# ATS 2022 Postgraduate course

# Friday, May 13, 2022, 8 am- 4 pm

# PG. Jump Start: A beginner's guide to drug and company development in an academic setting

## Morning session



- An introduction to drug development in lung diseases Academic perspective
- Challenges and excitement of commercializing ideas and drug candidates that result from basic research in an academic lab
- Pros and cons of engaging large corporate partners or forming a new start-up
- Pros and cons of enlisting venture capitalists in start-up formation

**Richard Gomer, PhD,** Thomas Powell '62 Professor of Science & University Distinguished Professor, Department of Biology, Texas A&M University, USA, and Co-founder of Promedior, Inc

## What's mine is mine: promoting and protecting your IP during publication



- Understanding the initial steps to protect your IP during the public disclosure process
- Discussion of all IP steps as well as training programs (ICorps@NIH program)

Nicholas Kenyon, MD/MAS, Division Chief of Pulmonary, Critical Care, and Sleep Medicine, UC David Health and ICORPS leader

#### The importance of target engagement studies in preclinical research



- Design of target engagement studies in academia vs pharma
- Importance and implementation of target engagement studies in preclinical research

Scott Turner PhD, Senior Vice President, Head of Research, Pliant Therapeutics

## Expert fireside chats: The future of pulmonary medicine

- Discussion of innovative approaches for drug development in pulmonary medicine
- Examples of development of the most successful and innovative drugs for lung diseases
- An academic and industry perspective on challenges in drug development



**Naftali Kaminski, MD,** Boehringer Ingelheim Boehringer-Ingelheim Endowed Professor of Internal Medicine, Chief of Pulmonary, Critical Care and Sleep Medicine, Department of Medicine, Yale School of Medicine



*Melanie Koenigshoff, MD, PhD* Professor of Medicine (under committee review), Associate Chief of Research, Division of Pulmonary, Allergy, and Critical Care Medicine, University of Pittsburgh

## Case based panel discussion – Taking the next steps after discovery

Building on earlier topics and discussions, this case-based panel discussion will be:

- Centered on the process of taking novel scientific discoveries from the bench to the bedside
- How academic basic scientists and clinical researchers can work with their own University resources
- How to work with outside investors and interested parties
- How to successfully advance novel discoveries into clinical development programs at both established pharma/biotech and newly formed research companies



**Robert Tarran, PhD**, Professor, Department of Cell Biology & Physiology, University of North Carolina and CSO of Eldec Pharmaceuticals that develops anti-inflammatory peptides for the treatment of chronic lung disease



**Alan H Cohen, MD** Global Clinical Leader, Bayer U.S. LLC. board-certified Pediatric Pulmonologist (x38+ years) responsible for a number of early/translational, mid and late stage clinical development programs. As entrepreneur, he worked with numerous pre-IPO start-ups as well as with public companies worldwide (Aridis Pharam, Therabron Therapeutics, Boehringer Ingelheim, Intermune)



Moderator: **Milica Vukmirovic, PhD**, Director of External Programs and Partnerships, Precision Medicine initiative, PRiME, University of Toronto, Canada. She specialized in entrepreneurship and commercialization in Life Sciences with a focus on development of new therapies and devices in lung field (Kaminski Lab and Blavatnik Fund for Innovation at Yale). Dr. Vukmirovic is currently developing programs and Industry-Academia partnerships for diverse portfolio of early-stage technologies.

## Introduction to pre-IND enabling studies and clinical trials



- Design and execution of pre-IND enabling studies in an academic setting
- Challenges of animal models and developing a pre-clinical package
- Developing trial protocols and working with Contract Research Organizations and regulatory agencies

Toby Maher, MD/PhD, Professor of Medicine, Keck School of Medicine of USC

#### Power Lunch - Navigating and growing an academic startup

- A how-to discussion on spinning out and continuing to lead an academic-based startup company (foundation, funding, operations and conflict of interest management)
- A unique perspective on commercialization of University-based technologies that are translated to the clinic



**Rama Mallampalli, MD**, Professor and Chair, Department of Internal Medicine, Ohio State University College of Medicine. Dr. Mallampalli serves as consultant and cofounder of Koutif, a startup company that has successfully acquired IND approval for a first-in-class oral E3 ligase compound for inflammatory lung disease.



