



# VIVACITAS ONCOLOGY, INC. OVERVIEW

2021

# Forward-Looking Statements

Certain statements, other than purely historical information, including estimates, projections, statements relating to our business plans, objectives, and expected operating results, and the assumptions upon which those statements are based, are forward-looking statements. These forward-looking statements generally are identified by the words "believes," "project," "expects," "anticipates," "estimates," "intends," "strategy," "plan," "may," "will," "would," "will be," "will continue," "will likely result," and similar expressions. Forward-looking statements are based on current expectations and assumptions that are subject to risks and uncertainties which may cause actual results to differ materially from the forward-looking statements. Our ability to predict results or the actual effect of future plans or strategies is inherently uncertain. Factors which could have a material adverse effect on our operations and future prospects on a consolidated basis include, but are not limited to: changes in economic conditions, legislative/regulatory changes, availability of capital, interest rates, competition, and generally accepted accounting principles. These risks and uncertainties should also be considered in evaluating forward-looking statements and undue reliance should not be placed on such statements.

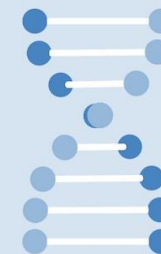
# Vivacitas: Legacy and Vision

- Privately held clinical stage biopharmaceutical company co-founded in 2015 by the late Dr. Joseph Rubinfeld (co-founder of Amgen) and Infusion 51a, LP to transform select chemotherapies with potency, toxicity, stability and/or pharmacokinetics challenges and unlock their efficacy and tolerability potential.
- Advancing next generation Camptothecins (AR-67/Rubitecan/Orathecin) in tough to treat cancers.

## Vivacitas

(vee' - və - see' - təs)

*n.* enduring life spirit, which we apply with clarity, tenacity and vision to our fight against intractable cancers



# Novel Therapy: Tough to Treat Cancers

## Novel Therapy With Potential to Address Tough to Treat Cancer Tumor Types

- Next generation Camptothecin (Topoisomerase-1 enzyme inhibitor)
- Vivacitas AR-67: Lipophilic small molecule with proprietary synthesis
- Intellectual property (IP) in Manufacturing Synthesis(2035) issued.
- IP Method to Treat(2040) pending.

## Substantial Unmet Needs, Treatment Opportunities and Regulatory Body Designation

- Brain (Glioblastoma), Colorectal (CRC), Pancreatic, Ovarian, Non-Small Cell Lung Cancer
- Tough to treat; especially recurrent and second-line therapy
- U.S. FDA Orphan Drug Designation

## Data Demonstrates Improved Safety, Toxicity and Tolerability With Evidence of Efficacy

- Phase I & II studies - Maximum Tolerated Dose (MTD), Pharmacokinetics (PK), Dose Limiting Toxicity (DLT); Refractory solid tumors (Colorectal, NSCLC)
- Phase II study (Glioblastoma): Progression Free Survival (6-29) months; improved tolerability
- U.S. FDA Orphan Drug Designation

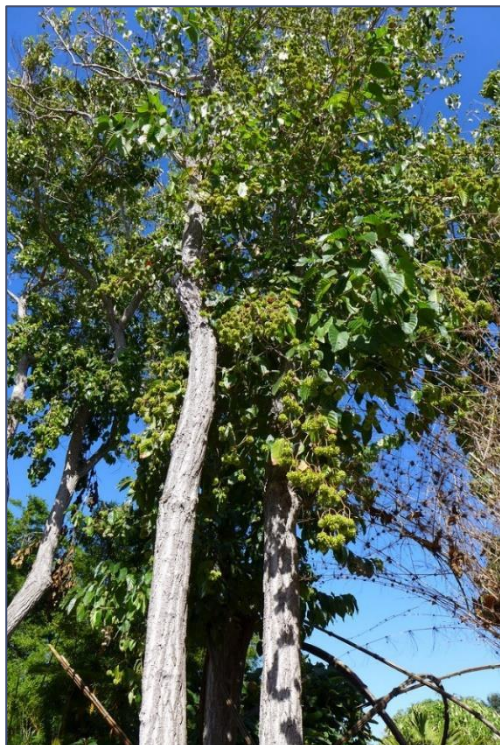
## Pursuing Funding: Clinical and Chemistry Manufacturing and Controls (CMC) Development

