2024–2025 | NCI SBIR

INVESTOR INITIATIVES

SHOWCASE COMPANIES

NATIONAL CANCER INSTITUTE | SBIR DEVELOPMENT CENTER

INVESTOR | INITIATIVES

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BIOPHARMACEUTICALS

Company	Technology Type	Indication(s)
7 Hills Pharma	Small Molecule	aPD-1-resistant melanoma, NSCLC, HCC, mesothelioma, RCC, CRC, other solid tumors
Allterum Therapeutics	Biologics/Vaccine	Acute lymphoblastic, acute myeloid, and chronic lymphocytic leukemias; non-Hodgkin's lymphoma
Canget BioTekpharma	Small Molecule	Treatment for pancreatic cancer
Cellinfinity	Cell/Gene Therapy	Solid tumors – specifically renal cell carcinoma
Duo Oncology	Small Molecule	First- and second-line pancreatic, biliary, ovarian, breast, and lung cancers
Kovina Therapeutics	Small Molecule	HPV-induced oropharyngeal and cervical cancers
Mabswitch	Cell/Gene Therapy	B-cell malignancies and Autoimmune disease
miRecule	Biologics/Vaccine	Head and neck cancer
pacDNA Therapeutics	Small Molecule	KRAS mutant NSCLC, rare neuromuscular diseases
Resolute Science	Small Molecule (Drug/Delivery Platform)	Soft tissue sarcomas (STS) and other solid tumors
Saros Therapeutics	Small Molecule	Solid tumors
Stingray Therapeutics	Small Molecule	Colorectal cancer
Symphony Biosciences	Drug/Delivery Device	Breast cancer
Tezcat Biosciences	Biologics/Vaccine (Protein-Drug Conjugate)	Mutant RAS solid tumors and myeloma
TrAMPoline Pharma	Cell/Gene Therapy	Cellular Immunotherapy for cancer; tumor infiltrating lymphocytes, solid tumors, oncology

DEVICES

Company	Technology Type	Indication(s)
Ananya Health	Surgical/Ablative Device	Ablation of high-grade cervical precancerous lesions
Calla Health Foundation	Cancer Screening and Diagnosis Device	Cervical cancer
CivaTech Oncology	Radiation Therapy Device	Cancer – pancreatic, lung, prostate, sarcoma, colorectal, gynecological
Eisana Health	At home/In clinic Device	Chemotherapy-induced periphera neuropathy
Magnetic Insight	Imaging Device	Lymphatic imaging
Ramona Optics	Imaging Device	Computational microscopy
TibaRay	Hospital Device	Cancer treatment

DIAGNOSTICS/TOOLS

Company	Technology Type	Indication(s)
Amplified Sciences	In Vitro Diagnostic	Risk stratification of pancreatic cystic lesions (high grade vs. low grade)
Applikate Technologies	In Vitro Diagnostic Tissue Imaging Device and Image Management Software	Prostate and breast core needle biopsies. Will extend to other tissues.
AtlasXomics	Research Tool	Discovery: Spatial multi-omics for interrogation of clinically annotated tissue samples
Precision Epigenomics	In Vitro Diagnostic	Multi-cancer early detection, liquid biopsy
Stem Pharm	Drug Development Tool	Glioblastoma, Alzheimer's disease, epilepsy

DIGITAL HEALTH

Company	Technology Type	Indication(s)
Alara Imaging	Software Bioinformatics: QA/Treatment Planning Tool	Radiology
Gradient Health	Bioinformatics Software: Algorithms & AI	All imaging
mPATH	Digital Health Educational Tool	Cancer screening

SHORT COMPANY SUMMARIES

Take a glance at this year's featured companies and their promising cancer technologies.

7 HILLS PHARMA

SMALL MOLECULE

LOCATION
HOUSTON, TX

STAGE
IN CLINICAL TRIALS:
PHASE I, PHASE II

7 Hills Pharma is advancing Alintegimod, a first-in-class oral small molecule, through a Phase Ib/IIa clinical trial in combination with dual immune checkpoint blockade to safely enhance anti-tumor immune responses against PD-1-resistant solid tumors. Alintegimod leverages a novel mechanism of action (selective allosteric integrin activation) pioneered by the Company's co-founders.

ALLTERUM THERAPEUTICS

BIOLOGICS/VACCINE

LOCATION
HOUSTON, TX

STAGE
PRE-CLINICAL
DEVELOPMENT

Allterum Therapeutics is developing 4A10, a first-in-class biologic for treating CD127+ cancers. CD127, also known as IL7R, is a validated anticancer target preferentially expressed in a number of hematological malignancies, including in patients with acute lymphoblastic leukemia (ALL), acute myeloid leukemia (AML), chronic lymphocytic leukemia (CLL), and non-Hodgkin's lymphomas. 4A10 will enter human clinical trials in the first half of 2025.

CANGET BIOTEKPHARMA

SMALL MOLECULE

LOCATION
BUFFALO, NY

STAGE
PRE-CLINICAL DEVELOPMENT

IN CLINICAL TRIALS:
PHASE I

Canget BioTekpharma (Canget) is a pharma company that was spun out of Roswell Park Cancer Institute in 2012. Canget focuses on the development of novel, cancer-targeting anticancer agents that exhibit low toxicity to normal tissue, the high efficacy to cancer, and addresses multi-mechanisms of drug resistance.

CELLINFINITY

CELL/GENE THERAPY

LOCATION
NEW HAVEN, CT

STAGE
PRE-CLINICAL DEVELOPMENT

Cellifinity has used unbiased whole-genome screens to identify genes that allow CAR-T and CAR-NK to cure solid tumors. The Company's lead products are autologous multigene-enhanced CAR-Ts against solid tumor target and an in vivo (in situ) generated gene-enhanced CAR-T.

DUO ONCOLOGY

SMALL MOLECULE

LOCATION
PITTSBURGH, PA

STAGE
PRE-CLINICAL DEVELOPMENT

IN CLINICAL TRIALS:
PHASE I

Oncologist founded and funded, Duo Oncology is developing ultra-small nanomedicines for patients with pancreatic cancer and other hard-to-treat tumors. Duo's optimized chemistry penetrates deep into cancer tissue where sensitive bonds trigger the release of potent drug combinations exactly where they need to be.

KOVINA THERAPEUTICS

SMALL MOLECULE

LOCATION
INDIANAPOLIS, IN

STAGE
PRE-CLINICAL DEVELOPMENT

Kovina Therapeutics is focused on stopping HPV premalignant infections before cancer develops and treating HPV cancers after detection. The Company's novel small molecule compounds bind to and inactivate HPV E6, which is always expressed in early, premalignant, and cancerous pathologies, resulting in death of HPV infected cells.

MABSWITCH

CELL/GENE THERAPY

LOCATION
LOS ANGELES, CA

STAGE
PRE-CLINICAL DEVELOPMENT

IN CLINICAL TRIALS: EARLY FEASIBILITY

Mabswitch is a pioneering biotech company developing regulatable immunotherapies based on its proprietary antibody affinity-switch technology. Their NIH-supported flagship project is a regulatable CAR-T cell therapy for blood cancers with best-in-class safety and efficacy potential. The Mabswitch leadership team comprises experts in antibody engineering, immunotherapy development, and clinical oncology.

MIRECULE

BIOLOGICS/VACCINE

LOCATION
GAITHERSBURG, MD

STAGE
PRE-CLINICAL DEVELOPMENT

IN CLINICAL TRIALS: EARLY FEASIBILITY

miRecule is a biotechnology company developing antibody RNA conjugate (ARC) therapies for cancer and muscular dystrophy. The Company's proprietary DREAmiR™ platform utilizes genomic and outcome data from thousands of patients to identify underlying genetic changes that cause their disease, and then creates a novel RNA therapeutic that can directly target and fix that genetic abnormality.

PACDNA

SMALL MOLECULE

LOCATION
BOSTON, MA

STAGE
PRE-CLINICAL DEVELOPMENT

IN CLINICAL TRIALS: EARLY FEASIBILITY

pacDNA is transforming the field of gene regulation therapeutics with their bottlebrush polymer-based oligonucleotide delivery technology. Multiple delivery challenges remain in the oligonucleotide drug space, reducing the scope of this drug modality to a few concentrated disease settings. pacDNA aims to leverage its Brushield™ platform and bring gene regulation therapeutics to more disease segments.

RESOLUTE SCIENCE

SMALL MOLECULE (DRUG/DELIVERY PLATFORM)

LOCATION
SAN DIEGO, CA

STAGE
PRE-CLINICAL DEVELOPMENT

Resolute Science is developing a novel class of pan-cancer therapeutics for solid tumors leveraging its proprietary MAC-TAC drug-delivery platform. Resolute is advancing a pipeline of first-in-class targeted therapeutics with its lead therapeutic undergoing IND-enabling studies. Resolute's mission is to help people with cancer recover and return to their normal lives.

SAROS THERAPEUTICS

SMALL MOLECULE

LOCATION
CHICAGO, IL

STAGE
PRE-CLINICAL DEVELOPMENT

Saros Therapeutics is a private, pre-clinical biotech company developing therapies that enhance the immune response against cancer by targeting the innate immune system. The lead program targets STING and was engineered to overcome problems of prior STING therapies through cell-specific targeting, increased potency, and a better route of administration.

STINGRAY THERAPEUTICS

SMALL MOLECULE

LOCATION
HOUSTON, TX

STAGE
IN CLINICAL TRIALS: PHASE I

Stingray Therapeutics is in-clinic with SR-8541A, an ENPP1 inhibitor. ENPP1 is the only known innate immune checkpoint. The Phase I single-agent study has produced 50% stable disease among patients treated, showing an active drug. In September 2024, Stingray will start a Phase I/II study in microsatellite stable colorectal cancer with double checkpoint inhibitor (Botensilimab/Balstilimab), which received a $14M award from CPRIT to pay for two-thirds of the study and half of the Company from 2024 through 2026. The team will also plan studies in metastatic prostate cancer with Pluvicto, in pancreatic and G/I cancers with beam radiation, and in triple-negative breast cancer.

SYMPHONY BIOSCIENCES

DRUG/DELIVERY DEVICE

LOCATION
LOS ANGELES, CA

STAGE
PRE-CLINICAL DEVELOPMENT

IN CLINICAL TRIALS: FEASIBILITY/PILOT

Symphony Biosciences seeks to orchestrate the immune response against solid cancers via innovative biomaterials. Symphony's product, SymphNode, is an implantable biomaterial which will be inserted right beside the tumor at time of surgery and will offer two unique benefits: focusing powerful immune-activating drugs locally onto the solid tumor environment and recruiting the body's natural immune cells and providing them with real-time training against tumor cells.

TEZCAT BIOSCIENCES

BIOLOGICS/VACCINE (PROTEIN-DRUG CONJUGATE)

LOCATION
NEW YORK, NY

STAGE
PRE-CLINICAL DEVELOPMENT

IN CLINICAL TRIALS: EARLY FEASIBILITY

Tezcat Biosciences is developing receptor-independent drug delivery technology that is both indication and payload agnostic, with a lead asset identified. Tezcat's target market is for the treatment of adult patients with mutant RAS solid tumors and myeloma.

TRAMPOLINE PHARMA

CELL/GENE THERAPY

LOCATION
AURORA, CO

STAGE
PRE-CLINICAL DEVELOPMENT

IN CLINICAL TRIALS: PHASE I

TrAMPoline Pharma was founded with a vision to support the next generation of cellular immunotherapies to treat solid tumors. The Company is developing viral vectors encoding proprietary proteins to improve the performance of all forms of cellular immunotherapy. TrAMPoline's first product, MightyTIL™, is a gene-modified tumor infiltrating lymphocyte (TIL) product.

ANANYA HEALTH

SURGICAL/ABLATIVE DEVICE

LOCATION
BERKELEY, CA

STAGE
PRE-CLINICAL DEVELOPMENT

Ananya Health is a medical device company building a self-contained cryoablation platform to freeze and destroy abnormal cells in the cervix without any consumable cryogen. The Company's proprietary platform enables clinicians to treat cervical pre-cancer at the point of diagnosis, and achieves standard of care outcomes at one-tenth the cost of traditional cryoablation.

CALLA HEALTH FOUNDATION

CANCER SCREENING AND DIAGNOSIS

LOCATION
DURHAM, NC

STAGE
COMMERCIALLY AVAILABLE

Calla Health seeks to commercialize and successfully bring to market intellectual property developed at Duke, seeing products from concept through to clinical use and, ultimately, market entry. The Company's core competencies include optical imaging system design, rapid prototyping, machine learning diagnostic algorithms, software development, and mechanical and electrical engineering. The Pocket Colposcope is an FDA 510(K) cleared device with the same designated uses as a traditional colposcope. The Pocket Colposcope can capture images that provide an equivalent diagnostic performance to a traditional colposcope, but at a fraction of the cost.

CIVATECH ONCOLOGY

RADIATION THERAPY DEVICE

LOCATION
RESEARCH TRIANGLE PARK, NC

STAGE
IN CLINICAL TRIALS: PHASE II;
COMMERCIALLY AVAILABLE

CivaTech Oncology® specializes in the development and manufacturing of radiation devices that provide therapeutic doses to cancerous tissues in a localized, targeted delivery method. This significantly reduces the side effects experienced with traditional radiation delivery methods.

EISANA HEALTH

AT HOME/IN CLINIC DEVICE

LOCATION
THE WOODLANDS, TX

STAGE
NON-CLINICAL TECHNOLOGY IN PROTOTYPE DEVELOPMENT

IN CLINICAL TRIALS: EARLY FEASIBILITY

As cancer survival rates improve, side effects remain a monumental issue. Chemotherapy-induced peripheral neuropathy (CIPN) is common, painful, debilitating, and has no cure. Payors spend $17K per year per patient just trying to deal with symptoms. Eisana Health is developing a safe, convenient, portable cooling system to prevent CIPN.

MAGNETIC INSIGHT

IMAGING DEVICE

LOCATION
ALAMEDA, CA

STAGE
PRE-CLINICAL DEVELOPMENT; FDA APPROVAL NOT APPLICABLE

IN CLINICAL TRIALS: EARLY FEASIBILITY

Magnetic Insight develops MPI, a non-radioactive tracer imaging technology. The innovation offers a radiation-free alternative to half of nuclear medicine scans, while expanding imaging capabilities and addressing supply vulnerabilities. With market leadership in small animal MPI established, the Company is now advancing to clinical applications.

RAMONA OPTICS

IMAGING DEVICE

LOCATION
DURHAM, NC

STAGE
NON-CLINICAL TECHNOLOGY IN FULL DEVELOPMENT/ TESTING STAGE, PROTOTYPE FULLY DEVELOPED; IN BETA TESTING

Ramona Optics develops proprietary computational microscopes that power the Company's AI video analysis software to propel high-throughput biological discovery.

