

Duncan H. Whitney, Ph.D.

25 Channel Center St., Boston, MA 02210; duncanhwhitney@gmail.com; (978) 460-1657 (mobile)

EXECUTIVE SUMMARY

Molecular diagnostics and technology development expert with a track record of success in emerging life sciences companies. Built and led teams, strategies, and technology/product development to meet corporate objectives. Have demonstrated expertise in genomics, biomarker discovery, cancer diagnostics, assay development, process development, clinical trials design and oversight, and biomolecule separations.

PROFESSIONAL EXPERIENCE

Gregor Diagnostics (Madison, WI), Mar 2022 – present **Chief Scientific Officer**

- Gregor Dx is developing improved diagnostics for early detection as well as to differentiate aggressive from more indolent forms of prostate cancer (PCa).
- The company relies on a multi-modal approach and a novel sample type (seminal fluid) to maximize test accuracy.

Johnson & Johnson; Lung Cancer Initiative, Oct, 2018-Sep,2021 **VP, Head of Early Detection**

- Responsible for developing the strategy of the Early Detection pillar within the Lung Cancer Initiative (LCI) and establishing collaborations with key external partners to develop and validate biomarkers and diagnostics to enable downstream pharmaceutical and medical device solutions.
- Built a small team to execute the strategy and help manage external collaborations and coordinate progress with internal stakeholders. The team consists of director-level scientists, technical project managers.

Curis Inc (Lexington, MA) July 2017-Oct 2018 **VP Diagnostics**

- Curis develops small-molecule compounds in hematological oncology and immunotherapy applications.
- Responsible for development of clinical diagnostics testing strategies, including companion diagnostics (as applicable). Led biomarker development for DLBCL drug-trials including established IHC tests and development of new gene-expression prediction tools.

Veracyte Inc (South San Francisco, CA) 2014-2017 **VP Discovery Research**

Veracyte develops disease-specific classifiers using machine-learning algorithms that are trained

to answer specific clinical questions based on high-content genomic data.

- Transferred technology of the lung cancer test originally developed at Allegro (Percepta™), which was acquired by Veracyte in 2014. The following milestones were achieved within the first 12 months post-acquisition:
- The lung cancer gene expression test developed at Allegro was successfully translated to Veracyte operations, including transfer of all clinical databases, clinical specimen repositories, bioinformatics algorithms, and clinical validation data.
- Results of clinical validation studies were published in New Engl J Med (July, 2015) and BMC Medical Genomics (May 2015).
- Percepta™ was launched as a CLIA-certified test at Veracyte's laboratories in South San Francisco, CA (with recent acceptance by NYSDOH).
- Clinical utility studies submitted for publication.
- Led the discovery work for the second-gen multi-gene assay as an aid in diagnosis of indeterminate thyroid nodules [Afirma™].

Allegro Diagnostics Corp (Maynard, MA) 2009-2014

SVP and CSO; Research & Development

- Responsible for all technical and development milestones of Allegro's gene-expression profiling lung cancer diagnostic test (acquired by Veracyte in 2014). Allegro sponsored parallel prospective, multi-center clinical trials enrolling over 2000 subjects to validate the test. Responsibilities and achievements include the following:
- Conceived, planned, and gained Board approval of technical direction of company to transition from an academic concept to a clinically validated commercial product. · Coordinated clinical sample analyses at the company's registered CLIA laboratory, and all data analysis in conjunction with external advisors and consultants.
- Presented strategy, plans and progress regularly at Board of Director meetings and Scientific Advisory Board meetings.
- Recruited/hired key technical and leadership personnel including the Manager of Bioinformatics, the CLIA Lab Director. Introduced Regulatory and Business Strategy consultants and advisors to the company.
- Met technical objectives of \$2.8M NCI-SBIR grant, and rescued final tranche (>\$800k). · Managed corporate IP and patent portfolio in conjunction with external legal counsel. · Represented the company and technological developments at scientific and professional conferences.
- Presented accepted oral presentations at professional society conferences (ATS and ACCP).
- Managed ongoing collaborations and data sharing with Academic partners at Boston University School of Medicine. Included on several abstracts and papers presented by BU scientists.