- Phase II Studies: Glioblastoma, Pan Tumor(pancreatic, colorectal, other)
- Demonstrate PFS, Overall Survival (OS) and improved tolerability
- Initiate 1Q23; Interim Analysis 2Q24; Top-Line Results 4Q24
- CMC Synthetic Active Pharmaceutical Ingredient Manufacturing Validation

## Leadership & Advisory Team Experienced in New Drug Development and Registration

- Leadership team with significant biotech clinical, operations, commercial experience
- Scientific and medical advisors from leading institutions
- Successful development, registration and monetization of biotech compounds and assets

# Development Platform: Scientific Rationale

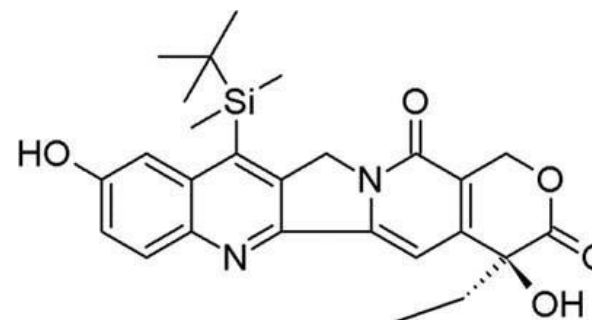


## Camptothecins:

- Camptothecins (CPTs) inhibit the Topoisomerase-1 enzyme
- Isolated from the bark and stem of *Camptotheca acuminata* (Camptotheca, Happy tree)
  - Chinese traditional medicine
- FDA approved CPTs:
  - Topotecan (Hycamtin®)
  - Irinotecan (Camptosar®)
  - Liposomal Irinotecan (Onivyde®)
- Commonly administered via intravenous (IV) injection
- Low solubility and serious adverse effects (SAEs) remain debilitating, can force treatment cessation

## Vivacitas: Next Generation Camptothecins

- AR-67: Lipophilic compound with proprietary synthesis to potentially improve efficacy and tolerability
- Rubitecan/Orathecin: 2<sup>nd</sup> generation, semi-synthetic compound; potential oral delivery

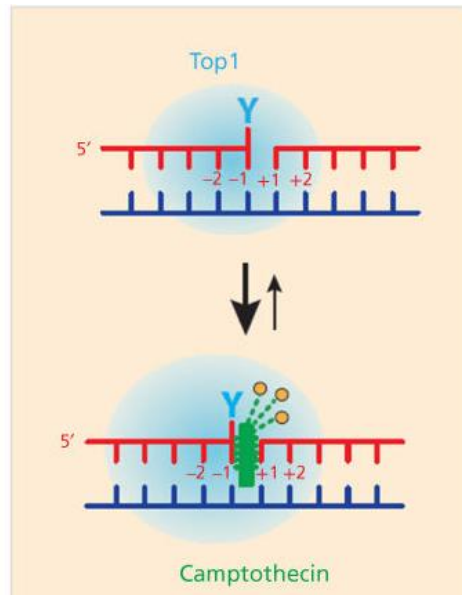


**AR-67**

# AR-67: Next Generation Camptothecin

## Compound:

- Acquired: Arno Therapeutics 2016
- Attractive Chemistry + Well Understood Target
- Highly Potent Lipophilic Compound
- U.S. FDA Orphan Drug Designation
- Intellectual Property: 2035 / 2040



From Thomas A, et al 2017  
<https://oncohemakey.com/dna-topoisomerase-targeting-drugs/>

