unstable angina), stable angina, coronary revascularization (PCI, CABG, and other arterial revascularization procedures), stroke and TIA, and PAD.  Unequivocally documented ASCVD on imaging includes those findings that are known to be predictive of clinical events, such as significant plaque on coronary angiography or CT scan (multivessel coronary disease with two major epicardial arteries having >50% stenosis), or on carotid ultrasound.  DM with target organ damage (microalbuminuria, retinopathy, nephropathy), or at least three major risk factors, or early onset of T1DM of long duration (>20 years).  Severe CKD (eGFR <30 mL/min/1.73 m2).  A calculated SCORE >_10% for 10-year risk of fatal CVD.  FH with ASCVD or with another major risk factor.
High-Risk	People with:  • Markedly elevated single risk factors, in particular TC >8 mmol/L (>310 mg/dL), LDL-C >4.9 mmol/L (>190 mg/dL), or BP >_180/110 mmHg.  • Patients with FH without other major risk factors.  • Patients with DM without target organ damage, a with DM duration >_10 years or another additional risk factor.  • Moderate CKD (eGFR 3059 mL/min/1.73 m²).  • A calculated SCORE >_5% and <10% for 10-year risk of fatal CVD.
Moderate-Risk	Young patients (T1DM <35 years; T2DM <50 years) with DM duration <10 years, without other risk factors. Calculated SCORE $>$ 1 % and <5% for 10-year risk of fatal CVD.
Low-Risk	Calculated SCORE <1% for 10-year risk of fatal CVD.

European Heart Journal (2019) doi:10.1093/eurheartj/ehz455





## **Regulatory Strategy**

#### Pursuing Streamlined 505(b)(2) Development Plan

#### **Development Activities:**

- 28-day comparative toxicology study Completed June 2019
- Comparative bioavailability study To Be Initiated in Q4 2019
- Head to Head Study vs. Vascepa expected to commence in January 2020; with topline data by Q4 2020
  - Seek FDA End-of-Phase 2 meeting following comparative studies to set up program to commence Phase 3
    - Projected FDA meeting date Q2 2020
    - Present design of Phase 3 registration SHTG study at EOP2 meeting



# **Clinical Development Plan**

Stage	Approval [505(b)(2) Pathway]	Market Differentiation		
Preclinical	Rat Toxicology Studies  • Toxicity parameters, toxicokinetics			
PK/PD Studies	Phase 1 Comparator vs. Lovaza®  • Single dose comparative bioavailability (n=36)  • Healthy volunteers  Drug-Drug Interaction Studies (TBD)  • Simvastatin: n=50  • Warfarin: n=40-50  • Aspirin: n=40-50	<ul> <li>Phase 2 PK/PD vs. Vascepa®</li> <li>PK/PD</li> <li>Crossover</li> <li>Patients with TG 175-499 (n=70)</li> </ul> MAT9001 (4g) vs Placebo in At-Risk HTG Patients <ul> <li>12-week study in 400 high risk, statin treated patients with TG 200 - 499 mg/dL (200 per group)</li> <li>Primary endpoint: % change in TG (PD)</li> <li>Additional safety</li> <li>Positions MAT9001 for potential label for patients with TG 200-499 mg/dL</li> </ul>		
Pivotal Clinical	<ul> <li>MAT9001 (2g or 4g) vs Placebo in SHTG</li> <li>12-week study in 270 patients with TG 500-2000 mg/dL (90 per group)</li> <li>Primary endpoint: % change in TG</li> </ul>			

## **Intellectual Property and Barriers to Entry**

#### **Omega-3 Portfolio**

## **22 Patents**

filed

2 Orange-book listable U.S. patents issued, extend to 2033

Q4 2014: U.S. 8,906,964Q3 2018: U.S. 10,058,521

 4 additional U.S. patents pending, plus opportunity for composition claims depending on outcome of USPTO debate