U.S. Genomics & Independent Consultant 2009

- Leveraged my expertise in clinical diagnostics in conjunction with emerging platform technologies to meet aggressive development plans and objectives. Brief descriptions of selected projects are as follows:
 - U.S. Genomics – collaboration with Becton-Dickinson to develop single-molecule mapping platform and methodology for rapid microbiological ID and strain-typing applications.
 - Myelogix – founding member of company to commercialize gene-expression

- microarray diagnostic test for multiple myeloma risk stratification.
- AlloHealth Diagnostics Inc. – partner in the development of company business plan and initial technical due diligence. Business model based on commercialization of a licensed gene-expression panel targeting renal-transplant monitoring.

Progenika, Inc. (Cambridge, MA) 2007-2008

Chief Scientific Officer

- Part of founding team for new US-based subsidiary of Progenika BioPharma (Derio, Spain) in the personalized medicine market.
- Established array-based test (LipoChip™) for Hypercholesterolemia testing in newly established U.S. labs (transferred from labs in Spain).
- Led technology transfer and helped commercialize a blood group genotyping test (BloodChip™) in the U.S., based on developments from the European Bloodgen consortium.
- Outfitted new clinical diagnostics labs and hired technical team and Medical Director.
- CLIA labs inspected and registered by MA DPH within 3 months of start-up.
- Investigated new platform technologies for future assays/products, including sequencing and microfluidics platforms.

US Genomics (Woburn, MA) 2005-2007

VP Research & Development

- Led research and development of a novel single molecule detection platform into genomic and protein applications. Transitioned company business model from general platform development to biomarker and diagnostics development model. Established collaborations with external diagnostics companies, technology development companies, and clinical diagnostics groups.
- Led multidisciplinary team of scientists, engineers, and applications specialists
- Focused on miRNA and protein biomarker applications
- Presented progress to the Board of Directors on a regular basis
- Established miRNA-based gene-expression diagnostics collaboration in lung cancer (Rosetta Genomics), and prostate and bladder cancer (Lahey Clinic).
- Led collaboration with Aviir (Palo Alto, CA) in single-molecule detection strategies for protein-based cardiovascular disease diagnostics tests. Also established and managed smaller research collaborations (including several academic partnerships) in a number of other disease areas.

EXACT Sciences Corp. (Marlborough, MA) 2000 - 2005

Led the process development leading to the commercialization of the company's first applied genomics assay for colon cancer screening. Developed novel DNA purification platform, formulated and led effort to automate and reduce costs, established and managed research collaborations with novel platform technology companies in search of ways to reduce assay complexity and improved analytical sensitivity and reproducibility.

VP Technology Development

- Defined and led Platform Automation strategy with CTO of Exact.
- Point of contact and technical liaison for PreGen-Plus assay at LabCorp. · Technical lead for Effipure™, DNA purification technology.

Director, Technology Development

- Developed strategy for high-throughput automation of colorectal cancer screening assay. · Developed new approach to DNA sample prep based on affinity electrophoresis. Product is FDA registered
- Implemented PCR and mutation analysis multiplexing and assay simplification strategies. · Prepared cost analysis of CRC screening assay as part of a milestone-driven deal for a multi million dollar business deal with LabCorp of America (LCA).
- Completed technology transfer of Exact's first commercial assay (PreGen-26™) to LCA (3Q 2001).
- Hired and managed multidisciplinary development team (10 scientists).

Molecular Geodesics, Inc. (Boston, MA) 1999 – 2000

MGI was founded by Dr. Don Ingber (Harvard Medical School) to capitalize on novel biomimetic principles, for the design of innovative biodefense and biomedical materials and devices. I joined to help identify and build product development concepts primarily in support of biohazard filtration and deactivation strategies.