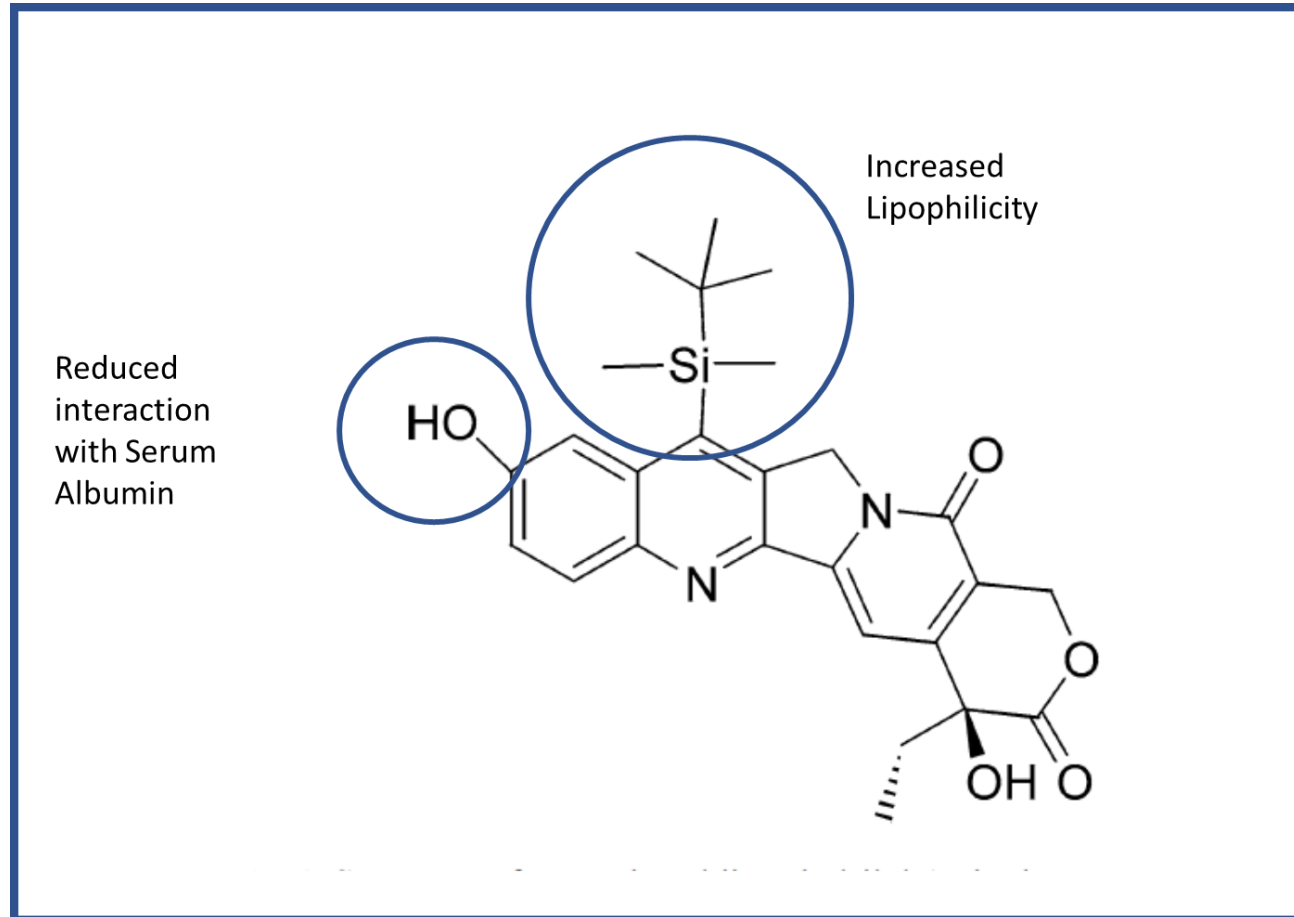
## Preclinical (please see Appendix for key publications) :

- University of Kentucky & University of Pittsburgh
  - In vitro: Potent inhibitory activity in all human malignant glioma cell lines tested, including a drug (temozolomide) resistant human glioma line
  - Potent radio-sensitizing activity on human glioma cells
- In vivo: Murine xenograft models
  - Significant efficacy in intracranial glioma xenograft model
  - Evidence of blood brain barrier permeability
  - Longer half-life of drug in tumor vs. plasma in NSCLC xenograft model

## Clinical (please see Appendix for key publications):

- Phase I studies (MTD, PK, DLT)
  - Refractory solid tumors (colon, NSCLC, SCLC, soft tissue sarcoma, head and neck, prostate, bladder, duodenal, esophageal, pancreas)
  - Dose regimen & MTD established
  - No diarrhea (dose limiting with current CPT's)
- Phase II study (recurrent Glioblastoma)
  - Progression Free Survival-6 (PFS-6): 21% (Range 6-29 months)
  - No Grade 3 or 4 diarrhea observed