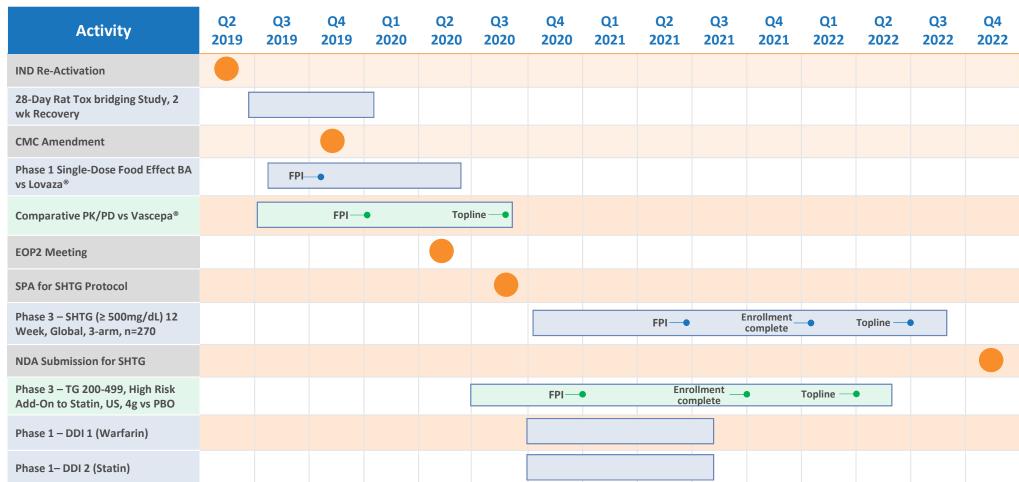
Additional IP to be developed as clinical development plan progresses

# **NCE Exclusivity**

The active moiety of MAT9001 is the entire mixture of omega-3 ingredients representing a single active ingredient, which makes MAT9001 eligible for 5-year NCE exclusivity



# MAT9001 Development Timeline –On Schedule





# MAT2203: A Novel Approach to Treating Invasive Fungal Infections

Positive FDA Meeting in June Set Stage to Advance Clinical Development Program in Cryptococcal Meningitis

**Amphotericin B** →

**Broad Spectrum**Antifungal Agent

**Gold Standard** of treatment for immunocompromised patients

MAT2203 Demonstrated to be Well Tolerated

Two Phase 2 studies

**Orally** administered

No drug-related serious adverse events reported in either Phase 2 clinical study

**LNC Platform Technology Benefits** 

Oral bioavailability

Reduction in toxicity and targeted delivery



### **Pursuing Indication in Cryptococcal Meningitis**

- Potential to be the only oral antifungal agent for treatment of cryptococcal meningitis
  - Strong preclinical Proof-of-Concept already established
  - 4<sup>th</sup> QIDP and Fast Track Designations received in July 2019 for Treatment of Cryptococcal Meningitis
- Potential for streamlined development plan to approval
  - Clinical studies can incorporate "early fungicidal activity" endpoint
- NIH financial support through key efficacy data
- Additional opportunities in developed world



#### **EnACT:** Phase 1 Safety and Tolerability in Subjects without Active Neuro-Infection



Recruitment of 27 HIV Infected Subjects, No Meningitis, No Acute Illness, Informed Consent

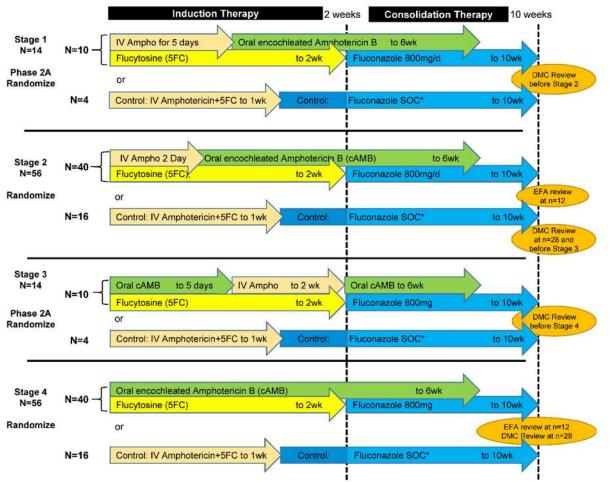


- CAMB administered in 4 to 6 divided doses over up to 24 hrs under observation
- High calcium drink and meals provided at scheduled times
- Safety and tolerability recordings over 24hrs
- Blood draws at 0, 6, 12, 18, 24 and 48-96 hours for PK and safety
- Advance to next dosing cohort if 7 of 9 complete full dose and have Grade 2 or less AEs



Well Tolerated Dose Moved ● Forward for 1wk Multi-Day Dose ● Cohort (n=9)

