WILLIAM SENAPEDIS, PHD

Newton, MA ▪ (781) 350-0868
www.biotargetedsolutions.com
wsenapedis@biotargetedsolutions.com
www.linkedin.com/company/biotargeted-solutions-llc

SUMMARY

Translational science and drug development leader with 20+ years of experience advancing first-in-class and best-in-class therapeutics from target discovery through IND, global clinical development, and FDA approval. Founder and Principal Consultant at BioTargeted Solutions LLC, advising biotech companies on biomarker strategy, translational positioning, and regulatory execution across oncology, immunology, and emerging longevity-associated biology. Deep expertise spanning small molecules, mRNA therapeutics, epigenomic regulation, and precision medicine, with a track record of FDA-approved therapies and high-impact publications.

WORK EXPERIENCE

BIOTARGETED SOLUTIONS LLC, Biotechnology Consultant, Newton MA — 2025-present

Founder and Principal Consultant

- Provide senior-level consulting in translational medicine, biomarker strategy, and drug development for biotech and pharmaceutical companies.
- Advise early-stage and emerging biotech programs on IND-enabling translational strategy, biomarker planning, and regulatory positioning across oncology, immunology, and RNA-based modalities.
- Collaborate with senior industry leaders on immune regeneration and longevity-associated biology programs, supporting target validation and early development strategy.
- Support redevelopment of clinically validated targets, leveraging prior first-hand discovery and translational experience to de-risk program execution.
- Guide clients through IND, NDA, and BLA strategy, including briefing book preparation, CRO selection, and alignment with FDA and EMA expectations.
- Provide scientific leadership for early-stage companies, including program differentiation, team mentorship, and investor-facing scientific narratives.

OMEGA THERAPEUTICS INC., Oncology Discovery, Cambridge MA — 2020 – 2025

Senior Director, Cancer Biology (2023 – 2025), **Director, Cancer Biology** (2020 – 2023)

- Established, recruited, managed and mentored the oncology discovery team including scientists and research associates.
- Led several oncology target programs using novel mRNA Epigenomic Therapeutics delivered via lipid nanoparticles, including Omega's first clinical candidate, OTX-2002, for the treatment of patients with MYC-associated advanced solid tumors (focused on hepatocellular carcinoma), which successfully completed the escalation phase (24 patients total) of a global Phase 1/2 clinical trial (November 2024).
- Led IND-enabling translational strategy for OTX-2002, including mechanism-of-action studies, non-clinical pharmacology, regulatory briefing books, IND submission, and integration of clinical biomarker strategy across a global Phase 1/2 trial.
- Developed novel epigenetic pharmacodynamic (PD) target engagement biomarkers both internally and in collaboration with CROs.
- Selected vendors for clinical sample management/logistics and bioanalysis through consensus building across departments.
- Prepared and presented non-clinical and clinical data on OTX-2002 at major conferences.
- Published a research article based on non-clinical OTX-2002 data in *Nature Communications* as first author (September 2024).

RESTORBIO, INC., Research Group, Boston MA — 2019 – 2020

Senior Director, Research

- Initiated discovery-stage programs targeting age-related diseases (e.g., sarcopenia, neurodegeneration), establishing early target pipelines through CRO partnerships.

KARYOPHARM THERAPEUTICS INC., Biology Department, Newton MA — 2011 – 2020

Clinical Research Scientist Consultant (2020), **Director, Research and Clinical Development** (2017 – 2019),
Associate Director, Biology (2016 – 2017), **Senior Scientist, Biology** (2012 – 2015), **Scientist, Biology** (2011)

- Managed/mentored groups of scientists and made individual contributions to novel oncology and non-oncology research projects.
- Co-led programs that discovered the second-generation Selective Inhibitor of Nuclear Export (SINE) compound KPT-8602 / eltanexor and the novel oral dual inhibitor of PAK4 and NAMPT, KPT-9274 / ATG-019 / padnarsertib.
  - Co-led clinical candidate selection, IND applications, and initiation of Phase I clinical trials for eltanexor and padnarsertib.
  - Contributed to clinical protocols and amendments, IBs, and DSURs.

- Prepared material for and trained clinical personnel during Site Initiation Visits.
- Determined time points and type of samples to collect from patients for prospective and retrospective biomarker determination.

- Shared translational data and maintained site engagement through weekly investigator meetings.
- Initiated and contributed to the padnarsertib clinical trials in companion dogs with spontaneous solid and hematological malignancies.
- Supported drug discovery efforts and established non-clinical mechanism of action research for the first-in-class SINE compound KPT-330 / selinexor / XPOVIO®.
- Prepared and reviewed non-clinical pharmacology reports supporting INDs and NDAs for XPOVIO® (FDA approvals in MM and DLBCL).
- Prepared and presented non-clinical and preliminary clinical data at internal Scientific Advisor Board meetings and major conferences (e.g., AACR, ASH, ESMO, ASCO GI, and others).

FOX CHASE CANCER CENTER, Department of Medical Oncology, Philadelphia PA. Sci. Tech. Mentoring with Dr. Elizabeth Henske

EDUCATION

Doctor of Philosophy, Cell Biology, Harvard Medical School, Boston, MA
Bachelor of Science, *with Distinction*, Biology, Minor in Chemistry, Pennsylvania State University, University Park, PA

HARVARD MEDICAL SCHOOL, Boston, MA

Ph.D. Candidate Mentoring with Dr. Pamela Silver, Department of Systems Biology

- Executed a high-throughput RNA interference (RNAi) screen to determine how a set of genes, when reduced, influence Akt signaling and FOXO1a localization.
- Dissertation: *Forkhead at the Crossroads of Cancer and Healthy Lifespan*.