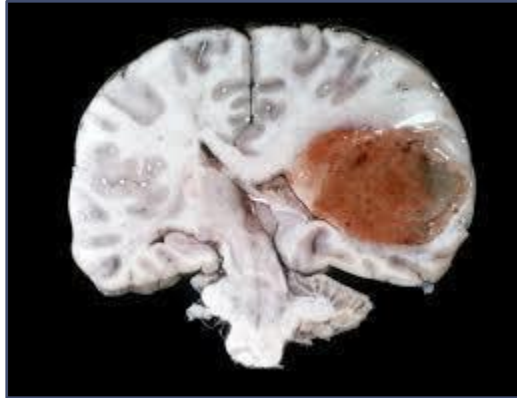
# AR-67: Differentiation Through Sophisticated Chemical Modifications



1. Increased blood stability of active form promotes greater exposure to active form
2. Lipophilicity favors greater uptake of active form across cell membranes
3. Different metabolic pathway may significantly reduce GI toxicities
4. Compound can be manufactured by patented synthetic process

# AR-67: Treatment Opportunities

## Brain Cancer Glioblastoma:



- Incidence: 24K annually in U.S.
- [Epidemiologic and molecular prognostic review of glioblastoma – PubMed \(nih.gov\)](#)
- [American Cancer Society Statistics – Brain and other nervous system](#)
- Standard of Care: Surgery and radiation & chemotherapy

## Colorectal Cancer\*:



- 149K annually in U.S.
- [American Cancer Society Statistics - Colorectum](#)
- Standard of Care: Surgery and radiation & chemotherapy

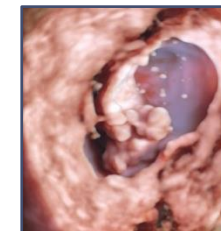
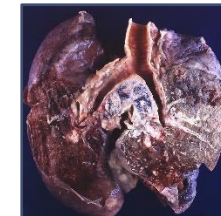
## Pancreatic Cancer\*:



- 160K annually in U.S.
- [American Cancer Society Statistics - Pancreatic](#)
- Standard of Care: Surgery and radiation & chemotherapy

## Small Cell Lung Cancer\*, Ovarian Cancer\*, other:

- Significant additional potential
- [American Cancer Society Statistics - General](#)
- Standard of Care: Surgery and radiation & chemotherapy



\* Indications for which earlier generation camptothecins are approved

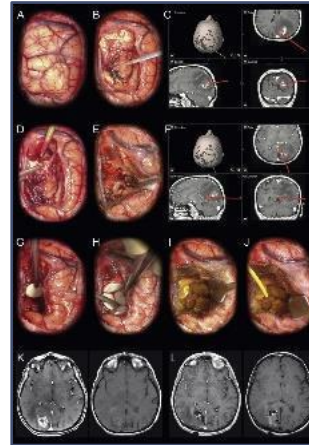


# AR-67 : Lead Indication Glioblastoma

\*Contingent on completion of Advisory Boards planned 2Q21

## Standard of Care:

- First Line/Initial Diagnosis
  - Surgery
  - Radiation & Chemotherapy
    - (e.g. Temodar®)
- First Recurrence
  - Lomustine (CCNU) (alkylating agent)
  - Avastin® (Bevacizumab) (VEGF inhibitor)
- Second Recurrence, and/or Treatment Failure
  - Physician preference



## Unmet Medical Need:

- Median survival 12-14 months; 3-5% overall survival (OS) 3+ years
- [Long-term survivors of glioblastoma: a closer look - PubMed \(nih.gov\)](#)
- Recurrence therapies suboptimal tolerability and efficacy, impacting survival
- U.S. FDA Orphan Drug Designation (7-Year Marketing Exclusivity)

## AR-67 Target Product Profile: recurrent GBM






- |   |  |
|---|--|
| <ul style="list-style-type: none"> <li>• <b>Safety/Toxicity</b> <ul style="list-style-type: none"> <li>○ Superior to: Topotecan, Irinotecan, Etoposide</li> </ul> </li> <li>• <b>Tolerability</b> <ul style="list-style-type: none"> <li>○ Equivalent/Superior: Lomustine</li> </ul> </li> <li>• <b>Dosing</b> <ul style="list-style-type: none"> <li>○ 7.5 mg/m<sup>2</sup> 1-hour daily, 5 consecutive days per 21-day cycle</li> </ul> </li> </ul> | <ul style="list-style-type: none"> <li>• <b>Efficacy</b> <ul style="list-style-type: none"> <li>○ PFS-6+</li> <li>○ OS-6+</li> </ul> </li> <li>• <b>Market Access</b> <ul style="list-style-type: none"> <li>○ \$11-20K/cycle</li> <li>○ Average 8 cycles/patient</li> </ul> </li> </ul> |
|---|--|