TIBARAY

HOSPITAL DEVICE

LOCATION
FREMONT, CA

STAGE
PRE-CLINICAL DEVELOPMENT

IN CLINICAL TRIALS: FEASIBILITY/PILOT

TibaRay will treat cancer 400x faster than today's radiation therapy, reducing collateral damage to normal tissue by up to 40%. The thought-leading founding team and well-patented technology from the SLAC National Accelerator Lab and Stanford University with a seasoned CEO from Varian Medical Systems position TibaRay to disrupt this $7B market.

AMPLIFIED SCIENCES

IN VITRO DIAGNOSTIC

LOCATION
WEST LAFAYETTE, IN

STAGE
IN CLINICAL TRIALS: PIVOTAL, PROTOTYPE FULLY DEVELOPED; IN BETA TESTING

Amplified Sciences is developing in-vitro diagnostics with a clinical-stage test that helps physicians more accurately detect risk for pancreatic cancer, built on their ultra-sensitive optical reporter platform.

APPLIKATE TECHNOLOGIES

IN VITRO DIAGNOSTIC TISSUE IMAGING DEVICE AND IMAGE MANAGEMENT SOFTWARE

LOCATION
FAIRFIELD, CT

STAGE
PRE-CLINICAL DEVELOPMENT/ COMMERCIALLY AVAILABLE

Applikate Technologies is a hardware and software technology company that provides an elegant solution to the difficult and time-consuming problems faced by pathologists and their staff. The Company's solution offers a revolutionary approach to histology without requiring new skills, extensive training, or prohibitive costs.

ATLASXOMICS

RESEARCH TOOL

LOCATION
NEW HAVEN, CT

STAGE
COMMERCIALLY AVAILABLE

AtlasXomics has commercialized a spatial multi-omics platform enabling the interrogation of tissue samples for gene expression. Cells function depending on their neighbors, so the proteomic, transcriptomic, and epigenomic profiles of tissue biopsy sections at cellular resolution help physician-scientists studying cancer, neurodegenerative diseases, and healthy aging.

PRECISION EPIGENOMICS

IN VITRO DIAGNOSTIC

LOCATION
TUCSON, AZ

STAGE
COMMERCIALLY AVAILABLE

Precision Epigenomics is a molecular diagnostic company in the liquid biopsy space. The Company has developed EPISEEK, a multi-cancer detection test that is capable of identifying more than 20 different cancer types from a single blood draw.

STEM PHARM

DRUG DEVELOPMENT TOOL

LOCATION
MADISON, WI

STAGE
PRE-CLINICAL DEVELOPMENT

IN CLINICAL TRIALS: EARLY FEASIBILITY

Stem Pharm is a drug discovery platform company targeting neuroinflammatory diseases using its proprietary 3D human neural organoid platform. Stem Pharm's therapeutic programs are focused on small molecule drug discovery for glioblastoma, Alzheimer's disease, and epilepsy, diseases where neuroinflammation offers new opportunities for therapeutic intervention.

ALARA IMAGING

SOFTWARE
BIOINFORMATICS:
QA/TREATMENT
PLANNING TOOL

LOCATION
WESTPORT, CT
SAN FRANCISCO, CA

STAGE
COMMERCIALLY
AVAILABLE

The Alara Gateway is a medical imaging and EHR integration software that connects modern compute and generative AI applications to radiology workflows. Alara has partnered with the Centers for Medicare and Medicaid Services (CMS), NVIDIA, AWS, and others to support modern radiology data applications.

GRADIENT HEALTH

BIOINFORMATICS
SOFTWARE:
ALGORITHMS & AI

LOCATION
DURHAM, NC

STAGE
COMMERCIALLY
AVAILABLE

IN CLINICAL TRIALS:
PIVOTAL

Gradient Health breaks barriers in healthcare by making data available to AI developers, speeding up AI development by 25x at a tenth of the cost.

MPATH

DIGITAL HEALTH EDUCATIONAL TOOL

LOCATION
WINSTON-SALEM, NC

STAGE
COMMERCIALLY AVAILABLE

mPATH Health improves the uptake of life-saving cancer screening tests with a clinically proven, direct-to-patient digital health platform that combines automation with behavioral science.

COMPANY OVERVIEWS

For an introduction to any of these companies, please contact Brittany Connors at brittany.connors@nih.gov.

7 Hills Pharma

Small Molecule

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COMPANY OVERVIEW

7 Hills Pharma is a clinical-stage drug development company advancing a new and safer approach to improving immuno-oncology. The Company's co-founding team, including CEO and co-inventor Upendra Marathi, are the pioneers of Selective Allosteric Integrin Activation, a novel mechanism of action that optimizes integrin-mediated cell-cell adhesion at multiple rate-limiting steps in the tumor immunity cycle to safely enhance the anti-tumor efficacy of immune checkpoint blockade with no added toxicities. With more than $34M in NIH and CPRIT grants awarded following multiple rounds of intensive due diligence, 7 Hills is progressing rapidly toward multiple value-inflection points and potential liquidity events.

MARKET AND COMMERCIALIZATION STRATEGY

7 Hills is strategically positioned for rigorous and cost-efficient development from discovery through clinical proof-of-concept (i.e., approximately Phase IIa), at which time the Company will out-license developmental assets to pharma to complete Phase III testing and commercialization. The Company has leveraged ongoing dialogs with multiple large pharma companies to shape the clinical program to deliver the specific data needed to de-risk this transaction. Based on recent comparable transactions, 7 Hills expects approximately a $150M upfront payment, $1B in milestones, and a 10-15% sales royalty.

TECHNICAL AND COMPETITIVE ADVANTAGE

There are a variety of companies attempting to improve the efficacy of immune checkpoint blockade. However, their approaches all suffer from one or both of the common drawbacks in this therapeutic space: the need for expensive and error-prone intratumoral injection and a mechanism of action that trades increased anti-tumor efficacy for increased toxicity. Alintegimod wins on both dimensions. Delivered as a simple oral pill, Alintegimod leverages a new biological mechanism that is inherently regulated in two different ways, preventing immune overactivation while enhancing tumor antigen presentation, T-cell proliferation and training, T-cell homing to the tumor, and tumor cell killing.

REGULATORY STRATEGY AND INTELLECTUAL PROPERTY

The Company has long maintained communication with FDA to guide and optimize Alintegimod's developmental pathway. Long-term dialogs with strategic pharma acquirers have further honed 7 Hills Pharma's regulatory vision for Alintegimod, resulting in a clear and well-defined road to approval. The Company's intellectual property portfolio is broad and pioneering, effectively cornering the market on immune modulation through integrin activation into the 2040s based on current filings. 7 Hills has issued claims covering Alintegimod's composition of matter as well as its use with immune checkpoint blockade, setting the stage for additional value-added combinations as the field of checkpoint inhibition continues to evolve.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2020	Orphan Drug designation – Alintegimod, IND activated, commenced Phase Ia trial
2021	Completed Phase Ia trial
2022	Fast Track designation – Alintegimod, first alintegimod publication
2023	Awarded $13.4M CPRIT and $2M NIH grants to fund Phase Ib/IIa Alintegimod trial
2024	Activated first clinical site for Phase Ib/IIa Alintegimod trial

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	AMOUNT
2014	Seed/Founders	$3K
2014-2020	NIH Grants	$7.2M
2016	Angel	$3.8M
2019	Angel	$1.7M
2021	Angel	$1.6M
2022	NIH Grant	$3M
2023	NIH Grants	$4M
2023	CPRIT Grant	$13.4M
2024	CPRIT Grant	$4.7M
2024	Angel	$1M

USE OF PROCEEDS

7 Hills is raising $20M via two vehicles: an open $5M convertible note and a planned $15M Series A equity offering in 2025. The Company will use ~$10M to complete the Alintegimod clinical trial, ~$6M to advance 7HP935 (first-in-class cell/gene therapy asset) through clinical PoC, and ~$4M for corporate operations.

KEY TEAM MEMBERS

Upendra Marathi, Ph.D., M.B.A. (CEO and Co-founder): Co-inventor of the novel technology; seasoned pharmacologist, 3-time biotech entrepreneur, and former venture capitalist; led the development of Vazalore, which recently gained FDA approval.

Lionel Lewis, M.A., M.B.BCh., M.D. (CMO): Experienced solid tumor trialist who has worked on 40 Phase I trials; Co-director of the Norris Cotton Cancer Center (NCCC) at Dartmouth.

William Schary, Ph.D. (VP of Clinical and Regulatory Affairs): Former clinical reviewer for the FDA and senior executive with Abbvie and Takeda.

ALLTERUM

Allterum Therapeutics

Biologics/Vaccine

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COMPANY OVERVIEW

Allterum Therapeutics is developing 4A10, a mAb targeting CD127 (IL7R), a validated anticancer target preferentially expressed by a variety of cancers. 4A10 is being developed in hematological malignancies including CD127+ acute lymphoblastic leukemia (ALL), acute myeloid leukemia (AML), chronic lymphocytic leukemia (CLL), and non-Hodgkin's lymphoma. 4A10 has demonstrated robust pre-clinical efficacy, including in-vivo activity with multiple PDX models. CD127 has limited normal expression, and 4A10 appears to be safe and well-tolerated, including in NHPs. 4A10 will enter the clinic in the first half of 2025 with a well-defined path to regulatory approval. Allterum's pipeline includes CD127-targeted drug conjugates for CD127+ solid tumors including lung, head and neck, colorectal, prostate, and pancreatic cancers.

MARKET AND COMMERCIALIZATION STRATEGY

Allterum is addressing blockbuster markets with both 4A10 (hematologic cancers) and drug conjugates (solid tumors). Further, because the Company's target markets include ALL, an orphan pediatric disease, Allterum is eligible for a transferable Priority Review Voucher. The Company's default plan is to take the ALL program through marketing approval, since it is fully funded through Phase II and has an abbreviated, well-defined path to approval, although they will consider commercially attractive partnership options. Allterum will actively seek partnering after Phase II proof-of-concept trials for the larger hematological and the solid tumor indications.

TECHNICAL AND COMPETITIVE ADVANTAGE

Mechanistically, 4A10 acts by inhibiting IL-7 signaling and inducing cytotoxicity through antibody-dependent cellular cytotoxicity (ADCC) and antibody-dependent cellular phagocytosis (ADCP). This dual MoA differentiates it from other CD127-antibodies in development for auto-immune indications that only inhibit signaling. 4A10's primary differentiator in oncology is expected to be as a first-in-class drug that is safe and well tolerated. Over-expression of the IL-7 receptor is an important escape mechanism with some drugs, suggesting that addition of 4A10 to standard regimens can reduce relapse. The expected lack of overlapping toxicity would facilitate its combination with standard therapy, and also permit its use as a single-agent in poor performance status patients.

REGULATORY STRATEGY AND INTELLECTUAL PROPERTY

Allterum has had meaningful engagement with FDA including a pre-IND meeting, Type D consultation, and orphan drug and pediatric rare disease designations. The Company has a well-defined, abbreviated path to marketing approval in acute leukemias. Based on regulatory guidance and precedence, they expect a pivotal Phase II trial to serve as the basis of approval. Other indications will traverse a traditional path. Allterum will seek guidance from overseas agencies before initiating pivotal trials. Broad issued 4A10 composition and method of use patents expiring in 2036 have been exclusively licensed to Allterum. 4A10 also benefits from biologics exclusivity and orphan drug exclusivity.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2018	Exclusively in-licensed 4A10 from Dr. Scott Durum at NCI
2019	Received $3M Seed award to support 4A10 product scale-up and IND-enabling work
2022	Awarded $2M SBIR D2P2 to support 4A10 clinical program
2023	Established CRADA with NCI to extend pre-clinical data; accepted into the NExT program to support GLP toxicology, regulatory submissions; accepted into NCI PIVOT program for testing 4A10 in osteosarcoma models; awarded $11.7M product development grant to support GMP manufacturing and Phase I/IIA clinical trials
2024	Initiated GLP toxicology and GMP manufacturing, both fully funded and currently ongoing; further advanced label expansion into other CD127+ cancer indications

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2019	CPRIT Seed Award: DP190025	Non-dilutive funding to support pre-clinical development	$2,912,313
2020	Seed Private Raise	Private seed raise from Fannin Allterum Holdings I, managed by Fannin affiliate	$1,795,360
2022	NIH SBIR Direct to Phase II: 1R44CA26850-01A1	Non-dilutive funding to support clinical development	$1,999,997
2023	NIH SBIR D2P2 Supplement: 3R44CA268530-01A1S1	Diversity supplement added to 2022 D2P2 to further support clinical development	$193,935
2023	CPRIT Product Development Award: DP230071	Non-dilutive funding to support GMP manufacturing and Phase I/IIA clinical trials	$11,721,150

USE OF PROCEEDS

The Company is fully funded through a Phase I/II clinical study ALL. Pre-clinical studies have identified a broader range of CD127+ cancers they can target. Allterum's $10M Series A financing will support 4A10 clinical trials in additional hematological cancers and bring the Company's drug conjugate into an IND for solid tumors.

KEY TEAM MEMBERS

Atul Varadhachary, M.D., Ph.D. (CEO): 30 years of drug development experience; Agennix (Phase III); Pulmotect (Phase II); Fannin (Phase I) RLS

Philip Breitfeld, M.D. (CMO): 30 years of oncology experience; Harvard/Dana Farber; IQVIA; Merck/EMD Serono; BioCryst; Champions Oncology

Jack Schaumberg, Ph.D. (Director of Clinical Operations): 35 years in drug development; Agennix (Phase III); Pulmotect (Phase II); Valentis (Phase I)

Mark Worscheh, M.B.A. (CFO): 30 years of finance/investment experience; Salomon Brothers; Merrill Lynch; Aquinas Co.

Canget BioTekpharma

Small Molecule

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COMPANY OVERVIEW

Canget BioTekpharma (Canget) is a startup company that was founded in 2012 for the discovery and development of novel anticancer drugs with high efficacy against resistant cancers and low toxicity (limited side effects) to normal tissues.

Canget has identified an orally available small molecule (FL118) and developed clinical compatible formulation-based FL118 drug product (DP). FL118 is a first-in-class small molecule that binds to and degrades the master oncogenic protein target DDX5 (p68) and thus indirectly inhibits DDX5 downstream targets (survivin, Mcl-1, XIAP, cIAP2, MdmX, c-Myc, mutant KRAS, etc).

MARKET AND COMMERCIALIZATION STRATEGY

All the completed FL118 IND-enabling studies indicate that FL118 is a high promising drug for clinical trials. Canget expects to file an FL118 IND application for clinical trials in early 2025, dependent upon securing funding. FL118 was granted orphan drug designation status by the FDA on October 23, 2023, for the treatment of pancreatic cancer. Canget seeks a collaborative development partner to license FL118 for clinical development, registration, and commercialization. Alternatively, given the Company's portfolio of products for various cancers, Canget could consider an IPO and evolve into a fully integrated pharmaceutical company.