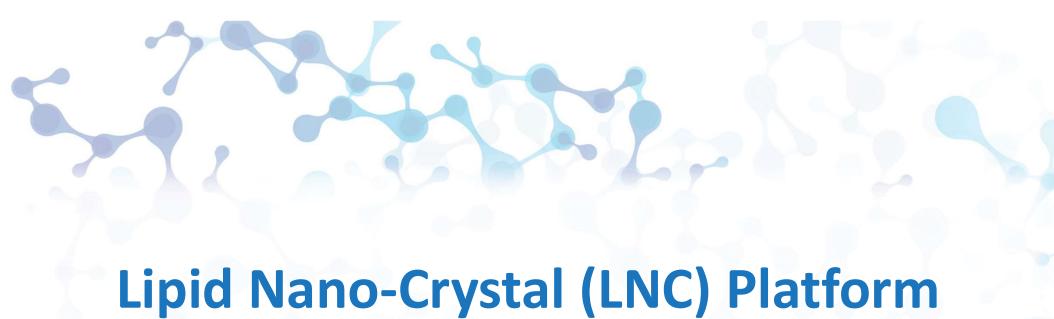
#### **EnACT**: Ph 2 safety, tolerability and efficacy of MAT2203 + 5-FC in HIV-infected pts w/ cryptococcal meningitis



- ➤ 100 pts receiving MAT2203 + flucytosine (5-FC) in 4 stages of escalating durations of MAT2203 and decreasing duration of IV Amphotericin B (AMB)
- 40 control pts receiving standard of care (IV AMB + 5-FC)
- 14 days for induction treatment in experimental arms, followed by consolidation (step-down) therapy for up to 10wks
- Will ultimately assess the potential for all-oral induction therapy w/ MAT2203
- Safety and efficacy monitored throughout study by independent Data Monitoring Committee

FPI estimated Q1 2020

<sup>\*</sup>Fluconazole Standard of Care (SOC) Dose is 1200mg/day to 2 weeks, 800mg/day week 3-10, and 200mg thereafter.





## LNCs Enable Safe, Targeted and Intracellular Delivery of Potent Medicines

Highly Efficient, Physiologic and Nontoxic Drug Formulation Platform



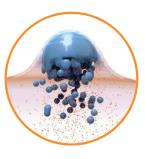
#### Flexible administration

Oral Intramuscular Intravenous Intranasal NO evidence of immunogenicity



toxicity of drugs

Enter cells through non-destructive, membrane fusion



Physiologically targets activated cells

Ability to deliver a

**broad range** of molecules

Validated in multiple clinical and preclinical studies



## **LNC Platform Provides Opportunity for Value Driving Partnerships**



Q1 2019: Signed first LNC Platform Research Evaluation of Oligonucleotide with top global pharmaceutical company

**Q2 2019: Signed Research Collaboration with ViiV Healthcare** to Evaluate Formulation of **Antiviral Drug Candidates** 



Advancing Discussions with Multiple Strategic and Research Partners to Expand Potential Successful Application of LNC Technology



# Financial Snapshot - NYSE AMERICAN: MTNB

#### \$32.4 Million Public Offering Completed March 2019

~\$36.8M

Cash Balance as of 6/30/2019

~\$112M

Market Cap<sup>1</sup>

~162M

**Common Shares Outstanding** 

~600,000

Average Daily Trading Volume<sup>1</sup>

# **Leadership Team**

#### **Executive Officers**

Jerome D. Jabbour Co-Founder, Chief Executive Officer, Director			James J. Ferguson III, M.D., FACC, FAHA Chief Medical Officer  AstraZene			AstraZeneca
Keith A. Kucinski, CPA, MBA Chief Financial Officer	PHARMACEUTICAL on endo international company	Oarr Pharmacoutcals, Inc.	Theresa Matkovits, Ph.D. Chief Development Officer	<b>©</b> CONTRAVIR	nps pharmaceuticals	The Medicines Company
Raphael J. Mannino, Ph.D. Chief Scientific Officer	RUTGERS  New Jersey Medical School	biodelivery				

#### **Board of Directors**

<b>Herbert Conrad</b> Chairman of the Board	PHARMASSET	Roche	Matthew A. Wikler, M.D., MBA FIDSA The Medicom	cines pany
Patrick G. LePore Vice Chairman	PARMAGEUTICAL	Roche	Adam Stern Director	IS VENTURES
Eric J. Ende, MBA, M.D. Director	genzyme	Merrill Lynch	Jerome D. Jabbour Co-Founder, Chief Executive Officer, Director	Reliant PHARMACEUTICALS, INC.
James S. Scibetta Director	MAVERICK THERAPEUTICS	PACCIENA FRANKELVISCALL, INC. Advance for Delivering Improved Prior Con*		

## **Positioning Our Lead Products for Near-term Success**

**MAT9001** Head-to-head dosing to Patient pre-screening set to **Initiate comparative PK** commence Q1 2020 with commence for head-tobridging study in Q4 2019 topline data expected head study vs. Vascepa Q4 2020 **MAT2203 EnACT study initiation set for EnACT updates** Q4 2019 periodically Financially supported by NIH throughout 2020

Cash runway into 2021 - through multiple data milestones and class catalysts