# AR-67 Intellectual Property: Patents

Title	Principal Claims	Status	Expiration
Methods and Systems for Camptothecin Analog Synthesis US 9,447,126 B2	Synthesis and Manufacturing Process	Issued in U.S., EU, select ex-U.S.	2035
Cancer Treatment Using Camptothecin Derivatives PCT/US20/61199	Method of Cancer Treatment to Reduce Adverse Events	International Filing Pending	2040

# Summary: Pipeline, Development and Strategic Intent

Compound	Preclinical	Phase I	Phase II	Phase III	Strategy
AR-67					<ul style="list-style-type: none"> <li>• Glioblastoma U.S. Orphan Drug Designation</li> </ul>
					<ul style="list-style-type: none"> <li>• Pancreatic/Colorectal(Pan-Tumor Trial)</li> </ul>
Rubitecan/ Orathecin					<ul style="list-style-type: none"> <li>• Determine viability as oral CPT for palliative therapy in end stage cancers</li> </ul>

***Seeking Funding to Advance Strategy/Execution Through 2023-24  
Strategic Exit/IPO Upon Successful Completion of AR-67 Phase II Study***



# APPENDIX

# Vivacitas Oncology, Inc. Team



**Mark Suseck**

**CEO & Director**

Mr. Suseck is a global business leader with successful experience in sourcing, developing, and launching products in biotech and specialty Medtech markets. Therapeutic experience includes oncology, hematology, neurology, and metabolic disorders. He has led businesses with up to \$500MM in P&L responsibility completed multiple licensing, acquisition, fund-raising, and alliance efforts, and commercialized several “first in class” technologies. His professional experience includes large diversified (J&J, Baxter) and start-up companies. He earned his BA in Economics from Rutgers University and completed the Executive Management Program in residence at the University of Michigan Ross School of Business.



**Scott VanderMeer, MBA**

**Interim CFO, Director & Co-Founder**

Mr. VanderMeer is a C-level business leader in the healthcare sector, venture capital, and private equity. He has been instrumental in forensic accounting, audits, cash management, starting businesses, and raising capital. He has founded and funded a venture capital firm International Infusion and private equity fund Infusion 51a with a focus on disruptive precision technology investments with a focus in oncology. He earned his BS in Business Marketing and MBA with a concentration in Real Estate from the University of Illinois at Chicago while playing collegiate basketball.



**Tina Runk, MBA**

**EVP - Clinical Operations Director & Co-Founder**

Ms. Runk has 35+ years of experience in research, preclinical & clinical development and operations, working with biopharmaceutical companies and CROs in the US and around the world, such as Oread, ILEX Oncology (Genzyme), PSI & Ergomed. She was instrumental in performing due diligence and acquiring AR-67, a major asset for Vivacitas Oncology. Her strengths lie in quick and accurate assessment of needs analysis and efficient implementation to maximize productivity while staying under budget. She earned her BS in Biology & BA in Psychology from SUNY Albany, and her MBA from University of Phoenix.



**Elise Brownell, PhD**

**EVP - Portfolio Management**

Dr. Brownell has diversified experience in the biopharmaceutical arena where she has played key roles in discovery, development, opportunity assessment, and Executive Leadership to drive innovation. She has deep experience in discovery research and development through her history at Bayer Healthcare and venture-backed startups, with a focus on rare/orphan diseases. She earned her BS in Biology from Allegheny College and MS, MPhil and PhD in Biology from Yale University.



**Peter Seperack, PhD, JD**

**Executive Director Intellectual Property**

Dr. Seperack has spent the last 32 years as a biopharmaceutical researcher and as a Biotech patent attorney. Dr. Seperack managed small molecule portfolios while drafting and prosecuting biological applications. He received his PhD from SUNY at Stony Brook, and his JD from Golden Gate University.