TECHNICAL AND COMPETITIVE ADVANTAGE:

FL118 is the first molecule that directly binds to, dephosphorylates, and degrades the master oncogenic regulator DDX5 (p68), and importantly, many of the proteins that showed cancer promotion and apoptosis inhibition are DDX5 downstream targets. This is consistent with FL118 possessing high efficacy against pancreatic ductal adenocarcinoma (PDAC) and colorectal cancer (CRC) tumors as Canget demonstrated and documented in their publications.

PDAC is a rapidly growing market and there are no highly effective drugs for treating PDAC. In contrast, FL118 has demonstrated high efficacy in eliminating PDAC tumors. More significantly, FL118 exhibits even higher efficacy if PDAC tumors have KRAS and TP53/p53 mutations.

REGULATORY STRATEGY AND INTELLECTUAL PROPERTY

- PCT/US2011/058558 Novel formulations ... and methods of using a formulation of compound FL118 for cancer therapy, issued: 2017 to 2019 in many different countries
- PCT/US2015/022095 Use of FL118 ... to generate FL118 derivatives for treatment of human disease Issued: 2019 (US 10,344,037 B2), issued: 2021 (US 11,084,828 B2)
- PCT/US2019/051595 Matter of composition, synthesis, formulation and application of FL118 platform PCT patent pending (September 27, 2019), issued 2023 (Indian), claims allowed by USTOP (2024)
- 2024 United States provisional patent: Triply targeting DDX5, USP2a, and UbE2T by FL118 alone or in combination

KEY MILESTONES

DATE/YEAR	DESCRIPTION
October 2023	FL118 obtained orphan drug designation (ODD) by FDA for pancreatic cancer treatment. Based on the funding availability, the following key milestones are expected.
2024-2025	Obtain FL118 ODD and rare pediatric disease designation (RPDD) for osteosarcoma treatment.
2025	File FL118 IND for clinical trials
2025-2026	FL118 Phase I clinical trials
2026-2027	FL118 Phase Ib clinical trials
2027-2029	Get FDA designation of FL118 for breakthrough therapy, fast track, priority review, and/or accelerated approval for pancreatic cancer and/or osteosarcoma treatment.

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
Prior 2012	NIH/NCI, and Foundations	The development of a new class of patentable drugs	~$3M
2012-2024	NIH/NCI, DOD and Foundations	Study FL118 targets and mechanisms of action	~$2M
2012-2024	Individual Investors, Equity Shares	Canget research and operations	~$650K
2012-2024	Three SBIR Grants plus Supplemental Funds	FL118 and FL118 analog development	$3M
2012-2024	Canget Partners	FL118 CMC studies and GMP manufacture	$5M

USE OF PROCEEDS

Canget is seeking $15M for the submission of an Investigational New Drug (IND) application, the manufacturing of Good Manufacturing Practice (GMP) products for initial clinical trials, and the execution of a Phase Ia/Ib clinical trial.

KEY TEAM MEMBERS

John Seman, M.S. (CEO): Seasoned pharmaceutical executive with expertise in new product development, marketing and establishing long-term growth strategies.

Fengzhi Li, Ph.D. (Founder, CSO): Initially involved in characterizing the antiapoptotic survivin and is one of the top leading scientists in this field.

Alex Adjai, Ph.D. (CMO): Chief of Cleveland Clinic's Cancer Institute. He provides leadership and direction, facilitates operations and is responsible for implementing strategic clinical trial initiatives.

Cellinfinity

Cell/Gene Therapy

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COMPANY OVERVIEW

Cellinfinity, seed funded in 2022, has operations in New Haven, CT and San Francisco, CA. Founded from Sidi Chen's (Yale University) parallel gene editing technologies, the Company has used unbiased evolution strategy using large/whole-genome CRISPR screens within CAR-T cells and CAR-NK (each cell with unique gain-of-function or loss-of-function of a specific gene). Following selection, the Company identifies 'winning' cells – those with improved specific biologic properties especially needed to combat solid tumors. These identified gene enhancements are incorporated into Cellinfinity's novel cell therapy-based products via two approaches: 1) ex vivo autologous CAR-T (or CAR-NK) and 2) in vivo (in situ) CAR-T.

MARKET AND COMMERCIALIZATION STRATEGY

The cell therapy market against cancers is projected to be more than $30B at the end of this decade, largely driven by therapy against solid tumors. Following successful registration, Cellinfinity's lead CAR-T will be marketed in patients with renal cell carcinoma ($2B opportunity). Notably, the Company's gene enhancements are 'universal' and can improve CAR-Ts against variety of targets, thus allowing efficient portfolio expansion (more than $10B opportunity). Notably, Cellinfinity has developed an integrating viral vector that allows efficient transfection of CARs into T-cells in vivo, thus enabling in situ generation of CAR-Ts. The Company anticipates, over time, this will be their lead product and approach.

TECHNICAL AND COMPETITIVE ADVANTAGE

Cellinfinity has developed an unbiased and genome-wide gene editing platform by either down- or up-regulation, exploring an unprecedented number of genes, and identified several gene enhancements that are superior to industry standard (e.g., better vs PD-1 knock out or cJun over-expression). The Company's products are multi-gene enhanced, and optimized for desirable properties (e.g., solid tumor infiltration, persistence and proliferation). Lastly, in addition to autologous gene-enhanced CAR-Ts, Cellinfinity is developing novel in vivo integrating vectors targeting T-cells for in situ CAR-T development. This technology aims to circumvent current complex manufacturing of CAR-Ts.

REGULATORY STRATEGY AND INTELLECTUAL PROPERTY

Cellinfinity will continue to engage with the FDA during pre-clinical and clinical development, as the Company carries their Phase I to registration trials, aiming to file BLA following successful demonstration of risk/benefit. Initial clinical program is in 2L+ renal cell carcinoma, with plans of indication expansion. Cellinfinity has an exclusive license with Yale University for use/development of the cell evolution technologies (termed KIKO/CLASH) and application of lead gene candidates. The licensed IPs are composition of matter, process and use patents, including application of engineered immune cells in cancer, autoimmune, and other diseases.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
July 2022	Seed funded ($13.2M convertible note)
Aug 2022	Finalized license for 7 novel IPs, including directed evolution platform, novel gene enhancements, unique antigen target
Sept 2022	New Haven lab opened and research staff hired. Initiated additional directed evolution experiments
Jan 2023	Novel kidney cancer CAR-T binder (ultimately, clean Retrogenix screen/data)
Aug 2023	Multiplexed gene editing CAR-T developed. Positive mice data with novel CAR-Ts
Nov 2023	Unbiased directed evolution for CAR-NK identified novel genes. New IP. San Francisco lab site focused on NK cell work
March 2024	Developed integrating vector for in vivo delivery of CARs

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	AMOUNT
2022	Seed Round – Convertible Note	$13.2M
2023	NCI SBIR Phase I	$400k

USE OF PROCEEDS

Cellinfinity aims to raise $30M, which will fund activities for more than three years, including:

- Manufacturing, IND, and Phase I/II trial for the lead gene-enhanced CAR-T in renal cell carcinoma.
- In vivo CAR-T product (i.e., novel integrating vector to create gene-enhanced CAR-T in situ) will be developed towards IND.

KEY TEAM MEMBERS

Premal Patel, M.D., Ph.D. (CEO): Led multiple allogenic and auto CAR-T projects; Prior: 1) CMO, Lyell Immunopharma, 2) SVP Clinical Development Juno Therapeutics, 3) VP Early Clinical Development, Pfizer.

Margo Roberts, Ph.D. (CSO): Led multiple research CAR-T teams from inception to registration trials; Prior: 1) CSO, Lyell Immunopharma, 2) CSO, Kite Immunopharma.

Sidi Chen, Ph.D. (Founder): Yale University professor. Multiple Nature, Science, and Cell journal publications that are foundation of Cellinfinity.

Duo Oncology

Small Molecule

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COMPANY OVERVIEW

Duo Oncology, founded and funded by University of Pittsburgh Medical Center (UPMC) oncologists, is dedicated to developing transformative therapies for patients with pancreatic and other tough-to-treat cancers. These cancers have low survival rates, and their treatments induce debilitating toxicities. Duo's lead product, DUO-207, is a potent two-drug nanomedicine that shows better efficacy results in animal studies than standard therapies and additionally avoids the most harmful side effects of the standard therapies. Duo's other products, DUO-307 and DUO-209, showcase platform potential with unique targets in immunotherapy and precision medicine. FDA Pre-IND feedback and GLP safety data support starting clinical trials for DUO-207 in late 2024.

MARKET AND COMMERCIALIZATION STRATEGY

Duo Oncology is developing a pipeline of nanomedicines to maximize the value of its patent portfolio. The pipeline uses related chemistries, trial designs, and regulatory strategies to achieve unprecedented efficiency across three development programs. DUO-207, nearing Phase I trials, targets two orphan indications and offers a $13B+ global opportunity in lung cancer. Follow-on products DUO-307 and DUO-209 also begin in orphan indications then expand to breast and prostate cancers, which include millions of patients. Duo's virtual pharma model pairs experienced employees with top experts to align with potential acquirers. Patent protection and orphan exclusivity further enhance market value.

TECHNICAL AND COMPETITIVE ADVANTAGE

Duo Oncology's nanomedicines are unlike any liposome, micelle, or albumin complex made to date. Their ultra-small size allows them to penetrate and remain in poorly vascularized tumors while sparing healthy tissue. Their simple-to-produce chemistry responds to the cancer microenvironment, releasing their payloads within tumors. These innovations have attracted an advisory board of top oncologists, including those responsible for Abraxane, the world's most successful cancer nanomedicine. In the clinic, Duo's first product will offer patients a more effective, less toxic therapy delivered in half the infusion time with a third fewer clinic visits.

REGULATORY STRATEGY AND INTELLECTUAL PROPERTY

Duo Oncology's core patent covers the prodrugs that form ultra-small nanomedicines. Duo is also filing patents for methods of production and of treatment. Lead product DUO-207 will begin clinical trials in Australia to quickly gather safety and efficacy data. In parallel, Duo will utilize the FDA's 505(b)(2) pathway, which reduces United States regulatory burden, and pursue orphan indications that grant market exclusivity. These indications are also eligible for the Fast Track program and Breakthrough Therapy designation, which expedite review. Duo's subsequent nanomedicines will benefit from DUO-207's established regulatory and clinical programs, de-risking development and maximizing patent life.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
Q1 2021	UPMC oncologists fund Duo with a $1.1M SAFE
Q4 2021	Completed favorable Pre-IND meeting with FDA clearing roadmap to human efficacy
Q1 2022	Signed exclusive license for nanomedicine chemistry IP with University of Pittsburgh
Q1 2023	Raised $3M priced, preferred seed round with BeiGene Pharmaceuticals as 40% investor
Q4 2023	Completed 4kg batch of nanomedicine platform polymer
Q3 2024	Completion of full GLP toxicology studies – final pre-clinical data
Q1 2025	First patient enrolled in Phase I/II clinical trial
Q4 2025	Maximum tolerated dose determined in solid tumor cancer patients
Q1 2027	Early efficacy data gathered for pancreatic cancer

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2021	Angel Round	UPMC oncologists founding investment in Duo Oncology	$1.1M
2023	Seed Round	Led by SeedFolio VC with BeiGene Pharmaceuticals taking 40%	$3.0M
2024	SBIR Grants	Two Phase I SBIR awards from NCI	$0.7M
2024-2025	Future Series A/B	Follow term sheet from Prevail Partners awaiting lead	$8M

USE OF PROCEEDS

Duo Oncology is seeking a $7M Series A in the third quarter of 2024 to fund:

- Phase I clinical trial through completion of the recommended Phase II dose expansion.
- Expanded patent prosecution for pipeline and regulatory filings.

Duo will seek an $18M Series B in the fourth quarter of 2025 to fund:

- Phase II/III trial to determine efficacy of DUO-207 in patients with pancreatic cancer.
- Phase I basket trial of DUO-307 immunotherapy nanomedicine.
- Negotiation with acquirer or IPO.

KEY TEAM MEMBERS

Sam Rothstein, Ph.D. (CEO and Cofounder): 20+ years of experience developing nanomedicines and 14 years as a life science startup CSO or CEO. Raised over $10M in investment and grants to date.

Katie Eichinger, Pharm.D., Ph.D. (COO): Broad expertise in drug development ranging from pre-clinical cancer models to toxicology to hospital formulary practice.

Victoria Manax, M.D. (Acting CMO): World leader in pancreatic cancer nanomedicines. Formerly CMO for PanCAN and pancreatic cancer lead at Abraxis/Celgene.

Kovina Therapeutics

Small Molecule

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COMPANY OVERVIEW

Kovina's science targets and inactivates the HPV-16 E6 protein which is always present in HPV cancers such as oropharyngeal and cervical cancer. The Company's compounds bind covalently in a pocket on HPV-16 E6, preventing E6 from interacting with its target, which restores P53 function and kills the HPV expressing cell. Kovina compounds can be used to reduce side effects from intense chemo/radiation and surgical regimens by shrinking tumors prior to resection or to treat HPV infections, preventing progression to cancer. The Company raised $5.4M in seed and grant funding and assembled a team of experts to advance its novel science.

MARKET AND COMMERCIALIZATION STRATEGY

Kovina's target United States market is ~$4B annually across multiple indications including cervical and oropharyngeal cancers and cervical dysplasia. OUS opportunities represent an even larger market with cervical cancer rates equal to 35-40x United States rates. Globally, HPV causes ~5% of all cancers and ~630,000 HPV-related cancers occur annually. While the existing HPV vaccine is effective, it has not been widely adopted and has no impact on existing HPV infections or malignancies which develop over years or decades. Competitive therapeutics in development include immunogens and non-specific antivirals with limited success. Kovina's compounds are the only specific antiviral compounds that kill HPV16.

TECHNICAL AND COMPETITIVE ADVANTAGE

Treatments for HPV-induced cancers include surgery, radiation, and chemotherapy with high morbidity and challenging side effects. Oropharyngeal (head/neck) cancer patients have the second highest suicide rate among cancer survivors due to serious complications from the current standard of care. Kovina's compounds are designed to specifically kill HPV-infected cells and reduce the side effects from intense chemo/radiation and surgical regimens by shrinking tumors prior to resection. HPV premalignant infections are treated with invasive procedures that may result in serious side effects. Kovina's first-in-class therapeutic would replace existing surgical interventions to treat HPV infections.