Jason J Rose, MD/MBA, Assistant Professor of Medicine and Bioengineering, University of Pittsburgh School of Medicine, President, CEO, and co-Founder of Globin Solutions, Inc that develops a rapidly acting antidote for carbon monoxide poisoning, the most common human poisoning.

#### Afternoon session

#### **Expert chats: Funding made easy**

- Different paths to obtain funding by early-stage companies before they are ready for VC
- Non-dilutive funding opportunities such as SBIR/STTR grants & University resources



**Richard Gomer, PhD,** Thomas Powell '62 Professor of Science & University Distinguished Professor, Department of Biology, Texas A&M University, USA, and Co-founder of Promedior, Inc, a company successfully acquired by Roche in 2020.



**Louise Hecker, PhD** is an Associate Professor at Emory Un iversity and the Founder and Chief Scientific Officer (CSO) of Fibronox. Dr. Hecker successfully obtained Federal funding from the Department of Defense, Department of Veterans Affairs, and the National Institutes for Health to develop novel technologies.

# Lessons from venture capitalists - Do's and don'ts when developing a new drug



- Demystify the world of venture capital
- Paths to secure venture capital funding
- What to expect when working with VC companies

**David Morris MD**, Ex-operating Partner, Novartis Venture Fund and Chief Medical Officer, Head of therapeutics at Valo Health. Previously he held multiple leadership positions in company development and clinical operation at Novartis and Roche.



Kambez Benam, PhD, Associate Professor, University of Pittsburgh, and Founder of Pneumax

## 6 min Presentations from 4 early-stage technology development companies

1. Pneumax (Presenter: Kambez Benam, PhD, Associate Professor, University of Pittsburgh)



Dr. Benam is the Founder of Pneumax and will briefly present his journey on setting up this startup to develop and commercialize an advanced lung organomimetic which reproduces human airway pathophysiology, to accelerate preclinical translational studies in pulmonary space.

2. Fibronox (Presenter: Louise Hecker, PhD, Associate Professor, University of Arizona).



Dr. Hecker is the Founder and Chief Scientific Officer (CSO) of Fibronox. Dr. Hecker was the first to identify a novel target, Nox4, and its critical role in mediating fibrosis (scar tissue). She will provide an overview on her journey from target identification and validation and the pre-clinical development of small molecule inhibitors that selectively target Nox4. Fibronox is actively working to bring these inhibitors through the pre-clinical pipeline in order to reach patients, and ultimately to revolutionize treatments for fibrotic disease.

3. Pliant Therapeutics (Presenter: Scott Turner PhD, Vice President of Translational Science)



Pliant Therapeutics is a clinical stage biotechnology company in South San Francisco. Dr. Turner will present an overview of the company and their approach to targeting integrins for the treatment of IPF.

4. Mediar Therapeutics (Presenter: David Lagares, PhD, Assistant Professor of Medicine at Harvard Medical School



Dr. Lagares is the Founder of Mediar Therapeutics. Seminal work from Dr. Lagares's laboratory includes the identification of the ADAM10-sEphrin-B2 pathway in lung fibrosis. During his talk, Dr. Lagares will discuss his entrepreneurial journey that has led him to co-found Mediar Therapeutics, a biotech company developing innovative anti-fibrotic therapies targeting pathological mechanisms identified in Dr. Lagares's research laboratory.

## AFTERNOON WORKSHOP (2h) – WORK IN GROUPS

Prepare 5min pitch slide deck to promote your key discoveries Work with Mentors from postgraduate course Present your pitch to postgraduate course participants and obtain feedback from experts