# Vivacitas Medical & Scientific Advisors



**Jai Grewal, MD**

NSPC Spine & Brain Surgery  
Long Island, NY  
Clinical Neuro-Oncologist  
Executive Board Member American  
Cancer Society



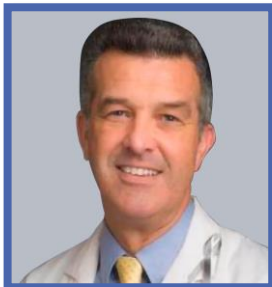
**Andrew Lassman, MD**

Columbia University Irving Medical  
Center New York, NY  
John Harris Associate Professor of  
Neurology and Chief Neuro-Oncology,  
Columbia University Irving Medical Center



**Katy Peters, MD PhD**

Department of Neurology  
Duke University School of Medicine  
Durham, NC  
Associate Professor of Neurosurgery  
Director of Supportive Care



**David Reardon, MD**

Dana-Farber Cancer  
Institute: Harvard  
School Boston, MA  
Clinical Director, Center for  
Neuro-Oncology



**Volker Stieber, MD**

Novant Health Cancer Institute  
Forsyth Medical Center  
Winston-Salem, NC  
Chair, IRB and Co-Chair, Neuro-  
Oncology Council



**Gerard Blobe, MD, PhD**

Duke University School of Medicine  
Durham, NC  
Professor of Medicine  
Associate Director, Duke Cancer  
Institute



**Erkut Borazanci, MD, MS**

HonorHealth Research Institute, University  
of Arizona College of Medicine  
Scottsdale, AZ  
Medical Oncology/Clinical Investigator  
Clinical Assistant Professor,  
Internal Medicine

# Board of Directors



**Chan Heng Fai**

Chairman Emeritus  
Alset International



**Mark Suseck**

CEO & Director



**Scott VanderMeer, MBA**

Interim CFO  
Director & Co-Founder



**Tina Runk, MBA**

EVP - Clinical Operations  
Director & Co-Founder



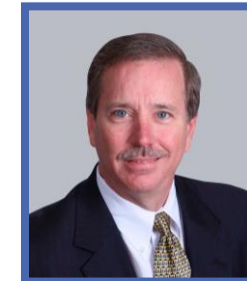
**Jeff Stephens**

Managing Director, Infusion 51a  
Director & Co-Founder



**Mamta Swaroop, MD, FACS, FICS**

General Director, Infusion 51a  
Founder, Sadanah Foundation  
Director, Sadanah Trauma & Surgical Initiative



**Frank Heuszal, JD, CPA, CIA**

CEO Document Security Systems,  
Inc; CEO American Pacific  
Bancorp

# AR-67: Key References

## Preclinical References:

1. Potent Topo-1 inhibition: Pollack IF, et al. *Cancer Res* Oct 1999; 59 (19) 4898-4905
2. Novel silatecan displays high lipophilicity, improved blood stability and potent anticancer activity. Bom D, et al *J Med Chem* 2000; 43:3970-3980
3. Silatecan DB-67 is a novel DNA Topo-1 targeted radiation sensitizer: Chen AY. *Mol Cancer Ther* 2005; 4(2): 317-24.
4. Antitumor activities and pharmacokinetics of silatecans DB-67 and DB-91: Yeh et al. *Pharm Res.* 2010; 61:108-115
5. PK modeling in rats: Adane ED, et al. *Pharm Res.* 2012; 29:1722-1736

## Clinical Study References:

1. Phase I study publication: Arnold SM, et al. *Clin Cancer Res.* 2010;6:673-680
2. Preclinical, clinical development: Tsakalozou E. 2013. University of Kentucky. PhD thesis
3. Dosing models in NSCLC xenografts and humans: Tsakalozou E, et al. *Cancer Chemother Pharmacol.* 2014;74:45-54
4. Phase II study publication (abstract): Kumthekar P, et al. SNO 2019. Poster ACTR-40, published in *Neuro-Oncology*(<https://academic.oup.com/neuro-oncology>)
5. Population PK in cancer patients with solid tumors: Tang F, et al. *Invest New Drugs* 2019; (<https://doi.org/10.1007/s10637-019-00744-0>)