REGULATORY STRATEGY AND INTELLECTUAL PROPERTY

Kovina's intellectual property is protected by a patent portfolio the Company co-owns with Indiana University and licensed to secure exclusive rights. The Company has three issued patents with additional filings in processes. Kovina submitted an INTERACT briefing document in 2024 to seek regulatory guidance for its first-in-class premalignant infection program. The FDA confirmed written feedback will be provided. While oncology small molecule regulatory pathways are well defined, the Company intends to explore accelerated approval for HPV-induced head and neck cancers.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
Ongoing	Cervical/Oropharyngeal cancer program: ADME characterization, formulation development, pharmacology/tox studies, and GLP Tox (funding dependent)
Q1 2026	Premalignant infection program: Maximum tolerable dose/dose range finding studies. Formulation development work scheduled to assess optimal forms for cervical delivery (funding dependent)
Q2 2026	Cervical/Oropharyngeal cancer program: Complete IND filing to enter Phase Ib/II human trials (funding dependent)
Q2 2026	Premalignant infection program: Complete IND filing to enter Phase I/Ib human trials (funding dependent)

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2021	Seed Round	Local venture funds and angel investors	$2.05M
2022	NCI Grant	Fast track grant (includes I-CORPS) – HPV cancer therapeutics	$2.34M
2022	NIAID Grant	Phase I SBIR HPV premalignant infections	$299K
2022	NIDCR Grant	Phase I SBIR HPV oropharyngeal cancers	$276K
2022	Grants/Convertible Note	Elevate Ventures	$275K
2024	Convertible Note	American Cancer Society/Elevate Ventures	$200K

USE OF PROCEEDS

Kovina is raising a $20M Series A round to fund its oncology program through Phase I/II clinical trials in oropharyngeal cancer.

KEY TEAM MEMBERS

Kristin Sherman, M.B.A. (CEO): 30 years of experience working in large pharma (Eli Lilly) and device companies and the prior CFO of 2 biotech organizations including Marcadia Biotech (sold to Roche) and Calibrium (sold to Novo Nordisk).

Elliot Androphy, M.D. (Co-founder and CSO): Dermatologist at Indiana University School of Medicine. Dr. Androphy's lab received continuous NIH funding since 1987, and he is regarded as one of nation's top HPV experts.

MABSWITCH

Mabswitch

Cell/Gene Therapy

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COMPANY OVERVIEW

Mabswitch is a pioneering biotechnology company focused on the development of regulatable immunotherapies based on a revolutionary universal allosteric-linker and switch module for antibodies (UNASMA) technology that enables the precise tuning of antibody single-chain variable fragments (scFv) affinity under physiological conditions.

The Company's flagship program, funded by the NCI, aims to develop anti-CD19 switchable affinity chimeric antigen receptor (SaefCAR) T-cell therapies that will mitigate intrinsic and off-target toxicities, and prevent CAR-T cell exhaustion. Mabswitch's leadership team comprises of experts in antibody engineering, immunotherapy development and clinical oncology.

MARKET AND COMMERCIALIZATION STRATEGY

Anti-CD19 CAR-T cell therapies have transformed B-cell cancer treatment, offering prolonged remissions after other options fail. Since 2017, four therapies for relapsed or refractory B-cell acute lymphoblastic leukemia (B-ALL) and non-Hodgkin lymphoma (NHL) cancers have been approved, generating $2.7B in 2023 sales and are projected to reach $14.6B by 2030. Challenges like adverse events, non-responders, and relapses persist due to T-cell hyperactivation and exhaustion. Mabswitch SaefCAR T-cell therapy will enable regulatable target engagement and effector functions crucial for enhancing efficacy and safety. The commercialization strategy includes establishing clinical proof-of-concept and forming strategic partnerships with CAR-T cell market leaders.

TECHNICAL AND COMPETITIVE ADVANTAGE

Key technical and competitive advantages of MabSwitch switchable affinity CAR (SaefCAR) T-cell therapy include:

- Ameliorating intrinsic toxicities such as CRS
- Preventing off-tumor toxicities by tuning affinities to a threshold that facilitates tumor discrimination and/or reversibly switching OFF the CAR-T cell without eliminating it
- Preventing exhaustion of tumor-specific CAR-T cells caused by tonic signaling and other mechanisms via intermittent ON/OFF switching of the CAR-T cell
- Fast response/Onset of action
- Reversible control
- Minimal immunogenicity/safety risk
- Broad applicability to all scFv-based CARs

REGULATORY STRATEGY AND INTELLECTUAL PROPERTY

Mabswitch's product is a "combination product" which the Company believes will be regulated by FDA (CBER). Mabswitch has been accepted into the NIH/FDA CARE program and will develop the regulatory strategy in consultation with regulatory experts.

Patents for the UNASMA technology have been granted in the United States and Europe, and ownership rights have been assigned to Mabswitch. Additional patents will be filed for new inventions as they are developed.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
December 2024	In vivo demonstration of SaefCAR T-cell regulatability
September 2025	FDA Interact meeting
June 2026	Lead candidate selection
January 2027	FDA Pre-IND meeting

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2021	Non-Dilutive Funding	JnJ QuickFire Challenge	$5K
2023	Non-Dilutive Funding	SBIR Phase I (NCI)	$399,958
2023	Non-Dilutive Funding	SBIR Phase I (NCATS)	$338,997

USE OF PROCEEDS

Mabswitch is currently seeking to raise a $5M seed round to advance their lead regulatable CAR-T cell immunotherapy program in oncology. With these funds Mabswitch will undertake lead optimization and early pre-clinical activities including pK/pD studies on candidates arising from the lead program.

KEY TEAM MEMBERS

Yemi Onakunle, Ph.D., M.B.A. (Founder and CEO): 25 years of biopharma experience. Previously chief business officer of Selexis SA (acquired in 2017) where he executed over 70 license agreements worth more than $1B.

Stefan Dübel, Ph.D. (Co-founder and CTO): Inventor of the UNASMA technology and one of the inventors of antibody phage display technology. Co-founder of 5 biotech companies including Yumab GmBH.

Saravanan Nandagopal, Ph.D. (Head of Immunology): Extensive experience in immune-oncology and immunotherapy development gained at Stanford University (post-doc), IGM Biosciences, and Astellas.

miRecule

Biologics/Vaccine

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COMPANY OVERVIEW

miRecule is focused on advancing next-generation RNA therapeutics treating a variety of diseases. The Company's DREAmiR genomics-based discovery platform identifies critical RNA targets for drug development in specific subsets of patients that would benefit from treatment. miRecule then creates proprietary RNA therapeutics with improved pharmacology and joins them with antibodies for targeted delivery to disease tissue. miRecule's lead program, MC-30, targets a gene lost in half of head and neck cancer patients. miRecule's second program, licensed by Sanofi, MC-DX4 for the treatment of Facioscapulohumeral muscular dystrophy (FSHD), eliminates expression of the DUX4 gene, which causes the disease in 95% of FSHD patients.

MARKET AND COMMERCIALIZATION STRATEGY

miRecule discovers and develops its novel compounds internally and then partners pre-clinical development with CROs with GLP/GMP certification. For the Company's two lead programs, they ran a dual track of looking for investment and partnering opportunities at the pre-clinical stage and successfully licensed the FSHD program to Sanofi. miRecule is currently running this track for MC-30, simultaneously looking for investment in the form of a series A round and working with the investment bank Evolution to identify a potential co-development partner. miRecule's CEO and CFO also regularly attend pharma business development conferences such as BIO and JPM to market miRecule's technology and programs.

TECHNICAL AND COMPETITIVE ADVANTAGE

miRecule's NavIgGator ARC platform allows for unprecedented targeted delivery of RNA therapeutics to specific tissues. This is achieved through:

- miRecule's DREAmiR genomic analysis process uses proprietary datasets and algorithms to identify therapeutics tailored to specific subsets of patients. The platform also identifies receptors that are highly tissue specific and rapidly internalized to deliver the RNA therapeutic.
- miRecule has developed novel chemistry to conjugate and formulate the Company's ARCs. Specifically, the Company's bio-coat technology masks the RNA component, reducing off-target and increasing on-target delivery. The resulting ARCs can safely deliver RNA at low doses.

REGULATORY STRATEGY AND INTELLECTUAL PROPERTY

Both of miRecule's lead indications, head and neck squamous cell carcinomas (HNSCC) and FSHD, potentially qualify for orphan status. For MC-30 in HNSCC, the Company had an interact meeting in

July 2023 and plans for an IND meeting by November 2024. Post-IND submission, miRecule is preparing their orphan drug application. The Company aims to test MC-30 as a monotherapy in recurrent patients, targeting a 10% overall response rate (ORR) improvement for accelerated approval and then first-line combination with radiation to expand the label. miRecule holds five patents covering the RNA oligonucleotide, method of use claims, ARC composition, and the final formulation. miRecule has received three issued patents in the United States, two European patents, and one in China, following this strategy for other cases.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
February 2017	Form company in Maryland LLC
February 2018	Reform company in Delaware as C corp. and recruit co-founders
February 2018	License Technology from NIH
February 2019	Demonstrate animal POC data for cancer program with nanoparticle delivery
March 2020	Demonstrate POC for ARC conjugates for oncology
January 2022	Demonstrate in vivo POC for ARC in muscle with MC-DX4 FSHD program
September 2022	Execute license agreement with Sanofi for MC-DX4

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2017	NCI SBIR	MC-30	$300k
2018	FFF Money		~250K
2019	Seed Round		$2M
2020	NCI SBIR Phase II	First cancer product	$1.9M
2020	Seed Extension		$3M
2021	Fast Track SBIR	FSHD program	$3.5M
2022	Upfront Payment	MC-DX4 from Sanofi	$20M
2023	Bridge Funding	Current Investors	$3M

USE OF PROCEEDS

miRecule is currently targeting a $20M raise:

- $10M will be devoted to advancement of miRecule's pipeline programs bringing MC-30 to IND.
- $10M will be devoted to development of the muscle-specific delivery antibody to develop a clinical candidate that can selectively deliver to muscle tissue and be applied to several neuromuscular programs.

KEY TEAM MEMBERS

Anthony Saleh, Ph.D. (CEO): Serial biotech entrepreneur with more than 20 years of experience in RNA therapeutics in the public and private sectors.

David Lemus, C.P.A., M.S. (COO/CFO): C-Level executive leading public and private financing, licensing, and M&A exits, with more than 20 years in the biotechnology industry.

Kevin Kim, Ph.D. (VP of Discovery): Previously senior director of Discovery Biology at Sarepta Therapeutics and Wave Life Sciences.

Anita Seto, Ph.D. (VP of Development): 20 years of experience in the biotechnology industry, with a focus on late pre-clinical to clinical transition for RNA-based technologies.

pacDNA

Small Molecule

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COMPANY OVERVIEW

pacDNA is transforming the field of gene regulation therapeutics with their proprietary Brushield™ oligonucleotide enhancer technology. The Brushield™ platform can rapidly generate potent clinical leads with fewer side effects at a lower dosage, while delivering to non-liver sites. In some pre-clinical models, Brushield™ reduces the dosage requirement by 100+ fold while suppressing side effects and immunogenicity. With a substantial expansion in targeted organ/disease area and a reduction in cost, pacDNA can access an exponentially larger patient population.

MARKET AND COMMERCIALIZATION STRATEGY

KRAS is the best-known oncogene, with the highest mutation rate among all cancers (~20% prevalence). Recent advances made inhibiting the G12C mutation possible (SMI: sotorasib from Amgen and adagrasib of Mirati). SMIs in cancer can lead to resistance, and in the case of Lumakras, liver injury and hepatitis. Antisense oligonucleotides (ASOs) are a strategic alternative for intervention. Additionally, ASOs are not affected by the smooth KRAS protein surface, and it is equally feasible to develop a pan-KRAS ASO depletion agent. The SAM should be appreciable for such a pan-KRAS agent. pacDNA plans to take the agent to IND stage or Phase I clinical trial and out-license the asset to an established pharma for further development.

TECHNICAL AND COMPETITIVE ADVANTAGE

pacDNA's Brushield™ technology overcomes three major challenges facing the gene regulation field:

1. Efficacy given immune responses
2. Nucleic acid stability
3. Delivery

With one self-contained, single-molecule construct and no additional carriers, modifications, or vectors, Brushield™ constructs produce powerful in vivo results at low dosages. In addition, targeting non-liver tissues with nucleic acid therapeutics is an emerging topic and is a unique strength of pacDNA.

REGULATORY STRATEGY AND INTELLECTUAL PROPERTY

The Brushield™ platform represents a unique and powerful IP portfolio that is independent of existing IP portfolios (five United States/PCT applications [two granted], two provisional applications). IP produced to date will be protected by Northeastern University's Center for Research Innovation. pacDNA has entered into a licensing agreement with Northeastern to use these patented technologies exclusively. Patents regarding further disease- and target-specific approaches, as well as additional optimizations, will continue to be filed as needed by the Company.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
September 2024	KRAS candidate nomination
December 2024	Candidate nomination for rare neuromuscular disease
January 2025	Pilot NHP tox/immunogenicity data
March 2025	Seed round raise
May 2025	First pharma licensing deal
September 2026	First IND

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	AMOUNT
2022	NCI STTR Fast-Track	$2.4M
2012-2024	DOD Grant + Non-Dilutive Funding from Pharma Partnerships	~$1M

USE OF PROCEEDS

pacDNA is raising a $10M seed round within the fourth quarter of 2024 to the first quarter of 2025 to initiate a CMC campaign and to get to the Company's first IND. An approximate top-down estimate of the use of proceeds: $1.5M internal R&D, $5M CDMO, $0.5M regulatory consultants, and $1M non-clinical CRO.

KEY TEAM MEMBERS

Ke Zhang, Ph.D. (Founder and CSO): Expert in oligonucleotide therapeutics; Chemistry professor at Northeastern University where his research focuses the design and synthesis of unique polymer structures, nucleic acid-polymer conjugates, and translational nanomedicine.

Carl LeBel, Ph.D. (CEO): Seasoned biotech executive, having served as CDO at Frequency Therapeutics, CSO at Otonomy, and CEO/President at Akesis Pharmaceuticals; previously at Amgen and Alkermes in numerous R&D and management roles.

Resolute Science

Small Molecule (Drug/Delivery Platform)

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COMPANY OVERVIEW

Resolute Science is developing a novel class of pan-cancer therapeutics aimed at treating soft tissue sarcomas (STS) and aggressive, hard-to-treat solid tumors. Resolute's proprietary MAC-TAC drug-delivery platform specifically targets tumor-associated macrophages (TAMs) to process and deliver cytotoxic agents to adjacent cancer cells. By harnessing the native endocytic processes of TAMs, the Company's approach may enhance treatment efficacy while being well-tolerated. Resolute's lead asset, RS-5, is undergoing IND-enabling studies, with two additional pre-clinical programs in the pipeline. Resolute Science is dedicated to advancing first-in-class targeted therapies to help patients recover and resume their normal lives.

MARKET AND COMMERCIALIZATION STRATEGY

Resolute's lead asset, RS-5, is a pan-cancer synthetic drug conjugate in development for the treatment of aggressive, difficult-to-treat, and rare tumors. Pre-clinical data suggests RS-5 may have the potential to treat a broad range of solid tumors. There are an estimated 1.8M newly diagnosed solid tumor cases in the United States, most of which are treated using outdated chemotherapies. The Company aims to address this unmet medical need by advancing a robust pipeline of first-in-class targeted cytotoxic payloads and radiotherapeutics. Resolute's commercialization strategy involves progressing the Company's programs through clinical trials as they work with key opinion leaders and explore strategic partnerships with big pharma.