VP R&D

- Managed all R&D scientific \$6.4M DARPA grant (Defense Sciences Organization).
- Secured an additional SBIR contract through DARPA, and early-stage private funding to help finance research.
- Built and R&D team of 7 professionals (3 Ph.D.'s) with specialization in polymer chemistry, tissue engineering, and molecular biology.

PerSeptive Biosystems (Life Technologies) 1990 - 1999

Held a number of senior technical management positions, with increasing levels of responsibility over nine years. Started as employee 20 (pre-IPO) and helped lead the growth to ~300 people and \$100M annual sales prior to the merger with Perkin Elmer Corp. in 1998.

Sr Director, Chromatography Chemistry R&D (1997-1999)

- Responsible for new product development, and technical management of all chemistry based product lines within the chromatography business unit. Products included proprietary POROS chromatography supports (columns and bulk media), Poroszyme (immobilized-enzyme media and columns), and ID (immunodetection columns and media).
- Planned portions of annual Roadshows (1997 and 1998), showcasing PerSeptives platform technologies in a series of technical and marketing presentations.
- Planned and delivered multiple conference presentations and customer site presentations in conjunction with the Sales & Marketing teams to develop large-scale customer accounts. · Developed annual plans and budget.

Senior Director, Materials & Surface Chemistry (1993-1997)

- Developed chromatography resin products, including design of surface chemistries and novel flow-through supports.
- Managed applications development for chromatography resins. Worked closely with marketing and manufacturing departments to launch new products.
- Built inter-disciplinary team of chemists, engineers, and analytical scientists. Managed group of 12 professionals.

- Coordinated projects for development of novel supports for solid-phase peptide and DNA synthesis.

Director, Materials Development (1990-1993)

- Designed and developed macroporous polymer supports for rapid purification of recombinant proteins and other biomolecules. Demonstrated benefits of flow-through design on protein purification processes.
- Expanded product-line to include multiple particle sizes and pore sizes for high-resolution analytical to large-scale purification processes.

VOLUNTEER

Bonnie J Addario Lung Cancer Foundation (San Mateo, CA) 2010-2015

Scientific Advisory Board

The BJALCF is a non-profit organization devoted to eradicating Lung Cancer through lung cancer awareness, support of medical innovations, and patient advocacy and support. The Foundation launched a grant program to support novel means of diagnosing and treating lung cancer early, with a focus on personalized approaches. As a member of the SAB I have worked to support the grant program.

EDUCATION

Ph.D., Chemistry

Massachusetts Institute of Technology, Cambridge, MA

Department of Materials Science & Engineering

M.S., Chemistry

Massachusetts Institute of Technology, Cambridge, MA

Department of Materials Science & Engineering

B.S., Chemistry

Colby College, Waterville, ME

Publications:

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10. Neely LA, Rieger-Christ KM, Neto BS, Eroshkin A, Garver J, Patel S, Phung NA, McLaughlin S, Libertino JA, **Whitney DH**, Summerhayes IC. A MicroRNA Expression Ratio Defining the Invasive Phenotype in Bladder Tumors. *Urologic Oncology: Seminars and Original Investigations*. 2010, 28: 1, 39-48.
11. Moore JK, Smith JA, **Whitney DH**, Durkee KH, Shuber AP. An electrophoretic capture method for efficient recovery of rare sequences from heterogeneous DNA. *Biotechniques* (2008), 44(3):363-74.
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Patents & Applications:

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3. Whitney DH, Luo J. Methods for Evaluating COPD Status. US Patent application 2016/0024583 A1 (Pub date, Jan, 2016).
4. Whitney DH, Elashoff M. Methods for Evaluating Lung Cancer Status. WO 2016/011068 (Jan 2016).
5. Whitney, DH, Luo J. Methods and Compositions for Detecting Cancer Based on miRNA Expression Profiles. US Patent application 2015/0080243 A1, (Mar 2015).
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