Rotating Ph.D. Candidate, **Biological and Biomedical Sciences Program**

- Worked with Dr. Alex Toker at Beth Israel Deaconess Medical Center, Boston MA and Dr. Robert Kingston at Massachusetts General Hospital, Boston MA

MENTORING EXPERIENCE

OMEGA THERAPEUTICS INC.

- Led and mentored multidisciplinary oncology teams through discovery-to-translational transition, supporting IND delivery and multiple internal promotions
- Established external collaborations with CROs for analysis of non-clinical and clinical samples.

KARYOPHARM THERAPEUTICS INC.

- Managed a multi-disciplinary team (2-5 researchers) as the head of biology within a matrixed organizational environment.
- Supervised technicians and post-doctoral level scientists within the biology group, supporting multiple clinical programs through projects and individual goal development.
- Set up and maintained over 50 academic and biotechnology external collaborations and CROs.

CAMBRIDGE INNOVATION CENTER (CIC), JAPAN DESK

- Selected mentor to a Japan-based, pre-established biotech company; conducted three structured advisory sessions focused on scientific narrative, translational positioning, and U.S. investor pitch readiness; invited to remain available as an advisor.

HARVARD MEDICAL SCHOOL

- Mentored undergraduate and Master's-level research scientists in the Silver laboratory.
- Taught BCMP/MCB 234: Cellular Metabolism and Human Disease.
- Served as teaching fellow for the 2007 Harvard iGEM (International Genetically Engineered Machine) team.

SCIENCE COMMUNICATION & SERVICE (SELECTED)

- Contributing writer (volunteer), Unbiased Science, an evidence-based science communication platform.
- Author of accessible content on drug development, translational biology, and clinical research literacy.

ADDENDUM

ORAL PRESENTATIONS

- In silico-designed covalent peptidomimetic inhibitors (KPT-SINE) of CRM1 modulate tumor suppressor protein nuclear export and induce apoptosis in cancer cells. AACR Chemical Systems Biology, June 28, 2012; Boston, Massachusetts, USA
- KPT-SINE (Selective Inhibitors of Nuclear Export) induce apoptosis in colon cancer cells in vitro and in vivo through nuclear localization of Tumor Suppressor Proteins (TSPs). AACR Annual Meeting, April 2, 2012; Chicago, Illinois, USA
- A nuclear localization switchable device reveals a regulatory network. Conference on Systems Biology in Mammalian Cells, June 3rd, 2010; Freiburg, Germany

PUBLICATIONS

- **Senapedis W**, Gallagher KM, Figueroa E, Farelli JD, Lyng R, Hodgson JG, O'Donnell CW, Newman JV, Pacaro M, Siecinski SK, Chen J, McCauley TG. "Targeted transcriptional downregulation of MYC using epigenomic controllers demonstrates antitumor activity in hepatocellular carcinoma models." Nat Commun. 16 Sept. 2024, Vol 15, Article number: 7875.
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- Khan HY, Uddin MH, Balasubramanian SK, Sulaiman N, Iqbal M, Chaker M, Aboukameel A, Li Y, **Senapedis W**, Baloglu E, Mohammad RM, Zonder J, Azmi AS. "PAK4 and NAMPT as Novel Therapeutic Targets in Diffuse Large B-Cell Lymphoma, Follicular Lymphoma, and Mantle Cell Lymphoma." Cancers (Basel). 2021 Dec 29;14(1):160
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PATENTS

- Combination therapies comprising myc modulators and checkpoint inhibitors. Witt, AE; Farelli, JD; Scheidegger, AW; **Senapedis, W**; Kennedy, JM; Belaghzal, H; Yarar, D; Lee, E; Palakurthi, SS. (2023), WO2024040229A3.
- Formulations for modulating myc expression. Witt, AW; Farelli, JD; Scheidegger, AW; **Senapedis, W**; Kennedy, JM; Belaghzal, H; Ansell, SM; Du, X; Lin, PJC; Tam, YK. (2023), WO2023250427A3.
- Combination therapies comprising myc modulation. Witt, AE; Farelli, JD; Scheidegger, AW; **Senapedis, W**; Kennedy, JM; Belaghzal, H; Yarar, D; Lee, E; Gallagher, K. (2023), WO2023250429A2.
- Compositions and methods for modulation myc expression. Witt, A; Farelli, J; Scheidegger, A; **Senapedis, W**; Kennedy, J; Belaghzal, H; Yarar, D; Lee, E.. (2021) WO2022132195A2.
- Preparationof(S,E)-3-(6-aminopyridin-3-yl)-N-((5-(4-(3-fluoro-3-methylpyrrolidine-1-carbonyl)phenyl)-7-(4-fluorophenyl) benzofuran -2-yl)methyl)acrylamide for the treatment of cancer. Baloglu, E; Shacham, S; **Senapedis, W**. From PCT Int. Appl. (2017), WO 2017031323 A1 20170223.
- 3-(Pyridin-3-yl) acrylamide and N-(pyridin-3-yl) acrylamide derivatives as PAK and NAMPT modulators and their preparation. Baloglu, E; Shacham, S; **Senapedis, W**. From PCT Int. Appl. (2017), WO 2017031213 A1 20170223.
- Preparation of 2-pyridylcyclopropane-1-carboxamide derivatives and their use as kinase inhibitors. Baloglu, E; Shacham, S; **Senapedis, W**. From PCT Int. Appl. (2017), WO 2017031204 A1 20170223.
- Preparation of benzothienylmethyl and benzothiazolylmethyl acrylamides for treating diseases. Baloglu, E; **Senapedis, W**; Shacham, S From PCT Int. Appl. (2016), WO 2016100515 A1 20160623.
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