TECHNICAL AND COMPETITIVE ADVANTAGE

Solid tumors are primarily comprised of cancer cells and tumor-associated macrophages (TAMs). TAMs can account for 30-50% of the cells in a tumor. Resolute Science targets this highly abundant non-cancerous cell population by leveraging their MAC-TAC drug delivery platform. TAMs process MAC-TACs to deliver cytotoxic payloads to adjacent cancer cells. By targeting stable and non-dividing TAMs rather than rapidly dividing and mutating cancer cells, Resolute avoids resistance mechanisms intrinsic to targeting cancer cells, as seen with cancer-cell targeting therapeutics such as antibody-drug conjugates (ADCs) and small molecules. RS-5 has shown significant pre-clinical anticancer efficacy and tolerability across 15 PDX and CDX studies.

REGULATORY STRATEGY AND INTELLECTUAL PROPERTY

Because Resolute's platform is chemically synthesized, the Company will work with the CDER division of the FDA and plans to have both INTERACT and pre-IND meetings before IND submission in the fourth quarter of 2025. The Company will also submit a request for orphan drug designation (ODD). Resolute's current intellectual property portfolio includes five PCT families with 20 pending applications. The foundational patent was published in 2020, and four additional PCTs were filed in February 2023 – Morrison and Foerster is the law firm responsible for Resolute's patent filings and prosecution under Lisa Silverman Ph.D., J.D. James Mullen, Ph.D., J.D., is the Company's senior patent advisor.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2020	Founded Resolute Science, filed foundational patent
2023	Established robust in vivo proof-of-concept for RS-5 in 15 CDX, PDX sarcoma, melanoma, and intracranial models, demonstrated it was well tolerated with twice-weekly dosing for up to two months
2023	Selected clinical candidate RS-5 to move into IND-enabling studies
2023	Awarded $2.1M Fast-track NCI SBIR Grant; Phase II approved Jul 2024
2024	Filed four additional PCTs covering additional composition of matter and method of use
2024	Initiated RS-5 IND-enabling activities
2024	Hired CDMO to manufacture/scale-up GMP material
2024	Initiated RS-7 radiotherapeutics program
2024	Named 2024 Cool Company by Connect.org

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	AMOUNT
2020-2023	Convertible Note	$2.03M
2023	NCI SBIR Grant	$2.1M
2024	SAFE Instruments	$750K
2024	Series A, $35M (currently raising)	$35M

USE OF PROCEEDS

Resolute Science is seeking a Series A raise for up to $35M for:

1. Completing IND-enabling work and file IND for RS-5
2. Manufacturing GMP material for Phase Ia/b clinical trial
3. Delivering proof-of-concept data in all-comers solid tumors Phase Ia/b dose escalation and expansion trials to establish safety, tolerability, and signs of efficacy for RS-5
4. Completing optimization of RS-7 radiotherapeutics
5. Expanding team

KEY TEAM MEMBERS

Faith Barnett, M.D., Ph.D. (Founder and CEO): Board-certified neurosurgeon, Director of Neuro-Oncology at Scripps Cancer Center, Harvard-MIT.

Andre Basbaum, M.B.A. (President): Previously served as CBO/CFO at Siolta Therapeutics and VP of Business Development at ACEA Therapeutics.

Sean Premeau, RAC (Executive Director, Head of CMC & Technical Operations): Previously served as Head of CMC at Amplyx Pharmaceuticals and Aristea Therapeutics.

Saros Therapeutics

Small Molecule

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COMPANY OVERVIEW

Saros has developed a nanoparticle capable of safely targeting and enhancing pathways of innate immune activation. Beginning with STING, the nanoparticle can overcome challenges of prior agonists. Saros' drug is targeting macrophages and dendritic cells which is where the STING pathway needs to be activated, and is delivering a highly potent agonist. Saros is delivering the drug systemically and has demonstrated safety in multiple species. By working with multiple STING agonists and TLR agonists, Saros has demonstrated the breadth of the platform. Successful development of Saros' lead program will bring tremendous benefits to patients with many different types of cancer.

MARKET AND COMMERCIALIZATION STRATEGY

Saros' therapy has the potential to ultimately benefit any cancer patient because of the broad immune activity which results from STING activation. The Company plans to start with cancers where immuno-therapies have already brought benefits but where there is significant room for improvement and where clinical trials can be run efficiently. This includes: colon, breast, prostate, head & neck, and bladder cancers.

Saros plans to partner with established, commercial-stage pharmaceutical companies during the development process. There have been several partnerships in the last two years for comparable companies with STING assets at a pre-clinical stage with upfront payments ranging as high as $100M.

TECHNICAL AND COMPETITIVE ADVANTAGE

Saros' therapy is differentiated from other STING agonists through cell specific targeting, increased potency, and a better route of administration (IV rather than intra-tumoral). Other companies have approached STING activation by attempting to extend the half-life of known STING agonists through chemical modifications or inhibiting degradation pathways. These have merit but generally do not enable the cellular targeting that Saros' approach does. Others conjugate STING agonists to antibodies although most target the tumor cells, which leads to other problems. Based on robust pre-clinical efficacy and safety data, Saros has a potential best-in-class immune activator for oncology.

REGULATORY STRATEGY AND INTELLECTUAL PROPERTY

As a small molecule delivered by a lipid nanoparticle system, Saros' drug is regulated by CDER within the FDA. The Company will pursue a dose escalation study in humans with monotherapy and combination therapy staggered to pursue an efficient path to a recommended Phase II dose and initial human safety data. The plan is consistent with the latest guidance from FDA's Project Optimus for new oncology drug development.

The Company has exclusive rights to global pending patents filed by the University of Michigan including composition of matter claims. Additionally, Saros is developing new intellectual property based on manufacturing optimization work performed in the Saros lab.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2022	Academic founder completed efficacy studies in multiple challenging tumor models.
2023	Received direct-to-phase II SBIR Grant from competitive NCI
2024	Completed tech transfer to new Saros lab and adapted synthesis to scalable, GMP methods
2024	Completed exploratory Nonhuman Primate (NHP) studies showing safety and tolerability

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	AMOUNT
2023	SBIR Grant from NIH/NCI	$2.04M

USE OF PROCEEDS

Saros is raising approximately $7M to fund remaining IND-enabling studies and support all CMC and regulatory work up to dosing the first patient. Another $6M to $10M will be needed to complete a first-in-human study and achieve a significant value inflection point.

KEY TEAM MEMBERS

Matthew Martin, Ph.D. (CEO and Co-founder): Startup leadership experience and biotech VC experience.

Jennifer Chadwick, Ph.D. (CBO): 20 years experience in therapeutics discovery and development as a biotech founder and in C-suite leadership of a CRO/CDMO for next generation therapeutics.

James Moon, Ph.D. (CSO and Co-founder): Full professor of pharmaceutical sciences at the University of Michigan; Serial biotech founder; World-renowned lipid nanoparticle expert.

The broader team includes multiple STING and immuno-oncology experts.

Stingray Therapeutics

Small Molecule

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COMPANY OVERVIEW

Stingray is in-clinic with SR-8541A, an ENPP1 inhibitor. ENPP1 is the only known innate immune checkpoint. The Phase I single-agent study has produced 50% stable disease among patients treated, showing an active drug. In September 2024, the Company start a Phase I/II study in microsatellite stable colorectal cancer with double checkpoint inhibitor (Botensilimab/Balstilimab), which received a $14M award from CPRIT to pay for two-thirds of the study and half of the Company from 2024 through 2026. The Company also plan studies in metastatic prostate cancer with Pluvicto, in pancreatic and G/I cancers with beam radiation, and in triple-negative breast cancer.

MARKET AND COMMERCIALIZATION STRATEGY

Stingray plans to bring SR-8541A, its innate immune checkpoint inhibitor, through several Phase II efficacy studies in combination with adaptive immune checkpoint inhibitors and in combination with different forms of radiation in poorly responsive immunologically cold tumors like colorectal, pancreatic, G/I, hepatocellular, and triple-negative breast cancers, to show the breadth of utility and enhancement of standard of care in these cancers. Stingray will then license to or be acquired by one or two big pharmaceutical companies for Phase III studies and commercialization across the world. If the public markets open up for biotech, Stingray might consider an IPO.

TECHNICAL AND COMPETITIVE ADVANTAGE

Stingray's SR-8541A has two clinical and four pre-clinical competitors in the field of ENPP1 inhibition. Stingray's competitive advantage comes from the Company's deep understanding of the pathway. First, Stingray has high bioavailability (~85%), which gives consistent blood levels patient-to-patient. This is important because there is a "Goldilocks zone" for interferon release for maximum efficacy. The competitors in-clinic have lower bioavailability; for example, Riboscience's drug is only 10%, giving them high variation in patient-to-patient blood levels. Secondly, Stingray is studying in more synergistic combinations – double checkpoint inhibitor or with radiation compared to the competition's sole PD1 or PDL1.

REGULATORY STRATEGY AND INTELLECTUAL PROPERTY

Stingray has an accepted United States FDA IND and just filed a second IND for a microsatellite stable colorectal cancer trial starting September 2024. Stingray has a seasoned cancer clinical and regulatory team that stays on top of all FDA reporting requirements and filings. The Company has four patents and

has two in process that would protect the intellectual property. The patent for SR-8541A, the clinical lead, is in process for protection in 32 additional countries around the world, and as Stingray comes up with additional patentable inventions, they plan to continue to file where justified.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
August 2024	Complete enrollment for final cohort in SR-8541A single agent dose escalation trial
August 2024	Submit proposal for NCI Bridge to Clinic Grant
September 2024	Start the microsatellite stable colorectal cancer trial with SR-8541A, Botensilimab and Balstilimab in the United States
March 2025	Start metastatic prostate cancer trial with Pluvicto
March 2025	Complete Series A financing
June 2025	Start trial with SR-8541A plus beam radiation in pancreatic, G/I cancers
March 2026	Complete Series A2 financing
September 2026	Complete MSSCRC clinical trial
March 2027	Complete mPC clinical trial
June 2027	Complete beam radiation trial
December 2027	Sign a deal with a big pharma

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	AMOUNT
2016	SAFE	$3K
2017-2023	Non-Dilutive Funding	$5.8M
2018	Seed Series 1	$2M
2022	Seed Series 2	$2.5M
2023	Seed Series 3	$4.5M
2024	SAFE (raised out of $5M)	$1M
2024	Series A (working on lead investor)	$15M

USE OF PROCEEDS

The SAFE into the Series A and the Series A funds of $15M for the third match go to the microsattellite stable colorectal cancer (MSSCRC) trial ($5M). Other funds raised will go to half of the Company's burn ($4M) and to start the next trial with Pluvicto ($6M). The final Series A2 of $15M will allow the Company to get to exit.

KEY TEAM MEMBERS

Jonathan Northrup, M.B.A. (CEO): Has accomplished 40 deals and launched 5 products for Lilly, and ran a venture group for Jubilant Life Sciences, a large CDMO in India, as his third biotech with Dr. Sharma.

Sunil Sharma, M.D. (CSO/CMO): An eminent oncologist and the primary investigator on over 150 clinical trials in Phase I/II oncology, the deputy director at TGen, prior deputy director of Huntsman Cancer Institute, and prior VP of Novartis.

Monil Shah, Pharm.D.: 15 years of experience in immune-oncology across five companies running clinical development.

Symphony Biosciences

Drug/Delivery Device

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COMPANY OVERVIEW

SymphNode is an implantable biomaterial which will be inserted right beside the tumor at time of surgery, offering two unique benefits. First, it focuses powerful immune-activating drugs locally onto the solid tumor environment. Second, it recruits the body's natural immune cells and provides them with a real-time training against tumor cells. SymphNode eliminates the outside-the-body programming and instead builds up a natural immunity against tumor cells on site and only within a few days. The Company's pre-clinical data show that by planting the Symphnode next to a primary tumor, metastatic tumor growth is also reduced.

MARKET AND COMMERCIALIZATION STRATEGY

Symphony's beachhead market of breast cancer constitutes a $16.98B annual market opportunity of which triple-negative breast cancer (TNBC) constitutes 15% of cases, or a $2.5B market. The market is dominated by the large players including Johnson & Johnson, Merck, Celgene, Pfizer, GlaxoSmithKline, Sanofi, and AbbVie. This is a fairly consolidated market with fierce competition from large entities, hence the commercial plan to target a licensing agreement with these large players to help arm their arsenal rather than going to battle with them. These large market incumbents maintain their control over their market share by acquisitions, collaborations, and expanding their geographical reach.

TECHNICAL AND COMPETITIVE ADVANTAGE

Immulus offers bespoke biomaterial for delivery of tumor specific antigens. Symphony's technology is not patient specific and SymphNode is a lot cheaper and suppresses regulatory T-cells (Tregs) as well. Eli Lilly develops potent, small molecule drugs for Treg suppression without any targeted delivery method. Global Treg suppression results in lots of side effects. Symphony bypasses this issue by localizing the treatment to the cancer area in addition to local enhancement of killer T-cells and is the first mover in this new market.

REGULATORY STRATEGY AND INTELLECTUAL PROPERTY

Symphony require pre-market approval from the FDA as a drug. Symphony has several worldwide exclusive option agreements with UCLA and has finalized the licensing negotiations with them.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
Q3 2024	Determining comparative immune response while comparing with standard-of-care immunotherapies
Q4 2024	Prepare the Company's pre-IND package for FDA
Q1 2025	Perform animal studies in larger animals
Q2 2025	Determine pharmacokinetic and toxicity in rats and dogs
Q3 2024	Determine small-scale GLP/GMP manufacturing
Q4 2025	Determine tumor suppression in patient-derived xenograft (PDX) model

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2022	Private	Sci-Founders	$400K
2023	Federal	NIH-NCI-SBIR	$399,586
2024	Federal	CASIS	$295K

USE OF PROCEEDS

The Company's business plan estimates the cost of product development, GMP product manufacturing, pharmacology/toxicology testing, IND-enabling studies, and a 30-subject Phase I clinical trial to be in the range of $10-12M. In the upcoming year, Symphony is planning to raise $3-5M for general corporate purposes from the venture capital community while the pharma partnership project plan is underway.

KEY TEAM MEMBERS

Negin Majedi, Ph.D. (CEO and President): Expert in biomedical engineering with more than 35 peer-reviewed publications in the top journals of her field and more than 1,400 citations by peers in this field.

Mahdi Hasani, Ph.D. (CSO): Polymer and bioengineering expert; more than 90 journal papers published including 25 during his four years of research at UCLA. Additionally, his UCLA work resulted in 14 patent applications.

Manish Butte, M.D., Ph.D. (Co-founder): An E. Richard Stiehm endowed chair, professor, and division chief at Pediatric immunology group at UCLA.

Laurence Nore, M.B.A. (VP of Business)

Erfan Dashtimoghadam, Ph.D. (VP R&D)

Tezcat Biosciences

Protein-Drug Conjugate

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COMPANY OVERVIEW

Tezcat Biosciences was founded to identify and develop the next generation of precision medicine in oncology. The Company is developing a receptor-independent drug delivery technology that is indication and payload agnostic. Born out of New York University Langone Health, the team is committed to refining and delivering the leading-edge technology from bench to bedside.

MARKET AND COMMERCIALIZATION STRATEGY

Tezcat's target market is for the treatment of adult patients with mutant RAS solid tumors and myeloma. Approximately 32,000 new cases of multiple myeloma (MM) will be diagnosed each year in the United States alone, with a total addressable market of $1.8B by 2030. Beyond the RAS mutant relapsed/refractory multiple myeloma (RRMM) patient population, Tezcat is positioning TZT-102 for solid tumors that express mutant RAS. Tezcat's TZT-102 will be targeted for use in patients with RAS mutated locally advanced or metastatic pancreatic ductal adenocarcinoma (PDAC) (TAM: $6.4B), colorectal cancer (CRC) (TAM: $11.7B), or non-small cell lung cancer (NSCLC) (TAM: $12.2B).

TECHNICAL AND COMPETITIVE ADVANTAGE

The mechanism of action behind TZT-102 addresses obstacles seen in other drug classes. Not only does Tezcat have straightforward patient selection criteria and an ideal therapeutic window, but by eliminating mutant RAS cancer cells, the Company is targeting the most aggressive clones that are responsible for resistance/relapse. Pre-clinical and clinical studies suggest that patients treated with direct RAS inhibitors are acquiring resistance to their treatments through the development of additional mutations and bypass mechanisms that reactivate the RAS pathway. This type of resistance is promising for Tezcat's approach as it relies on the RAS pathway activation for the delivery of the compound.

REGULATORY STRATEGY AND INTELLECTUAL PROPERTY

TZT-102 will be regulated in the United States by the FDA through the Center for Drug Evaluation and Research (CDER) and is required to submit an Investigational New Drug (IND) application for conducting clinical studies and a Biologics License application (BLA) for market approval. Tezcat has an exclusive, worldwide rights to the underlying technology through a License Agreement with NYU Langone Health. Tezcat has also filed an additional defensive patent.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
Q1 2026	IND submission
Q4 2026	1st patient dosed
Q2 2028	Completion of Phase Ia/Ib clinical trial

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	AMOUNT
2020-2024	NCI SBIR Phase I and II Grants	$~3M

USE OF PROCEEDS

Tezcat Bio's $4M seed round will be utilized alongside non-dilutive grants and an NCI partnership to bring the lead asset, TZT-102, through the completion of a Phase I clinical trial.

KEY TEAM MEMBERS

Craig Ramirez (Co-founder & CEO): Expert in cell biology and inventor of Tezcat's core technology; has engaged in various entrepreneurship and executive programs, including Johnson & Johnson's CEO Development Program.

Andrew Hauser (Co-founder & COO): Trained molecular biologist with more than 13 years of experience in cancer research.

Vance Sohn (Part-time CMO): MD Anderson Cancer Center-trained surgical oncologist who is now a practicing surgeon across the entire spectrum of general surgery at different practice environments from critical access hospitals to quaternary level cancer centers; the director of Medical Affairs for LumaBridge, a clinical research organization with focus on oncology trials.

TrAMPoline Pharma

Cell/Gene Therapy

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COMPANY OVERVIEW

TrAMPoline Pharma was founded with a vision to support the next generation of cellular immunotherapies to treat solid tumors. The Company is developing viral vectors encoding proprietary proteins to improve the performance of all forms of cellular immunotherapy. TrAMPoline's first product, MightyTIL™, is a gene-modified tumor infiltrating lymphocyte (TIL) product that will build on the initial success of Amtagvi™, Iovance's recently FDA-approved conventional TIL therapy. MightyTIL introduces critical signaling components designed to (1) reduce production times; (2) reduce the number of cells that need to be administered; (3) lessen costs; and (4) generate more effective cellular immunotherapy products.

MARKET AND COMMERCIALIZATION STRATEGY

Since Amtagvi was only recently approved, there have not been any extensive data collected to estimate the addressable market for TIL therapies. Since 75% of solid tumor patients are estimated to be refractory to checkpoint inhibitors, the most prevalent form of immunotherapy, the Company estimates that the market size for cellular immunotherapies exceeds 1.4M patients annually in the United States alone. TrAMPoline's commercialization strategy is to explore partnerships with established companies that focus on cellular immunotherapy. The Company is also seeking to partner with institutions that have heavily invested in TIL manufacturing including the Moffit Cancer Center and MD Anderson.

TECHNICAL AND COMPETITIVE ADVANTAGE

MightyTIL™ leverages TrAMPoline's patented coR8:Amp™ technology which enables enhanced binding of the T-cell receptor (TCR) to the cancer cells and enhanced TCR signaling that significantly increases T-cell activation and killing of cancer cells. MightyTILs demonstrate numerous advantages over unmodified TIL and CAR-T therapies: (1) expanded reactivity to multiple tumor antigens; (2) higher functional activity and increased proliferation; (3) increased persistence and reduced exhaustion due to reduced expression of key immune checkpoint receptors; (4) lower amounts of IL-2 in vivo (less toxicity); (5) increased survival in vivo; and (6) shorter manufacturing times.

REGULATORY STRATEGY AND INTELLECTUAL PROPERTY

TrAMPoline's regulatory strategy is to follow the pathway taken by Iovance to gain approval for Amtagvi as well as the clinical trial strategies employed for other gene-modified TIL therapies (e.g., NCT05470238 and NCT05393635). The Company has had an INTERACT meeting with the FDA and will have a pre-IND meeting with the FDA in the fourth quarter of 2024. TrAMPoline has an exclusive license to worldwide issued patents covering the compositions and uses of the MightyTIL technology (e.g., US/10,975,137). The Company has also licensed or intends to license three additional patents from the founder's academic laboratory that complement the existing MightyTIL technology and expand its application to other cellular immunotherapies.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2017	Cancer Research publications regarding foundational MyD88 technology; Company formed
2019	Exclusive License Agreement with UMB; Founder and Company relocate to Colorado
2021	Foundational patent issued in United States (10,975,137 B2); INTERACT meeting with the FDA
2022	SBIR Grant funded; Seed financing completed; Company operations initiated
2024	GMP viral vector manufacturing initiated; funding secured for Phase I trial (anticipated July 2024); pre-IND meeting with the FDA (anticipated December 2024)
2025	IND-enabling studies completed (anticipated March 2025); MightyTIL Phase I clinical trial initiated (anticipated Summer 2025)

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2022	NCI direct-to-phase II SBIR Grant		$2M
2022	Seed Round	Convertible Debt	$2M
2022	State of Colorado	Economic Development Grant	$250K
2023	State of Colorado	Strategic Infrastructure Grant	$500K
2024 (anticipated)	Funding for MightyTIL	Phase I Clinical Trial	$10M

USE OF PROCEEDS

TrAMPoline is seeking $10M in bridge financing to expand the operational capabilities by employing additional research staff and regulatory consultants, advance two new pipeline products to IND enabling status while the MightyTIL Phase I clinical trial is enrolling, and prepare the Company for series A financing ($50M) by adding senior management positions.

KEY TEAM MEMBERS

Eduardo Davila, Ph.D. (Co-founder and CSO): Professor of medicine and director of immunotherapy, UC School of Medicine; serial entrepreneur (10+ years of company experience).

Richard Duke, Ph.D. (President and Interim CEO): Professor of medicine and deputy associate director of commercialization, UC Cancer Center; serial entrepreneur (25+ years of corporate experience).

Douglas Swirsky, M.B.A. (Co-founder, Senior Business and Finance Advisor): C-level executive and board member with multiple publicly traded biotech companies.

Ananya Health

Surgical/Ablative Device

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COMPANY OVERVIEW

Every two minutes, a woman dies of cervical cancer. Even though the disease is 95% preventable, it is the fourth-largest cancer cause of death for women globally. Routine screening tools (HPV tests, Pap smears, colposcopy) are widely available, but less than 30% of women have access to early treatment options when the test comes back positive, because current treatment tools require hospital-level infrastructure or highly trained specialists. Ananya Health is building a self-contained cryoablation device that delivers standard-of-care ablation without consumable cryogen, making early treatment possible in any clinic, without the cost, hassle, or safety concerns of CO2 or N2 tanks.

MARKET AND COMMERCIALIZATION STRATEGY

An estimated 50 million women per year worldwide have CIN lesions, and current early treatment technologies reach less than half of them. Cervical cancer prevention represents a $1.8B market.

Following an FDA 510(k) clearance, Ananya Health will go to market with a limited commercial launch in Kenya. To facilitate this launch, Ananya Health is working with a distributor in Kenya with 1,000+ clinics in their network. This launch allows the Company to pilot roll-out, training, and device maintenance strategies while gaining traction with global health purchasers. In 2027, Ananya Health will launch a gen 2 platform with a disposable probe sheath aimed at the United States and India.

TECHNICAL AND COMPETITIVE ADVANTAGE

Ananya Health's Cryo Refrigerant Closed Loop (CRCL) platform provides effective cryotherapy without requiring consumable cryogen gas. Eliminating the gas supply chain enables adoption at the primary care levels where screening for cervical abnormalities is currently happening. It also significantly reduces the cost of each procedure, resulting in a cost savings to the patient and higher margins for providers. The system is highly portable and battery operated, allowing for use in a variety of clinical settings. Finally, the provider burden is low; cervical cryotherapy can be (and often is) performed by nurses, physicians' assistants, or other nonphysician providers.

REGULATORY STRATEGY AND INTELLECTUAL PROPERTY

Ananya is planning for FDA 510(k) clearance in early 2025. Nonprovisional (PCT) patent application filed through the United States PTO in 2023; additional provisional patents pending. Initial FTO assessment was completed in the fourth quarter of 2022.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
August 2021	Second acute animal study showing 5mm freeze on a fully battery-powered system
December 2021	Hired a CTO
December 2022	Achieved -60C on a single-stage compressor system
Q1 2023	Regulatory strategy developed
Q4 2023	Non-provisional (PCT) patent application filed covering refrigeration system

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	AMOUNT
2021	Initial Seed Round Angel investors, Seed funds, Y Combinator	$1M
2022	NCI SBIR Phase I	$400K
2023	Seed Round – 2nd Tranche	$600K
2024	Anticipating Phase II Grant	

USE OF PROCEEDS

In 2025, Ananya Health anticipates raising a priced Series A round to support manufacturing transfer and commercialization.

KEY TEAM MEMBERS

Anu Parvatiyar (Co-founder & CEO): 10 years of medical device R&D (previously at C. R. Bard), two 510(k)s, three products launched. Four years working with WHO, Gates Foundation, Govt of Nigeria to design and deploy technology for global health.

Allen Chang (CTO): Co-founder of Vertera Spine; acquired by NuVasive in 2017. Forbes 30 Under 30 in Manufacturing. More than 10 products launched and nine 510(k)s cleared.

Julie Yip (Co-founder & Project Lead/ Engineer): 6 years of med device startup experience in R&D. Co-founder of a femtech startup prior to Ananya Health.

Calla Health Foundation

Cancer Screening and Diagnosis

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COMPANY OVERVIEW

Calla Health is a university-born spin off company that seeks to commercialize and successfully bring to market IP developed at Duke University and the Center for Global Women's Health Technologies. Calla Health develops products from concept through to clinical use and ultimate market entry. The Pocket Colposcope is an FDA 510(K) cleared device with the same designated uses as a traditional colposcope. The Pocket Colposcope can capture images that provide an equivalent diagnostic performance to a traditional colposcope, but at a fraction of the cost.

MARKET AND COMMERCIALIZATION STRATEGY

Invasive cervical cancer (ICC) affects the lives of 500,000 women worldwide each year, resulting in more than 270,000 deaths. Unlike most cancers, ICC is highly preventable through the screening, diagnosis, and treatment of cervical precursor lesions. The Pocket colposcope has the form factor of a tampon with comparable resolution and field-of-view to a state-of-the-art digital colposcope. The device connects to a laptop, tablet, or cellphone via a USB cable for image capture. Calla Health utilizes outside contract manufacturing services to produce products for the worldwide market and has identified three potential contract manufacturers and is currently having them bid on production of the Pocket Colposcope. Calla Health has the quality systems and processes in place to produce regulated, medical devices for sale world-wide.

TECHNICAL AND COMPETITIVE ADVANTAGE

There are two main competitors in the space of alternatives to traditional colposcopes – Gynocular by Gynius and EVA system by MobileODT. Gynius is located in Sweden and has been in business for 10 years. MobileODT is based in Israel and states that it has raised $13M since its founding in 2012. Their presence proves that there is a strong market demand for a lower-cost alternative to traditional colposcopes. Both companies have designed products to be used in conjunction with a cell phone. While seemingly a clever approach, both products are lacking in several key areas including design and cost. The Pocket Colposcope is more than 10X less expensive and lighter than a clinical colposcope and at least 5X less expensive and lighter than low-cost MobileODT and Gynocular colposcopes. The Pocket Colposcope has been validated in clinical investigations on more than 1,000 patients in hospitals across the globe. These clinical investigations informed evolution of the Pocket Colposcope into a beta version, demonstrated that its image quality is comparable to that of standard clinical colposcopes (when validated against pathology), and enabled a wide range of health providers from different geographical settings to provide critical input that informed the development of the commercial product.

REGULATORY STRATEGY AND INTELLECTUAL PROPERTY

The core innovations within the portable colposcope are defined by two PCT patent applications filed by Duke University with the World Intellectual Property Organization. The patent applications and their follow-on rights are licensed to Calla Health for the purpose of commercialization and further development. The Pocket Colposcope is cleared by 510(k) and Calla Health is currently seeking registration in India.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2025	Device registration in India
2025	Device registration in Peru
2025	Device registration in Kenya
2025	Sell 1,000 units

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	AMOUNT
2019	NCI SBIR Phase I	$299,992
2020	NCI SBIR Phase I	$300,000
2022	NCI SBIR Phase II	$1.99M
2023	NCI SBIR Phase II	$909,585

Calla Health has been sub-grantee, sub-recipient, and consultant on various federally funded projects through: USAID DIV, NCI, and NIBIB. Additionally, the Company's global health project work for non-governmental organizations has been supported by major foundations such as Duke Global Health Institute, Duke University Pratt School of Engineering, Duke Institute for Health Innovation, Fogarty Institute, International Society of Photonics and Engineering (SPIE), Optical Society of America, Schmidt Foundation, and the Lemelson Foundation. In total, Calla Health has raised nearly $5M.

USE OF PROCEEDS

Calla Health is currently raising primarily non-dilutive funding and is planning to use these funds to optimize and scale the manufacturing procedure.

KEY TEAM MEMBERS

Marlee Krieger, M.S. (CEO): Extensive experience in implementation of clinical trials and regulatory and financial management of entrepreneurial ventures; has managed international partnerships in multiple LMIC clinical settings.

Brian Crouch, Ph.D. (CTO): Expert in translating diagnostic technologies from the bench to bedside using in vitro cell culture and cell-based assays, small animal models, fluorescence microscopy, image processing, machine learning, and clinical trial design.

Nimmi Ramanujam, Ph.D. (Advisor): More than 20 years of optical imaging and spectroscopy system design and manufacturing; founded Zenalux, a startup focused on commercialization of spectroscopy technology development in her laboratory for quantitative noninvasive measurements of tissue.

CivaTech Oncology

Radiation Therapy Device

Suzanne Babcock | sbabcock@civatechoncology.com | 919-314-5515 | civatechoncology.com

COMPANY OVERVIEW

CivaTech Oncology® has created major technological breakthroughs in the treatment of cancerous tumors. CivaTech Oncology has three FDA-cleared, commercially available product lines – CivaString®, CivaSheet®, and CivaDerm®. Products are polymer-encapsulated radiation devices that are bio-compatible and bio-absorbable, designed to be easily implemented in the workflow of the current cancer care pathways. The product lines meet all required regulatory clearances and a strong patent portfolio protects the Company in the pursuit of treating patients with this revolutionary technology. The products have been used in more than 20 clinics nationwide with new customers in the onboarding process.

MARKET AND COMMERCIALIZATION STRATEGY

CivaTech Oncology is committed to commercializing CivaString, CivaSheet, and CivaDerm. CivaSheet especially has a huge market potential because it provides an opportunity to deliver radiation therapy in patient populations where external beams cannot. CivaSheet adds a revenue stream for hospitals to give the patients an option for receiving a clinically beneficial dose of radiation therapy, which they may not otherwise be able to receive. CivaSheet has the potential of treating the 250,000 cases of cancer in the United States if adopted. The total market is estimated to be over $4B in the United States alone.

TECHNICAL AND COMPETITIVE ADVANTAGE

A uni-directional radiation device truly satisfies an unmet medical need, and thus, many cancer types are likely to be amenable to treatment with CivaSheet. Any malignancy that is located near radio-sensitive structures is a prime candidate for CivaSheet treatment, which includes most cancers in the abdomen and pelvic regions. For some malignancies, CivaSheet provides a completely new radiotherapy treatment modality. It provides a safer, localized, and customized treatment option as opposed to external-beam radiotherapy (EBRT) that irradiates a whole region.

REGULATORY STRATEGY AND INTELLECTUAL PROPERTY

CivaTech Oncology's product lines meet all required regulatory clearances and a strong patent portfolio protects the Company in the pursuit of treating patients with this revolutionary technology.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2013	First CivaString patient implanted
2015	First CivaSheet patient implanted
2024	First CivaDerm patient implanted

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	AMOUNT
2007-2023	Angel Investor Rounds	~$15M
2008-Present	Grants	~$11M

USE OF PROCEEDS

CivaTech is seeking $20M in equity to provide working capital for purchase orders, fund post-market clinical studies, and expand sales and corporate infrastructure and is seeking this funding as soon as possible.

KEY TEAM MEMBERS

Suzanne Babcock (CEO): 30+ years of experience in business development of radiation devices

Greg Briley (CFO): Co-founder of Etix, independent ticket provider

George Paschal, M.D. (CMO): 44+ years of general surgical experience

Mark Rivard, Ph.D. (CSO): International brachytherapy expert

Kristy Perez, Ph.D. (COO & VP): Leading clinical trials, operations, R&D

Eisana Health

At home/In clinic Device

Carole Spangler Vaughn | carole@eisana.com | 619-693-7800 | eisana.com

COMPANY OVERVIEW

Eisana Health is preventing side effects from cancer treatment, starting with a cooling system for hands and feet, to prevent painful and incurable nerve damage caused from many common chemo drugs. In a recent study, nerve damage was reduced by 55% with cooling, recommending that all patients receiving neurotoxic drugs should cool their hands and feet on the day of chemo. Unfortunately, there's no easy way to do it. Patients are struggling with ice cold solutions, designed for injury or rehabilitation. Eisana Health is incorporating extensive input from oncologists, nurses, and patients, to easily allow several hours of uninterrupted, comfortable cooling.

MARKET AND COMMERCIALIZATION STRATEGY

By 2040, it is estimated that there will be 29.5M new cancer diagnoses globally, resulting in 15M patients receiving chemo, of which 10M will be exposed to drugs that cause CIPN. CIPN not only destroys qualify of life for survivors but it adds great cost to healthcare systems because there is no cure and the symptoms can be devastating. In Eisana's independent, qualitative market research, it became very clear that the best way to market is direct to consumer. Clinics are motivated to deliver the best healthcare and will recommend Eisana's device. The Company will start by embedding into one healthcare system. It is currently in discussions with five healthcare systems and is a member of Mayo Clinic's Innovation Exchange.

TECHNICAL AND COMPETITIVE ADVANTAGE

To the Company's knowledge, Eisana Health is the first company to tackle the problem of having functionality in your hands and feet while simultaneously cooling. Even NASA did not take on this challenge as their space suits have cooling in all areas but the hands. Eisana will be first to market with their novel design – technical apparel that also cools. Extensive patents have been filed.

REGULATORY STRATEGY AND INTELLECTUAL PROPERTY

There is significant pent-up demand for Eisana's product as major cancer centers are encouraging patients to cool using what is available, which is far from ideal. Because of this, the Company will not have to market specifically for the intended use of preventing CIPN, and can launch as 510(k) exempt. Once Eisana is revenue generating, the Company will run a larger study to support a 510(k) submission and a reimbursement pathway. Eisana has filed two patents through the PCT. The first has gone through national phase and Eisana has entered eight countries and the EU. They will do the same for the second application.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2022	Closed $900K pre-seed round
2022	Completed regulatory, reimbursement strategies; independent market research
2022	Completed first prototype; held oncology nurse focus group
2023	Received $400K Phase I NCI SBIR contract
2024	Completed alpha prototype
2024	Completed formative human factors study

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2022	Pre-seed Convertible Note Round	Angels and Family Offices	$900K
2023	Phase I NCI SBIR Contract		$400K

USE OF PROCEEDS

Eisana is currently raising $1M, which will get the Company to revenue (43% goes to engineering development, 24% goes to manufacturing, 13% goes to clinical, 12% to salaries, and 8% to legal).

KEY TEAM MEMBERS

Carole Spangler Vaughn, Ph.D., M.B.A. (CEO): Received Ph.D. in Biophysics and an M.B.A., and has been in the life science start-up industry for decades, mostly bringing oncology products to market.

Lisa Malina (CFO): CPA with extensive experience managing finances for large and small companies.

Jennifer Urban (Engineering): Helped bring numerous medical devices to market.

Eisana's team is highly qualified, each with more than 20 years of relevant experience.

Magnetic Insight

Imaging Device

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COMPANY OVERVIEW

Magnetic Insight aims to transform medical imaging by enabling new clinical insights without radiation exposure. The Company is pioneering Magnetic Particle Imaging (MPI), a breakthrough non-radioactive tracer technology that combines the high contrast and sensitivity of nuclear medicine with the SNR and temporal resolution of modern anatomical methods. With 15+ pre-clinical systems deployed globally, Magnetic Insight is now developing the world's first clinical whole-body MPI scanner. Initial applications focus on lymphatic imaging, with potential to expand into cancer detection and cell therapy tracking. The Company is backed by a strong IP portfolio and an experienced team.

MARKET AND COMMERCIALIZATION STRATEGY

Magnetic Insight targets the $4B+ functional imaging market. The Company's initial focus is on lymphatic imaging using an existing tracer ($180M), with plans to expand into new (immune system, cell therapy, bleed detection) and replacement (brain and cardiac perfusion) applications after approval. The commercialization strategy involves developing and selling MPI scanners to healthcare providers and research institutions while creating a recurring revenue stream with tracer sales. Partnerships with key opinion leaders and imaging centers will drive clinical adoption, while collaborations with pharmaceutical companies will explore new applications such as cell therapy tracking.

TECHNICAL AND COMPETITIVE ADVANTAGE

MPI offers the technical advantages of a functional imaging technique, including high contrast, sensitivity, and full-body signal penetration, while also providing the temporal resolution and image quality seen in modern anatomical imaging techniques. By using non-radioactive, biocompatible iron oxide tracers, the MPI technology enhances patient safety and reduces supply chain costs when compared with nuclear medicine. The Company's competitive edge includes being the pre-clinical MPI leader with 3-fold more shipped systems than the competitor Bruker (the first-mover in clinical MPI), a strong IP portfolio, and an experienced team.

REGULATORY STRATEGY AND INTELLECTUAL PROPERTY

Magnetic Insight will pursue FDA approvals for both MPI scanners and for a series of magnetic particle tracers (or iron oxide tracers), with the initial tracer based on an FDA-approved active ingredient. With 20+ patents, the Company's IP covers MPI technology, hardware, and tracers.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2015	Company was founded as a university spin-out from UC Berkeley
2017	First pre-clinical MPI system installed
2023	Fifteen pre-clinical MPI systems installed worldwide (MSRP $0.9–1.5M, depending on options)
2023	Clinical hardware safety testing (N=3) under IRB oversight
Q2 2024	IRB approval for first in human imaging including an injection
Q3 2024	First-ever human MPI images anticipated

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2015–current	NIH (SBIR & U01)	Multiple SBIR Phase I and II trials, including: pre-clinical hardware, clinical hardware, nanoparticles, electronics, and combined MPI/hyperthermia for treatment	$9M
2015	Seed Funding	Pre-clinical technology development and company formation. Lead: Sand Hill Angels	$3.6M
2019	Series A	Pre-clinical system development and deployment. Lead: 5AM Ventures	$13M
2022	Series B	Clinical prototype development and initial human studies. Lead: Celesta Capital	$18M
2024	Bridge Round	Complete first-in-human studies. Lead: Celesta Capital	$1.7M

USE OF PROCEEDS

Magnetic Insight is raising $30M to advance the clinical MPI program through Phase I/II trials. This funding will support: (1) full-body scanner development, (2) FDA submissions for hardware and tracer, and (3) clinical trial setup and execution.

KEY TEAM MEMBERS

Chris Raanes (CEO): Seasoned executive with 20+ years in medical imaging/devices. Formerly CEO at Spire Health & ViewRay, C-suite at Accuray, and a senior executive at Perkin Elmer.

Patrick Goodwill, Ph.D. (Founder/CTO): Developed MPI over two decades. Led small animal MPI development, now focused on clinical hardware.

Joan Greve, Ph.D. (VP clinical development and regulatory strategy): Former NIH/NCI program director, U. Michigan faculty, Genentech researcher.

Ramona Optics

Imaging Device

Gregor Horstmeyer | gregor@ramonaoptics.com | 650-714-6490 | ramonaoptics.com

COMPANY OVERVIEW

Ramona Optics was founded in 2018 by Dr. Mark Harfouche and Dr. Roarke Horstmeyer, two recent Ph.D. graduates from Caltech. Now based in Durham, NC just a few blocks from Duke University, Ramona Optics is actively supporting dozens of customers for its multi-camera array microscope (MCAM) technology access systems and is selling dozens more. With 16 full-time employees and multiple partners at large universities and medical centers, Ramona Optics is currently preparing to launch its flagship real-time cellular imaging product and is seeking funding to help propel productization and marketing efforts.

MARKET AND COMMERCIALIZATION STRATEGY

$80B per year is spent on life-science instrumentation across academia, biotech/CRO, and large pharma. The Company's strategy has been to partner with key opinion leaders in academia to establish proof-of-performance through publications, build a respected customer base in the research community, and form data-sharing agreements to accelerate development of the Company's foundational machine learning models. With more than 35 systems operating globally including sales to biopharma, the Company is preparing to launch its product for pre-clinical assays in early 2025. This will drive commercial revenue without need for regulatory approvals while Ramona Optics continues to advance toward the clinical space for cytopathology and therapeutics.

TECHNICAL AND COMPETITIVE ADVANTAGE

Ramona's proprietary imaging GPU packs an array of 96 microscopes in the footprint of a multi-well plate to capture cellular-scale detail and dynamics in real-time. Compared to existing products, which consist of a single objective lens and image sensor, Ramona's technology is simply 96X faster. Its data management and machine learning analysis pipeline are likewise optimized for next-generation discovery and clinical review. By rapidly distilling large, multi-gigabyte datasets into key measures of salient details, the Company uniquely allow biologists and clinicians to be better informed by an order of magnitude more data without sacrificing any additional time.

REGULATORY STRATEGY AND INTELLECTUAL PROPERTY

Ramona Optics primarily serves the biomedical research market and its products currently do not require FDA approval. The Company has eleven granted United States utility non-provisional patents, nine United States utility non-provisional patents under review/at the PCT stage and six provisional patent applications. The general space of Ramona's IP coverage includes its unique micro-camera array design, its extensions into unique high-resolution imaging regimes (including at the cellular and sub-cellular scale), and several unique clinical imaging capabilities.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2020	Ramona Optics moves to Durham, NC and grows to five employees
2021	Ramona Optics demonstrates world-leading gigapixel video and ML analysis
2022	Ramona Optics secures first five sales to academic laboratories
2023	Ramona Optics achieves more than $1M in annual revenue
2024	Ramona Optics delivers early-access product to five academic partners and two industry partners capturing and processing over 50M images in less than six months

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2020-2021	Convertible Note	Working capital to deploy technology access (gen 1) systems	$2M
2023-2024	SAFE	Working capital to accelerate early-access placements for real-time cellular screening (gen 2) systems	$3.5M

USE OF PROCEEDS

Ramona Optics is raising its first equity financing of $12M. Funds will be used for the following:

- 50% for commercialization including product marketing, sales, and field application support (FAS/FSE) functions.
- 20% for working capital
- 15% for engineering and data science
- 10% for consumables development
- 5% for IP continuation and filings

KEY TEAM MEMBERS

Gregor Horstmeyer (CEO): B.S.E. at Princeton University in 2010. 12+ years of engineering lead with Apple, Uber, Google

Mark Harfouche, Ph.D. (CTO): Ph.D. at Caltech Electrical Engineering in 2017

Roarke Horstmeyer, Ph.D. (Scientific Director): Duke University assistant professor (2018-current)

Margaret Aery (COO): B.A. at Duke University in 2009. 15+ years of leading operations at PBS & NPR

Natalie Alvarez, M.B.A. (Product Lead): M.B.A. at Columbia University in 2015. 10+ years of clinical and pre-clinical product development

TibaRay

Hospital Device

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COMPANY OVERVIEW

TibaRay will treat cancer 400x faster than current radiation therapy, reducing collateral damage to normal tissue by up to 40%. This could become the standard of care for 60% of cancer patients. The Company is led by thought-leading founders and a CEO with 28 years of experience at Varian Medical Systems. TibaRay has well-patented technology from the SLAC National Accelerator Lab and Stanford University with many applications outside of cancer therapy. After a decade of work on the enabling technology, partially funded by $11M in non-dilutive grants, TibaRay is ready to transition to commercial application in 2025 and is projected to be profitable in 2028 with the potential for an IPO in 2029.

MARKET AND COMMERCIALIZATION STRATEGY

Radiotherapy equipment is a $7B market growing at 6% per year. TAMs for applications of TibaRay's core technology are $97B.

The Company will introduce products in three phases.

1. **TibaRay Inside:** Sell the extremely efficient linear accelerator technology to enable companies to make breakthrough products for their customers in multiple markets. Available: Now.
2. **Falcon:** Radiation therapy 30x faster (less than 5 seconds) than the current state-of-the-art systems, eliminating tumor motion from breathing for better outcomes. Available: 2026.
3. **PHASER:** New class of FLASH therapy 400x faster (less than 1 second) than the current radiotherapy. Could reduce collateral damage by as much as 40%. Available: depends on funding.

TECHNICAL AND COMPETITIVE ADVANTAGE

Varian Medical Systems and Elekta are TibaRay's primary competitors. Together they dominate the current external beam radiation therapy market, accounting for nearly 70% share. Neither Company has the technology for ultra-fast radiation therapy in an affordable package. Falcon will be 30x faster and PHASER will be 400x faster than their best machines.

Varian is developing a FLASH treatment with its proton systems. However, these systems are very expensive (10x) and not cost competitive. Other proton therapy vendors are also competitors, but they have the same significant cost problem.

REGULATORY STRATEGY AND INTELLECTUAL PROPERTY

From a geographic perspective, TibaRay will start with regulatory clearance in the United States, followed by approvals in the United Kingdom, European Union, Canada, Japan, China, and the rest of the world in line with the Company's customer penetration plan and as country-by-country regulatory requirements dictate.

United States clearance will start with a 510(k) for Falcon followed by a 510(k) for PHASER. Then the Company will pursue FLASH trials and a FLASH Therapy Pre-Market Authorization.

TibaRay's intellectual property originated in the SLAC National Accelerator Laboratory and Stanford University. It is protected by 15 issued patents, 6 pending patents, and trade secrets.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
Q4 2024	TibaRay inside: Deliver all first article units to Arizona State University
2025	TibaRay inside: Deliver all components to Arizona State University
2025	TibaRay inside: Book $1.5M in orders
Q4 2026	Falcon ("Done in a breath"): FDA 510(k) clearance in Q4 2026
Q4 2026	Falcon ("Done in a breath"): Orders for first 2 systems in Q4 2026
2028	Business Milestones: Profitable
2029	Business Milestones: $145M in revenue
2029	Business Milestones: IPO
PHASER ("Done in a FLASH"): The above milestones will allow TibaRay to fund PHASER development out of the business.	

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2017-2024	DOE & NCI SBIR Grants and Contracts		$11.3M
2021	Seed	SAFE with 20% discount and $20M cap	$2.2M
2023	Seed	Convertible note with 20% discount and $35M cap	$6.0M
2024	Bridge	Convertible note with 25% discount and $45M cap	$1.7M
Various Years	Commercial Revenue		$1.3M

USE OF PROCEEDS

TibaRay is raising $15M in Series A equity to:

- Deliver TibaRay Inside accelerators for $2.5M in revenue
- Develop prototype Falcon system
- Build the team

This raise will be leveraged with additional non-dilutive grants, $2.2M of which starts in September 2024.

KEY TEAM MEMBERS

Bill Loo, M.D., Ph.D. (Founder & Board Member): Radiation oncologist and bioengineer; global thought leader in lung cancer, stereotactic ablative radiotherapy, and FLASH therapy.

Sami Tantawi, Ph.D. (Founder & Board Member): Led global accelerator collaboration; inventor of underlying technology; world expert in linear accelerators and RF physics.

Jeff Amacker, M.B.A., C.F.A. (CEO & Board Member): 28 years at Varian, the market leader in radiotherapy systems; led their worldwide engineering team and built the treatment planning business from infancy to an annual $250M+ business.

Amplified Sciences

In Vitro Diagnostic

Diana Caldwell | diana.caldwell@amplifiedsci.com | 317-490-0511 | amplifiedsciences.com

COMPANY OVERVIEW

Amplified Sciences is a clinical-stage life science diagnostics company focused on accurately detecting and pre-empting the risks of debilitating diseases, with R&D operations in Purdue Research Park, a CLIA lab in Irvine, California, and key alliances in San Francisco and Boston. The Company is developing a portfolio of diagnostic assays for early detection of some of the most challenging diseases. BioMatra™, an ultra-sensitive universal optical reporter platform technology licensed from Purdue University, enables a new class of multi-omics diagnostic tests. The lead assay in development targets early detection of undiagnosed pancreatic cancers.

MARKET AND COMMERCIALIZATION STRATEGY

Pancreatic cystic lesions are detected in three million patients each year, but the relative risks of those being benign versus potentially malignant are not accurately diagnosed leading to potential missed malignancies (high false negatives), overtreatment (high false positives), and significant cost burdens. The total pancreatic cancer diagnostic market is more than $2.9B. The customers include gastroenterologists and pancreatic surgeons (decision makers), hospitals/clinics (influencers), and payers (buyers). Tests will be launched as lab-developed tests initially to a small group of “early access” thought leaders and high-volume advanced endoscopist gastroenterologists.

TECHNICAL AND COMPETITIVE ADVANTAGE

This assay provides a highly accurate (+95% specificity, +90% sensitivity) solution for pancreatic cyst risk stratification, enabling clinicians to better identify patients at risk for developing cancer as well as reduce unnecessary surgeries and costly imaging. The primary competitors are a molecular diagnostic assay, CEA, with low accuracy and an NGS test offered by Interpace, which has limitations including large sample volume, false negative rates in high-grade dysplasia, and long processing times. Amplified’s test is a superior solution that rules out disease, requires significantly smaller amount of cyst fluid, and can crosswalk to a $2,500/test reimbursement rate.

REGULATORY STRATEGY AND INTELLECTUAL PROPERTY

Market entry begins through a CLIA laboratory model processing the Company's assays as lab developed tests (LDTs). The Company received CLIA regulatory approval of their California CLIA lab in November 2023, which enables quick scale and commercial launch of company assays.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
November 2023	Clinical accuracy demonstrated and published in peer-reviewed articles, raised $4.4M of investor capital and $1.4M of non-dilutive funding, achieved regulatory certificate of CLIA lab.

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2021	Series Pre-Seed		$1.78M
2021	Convertible Note	Pre-money valuation cap	$3.5M
2024	Series Seed Preferred		$2.6M
2024	Series Seed Preferred	Pre-money with OCA Ventures/Elevate Ventures co-leads	$6.5M
2024	Non-Dilutive Funding	NIH-NCI SBIR Phase I ($450k), NSF SBIR Phase I ($325k), 2 Research Use Only projects ($400k), other State of Indiana Grants	$1.4M

USE PROCEEDS

Amplified Sciences is seeking a $2.6M Series seed preferred for regulatory clearance, early access commercial launch, clinical utility study needed for reimbursement, and building two more assays.

KEY TEAM MEMBERS

Jo Davisson, Ph.D. (Founder and CSO): Purdue University biochemistry inventor with track record of industry collaboration and technology translation; $30M of grants earned

Diana Caldwell, M.B.A. (Co-founder and CEO): Serial life science entrepreneur, sold first startup in regulatory/clinical trials services sector, former Eli Lilly executive

Daniel Sheik, Ph.D. (Director, Research and Technology): Leads scientific team (4 Ph.D.s) and outside collaborators, PI on SBIR grant, third stint in startup

Applikate Technologies

In Vitro Diagnostic Tissue Imaging Device and Image Management Software

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COMPANY OVERVIEW

Applikate Technologies is a hardware and software company that has developed the first automated histology platform with integrated digital imaging. Applikate's direct-to-digital technology is a multi-component solution comprised of an ultrafast multiphoton microscope, one-of-a-kind lab consumables, and AI-ready data viewing software. It will establish a new standard for pathology, reducing medical errors by increasing digital data access and providing instant, globally accessible, in-depth tissue analysis, while markedly improving efficiency.

MARKET AND COMMERCIALIZATION STRATEGY

A limited number of units are actively being offered for non-clinical applications including academic and commercial research histology laboratories, veterinary clinics, contract research organizations, biorepositories, and autopsy laboratories.

New microscope and associated software platform systems designed for FDA-directed clinical trials are expected in Q2 2025. As they undergo clinical testing, they will be made available to non-clinical clients.

Clinical offerings are anticipated to begin in 2026. Initial targets are prostate and breast core needle biopsies, with general tissue applications to follow.

TECHNICAL AND COMPETITIVE ADVANTAGE

Applikate's patented technology stains and images whole samples without the need for physical slicing. The platform automates the pathology workflow, cuts processing time, lowers labor and materials costs, improves image quality, augments data extractable from each specimen, and reduces the risk of misdiagnosis by enabling routine data sharing with experts and image analysis tools.

REGULATORY STRATEGY AND INTELLECTUAL PROPERTY

The regulatory path overview is:

- Register reagents and holder consumables with FDA – both 510(k) exempt
- Initial FDA submission in 2025 for educational and research data collection (e.g. AI development) purposes in clinical specimens. This enables routine clinical sample use with no clinical impact, so as to gather data and gain confidence, even before a more detailed study on diagnostic equivalency.
- Clinical Data collection Q3/4 2025

- Follow-on FDA De Novo 510(k) submission in 2026 for equivalency in primary clinical diagnosis of prostate and breast
- Seek superiority claim in primary clinical diagnosis
- Expand tissue indications

KEY MILESTONES

DATE/YEAR	DESCRIPTION
2014	First NIH Grant awarded
2014	Initial viewer software version
2015	Proprietary tissue processing protocol developed
2016	Human renal tissue demonstration published
2017	First proprietary fast imaging multiphoton system tested
2018	First proprietary CHiMP tissue processor system built
2019	Breast, liver, kidney sample testing presentations
2020	First key patents granted
2020	Prostate cancer biopsy study published
2021	Elected to Super Session at CDL incubator
2022	Clinical validation in Kidney Biopsies begun
2023	MVP completed
2024	Non-clinical commercial offering begun

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2014-2018	NIH Grants	SBIR Grants for technology development and testing	$3.4M
2021	Seed Round	After participation in Creative Destruction Lab incubator	$2.6M
2023	NIH Phase IIb	Commercialization readiness for FDA submission	$4M
2024	Bridge Round	Convertible Note	$2.9M

USE OF PROCEEDS

The Company is raising its Series A round, targeting $10–$15M from external investors, to:

- Expand pre-clinical and clinical commercialization
- Complete clinical trials for FDA approval for definitive diagnosis
- Build add-on AI development and analysis software products
- Complete development of processor product

KEY TEAM MEMBERS

Michael Levene, Ph.D. (Co-founder, COO): Pioneer in multiphoton microscopy and optical clearing who served on the Yale faculty for 10 years and holds 20 granted patents.

David Hunt, M.B.A. (Board Chairman): Serial entrepreneur, recently of Landon IP, and investor in several medical device and AI-focused companies, concurrently CEO and majority shareholder at Ensemble IP.

Richard Torres, M.D., M.S. (Co-founder, CEO): Pathologist and engineer with focus on laboratory instrumentation who served on Yale faculty for 19 years and holds patents in several disciplines.

AtlasXomics

Research Tool

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COMPANY OVERVIEW

AtlasXomics has commercialized DBiT-seq, a transformative spatial multi-omics platform that has enabled novel applications (proteomics, transcriptomics, and epigenomics) published in Cell, Science, and Nature. AtlasXomics' first-to-market (and still only) assays provide spatial data to more than 60 labs worldwide, including KOLs at MD Anderson, Mount Sinai, and the National Cancer Institute. Data quality from assays is driving reorders. Commercial sales in 2023 totaled $1.1M, 10x prior year sales. AtlasXomics is the third company based on technology developed by scientific founder Yale Professor Rong Fan; the first company went public and the second has more than 500 employees.

MARKET AND COMMERCIALIZATION STRATEGY

The spatial biology market represents a TAM of $12B-$16B. To realize the commercial potential of the DBiT-seq platform exclusively licensed from Yale, AtlasXomics is focused on developing and communicating the ease of use and affordability of its products. While introducing its products through service and scaling its business through consumable products, the Company is also seeking partnerships with large life science tools companies to democratize the platform. Data generated by the Company's assays are complementary to data produced by their traditional instruments. Comarketing will enable leveraging of their existing sales forces and enable them to offer one-stop spatial multi-omics.

TECHNICAL AND COMPETITIVE ADVANTAGE

Moore's Law and continued advances in next-generation sequencing (NGS) to deliver exponentially more data to a larger market every year: The proprietary DBiT-seq platform depends on microfluidic chips and NGS, which are expected to continue exponential gains in price-performance. With a rich pipeline of first-to-market assays, the Company expects to deliver more data per dollar each year to an expanding set of investigators. As the cost of spatial omics data decreases, it will become more accessible, driving increased demand. This pattern will follow the precedent set by the rising demand for gene sequencing data as its price declined.

REGULATORY STRATEGY AND INTELLECTUAL PROPERTY

Regulatory approval is not required for the Company's current products.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
February 2020	Organized AtlasXomics
July 2020	Opened lab in New Haven, Connecticut across street from Yale Medical School
June 2022	Launched first-to-market (and still only) spatial assay for chromatin accessibility
June 2023	Launched first-to-market (and still only) spatial assay for histone modifications
June 2024	Internal launch of FlowGel chips for service and early access customers
Sept 2024	Launch FlowGel chips for use by customers in external labs
June 2025	Launch Patho-DBiT for interrogation of whole transcriptome and regulatory RNA

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	AMOUNT
2020	Seed-1 SAFE Financing	$1M
2021	Seed-2	$3.5M
2022	Series A Preferred	$7.2M
2023	Series A Preferred	$1.5M
2024	Series A Preferred	$1.3M

USE OF PROCEEDS

AtlasXomics is seeking $4M to develop and launch new products and add staff to support customers in external labs. The Company will scale the commercial business through kit sales of consumables. Kits (blades) with easy-to-use chips, reagents, and reusable, affordable hardware (razors) allow investigators to perform the assays in their own labs.

KEY TEAM MEMBERS

Ken Wang, M.S., M.B.A. (CEO): More than 30 years of experience in the chemical and life sciences industry as a research engineer, investment banker, and entrepreneur; served on the Board of Aristech Acrylics (Mitsubishi Corporation); helped found two advanced materials companies with life science applications. As a banker, Mr. Wang worked on transactions including privatizations that resulted in proceeds of over $500 million.

Colin Ng, M.S. (VP Business Development): Previously the VP of Consumable and Process Development at IsoPlexis Corporation, where he led the development, launch, and scaling of the IsoCode suite of products, which is currently in over 100 labs across the globe.

Jeffrey Sabina, Ph.D. (Director of R&D): Vast experience leading technical teams launching NGS intruments and workflows.

Precision Epigenomics

In Vitro Diagnostic

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COMPANY OVERVIEW

Precision Epigenomics is focused on improving cancer patient diagnosis, management, and treatment by providing innovative molecular diagnostic tests. The Company's target markets include people at risk of developing cancer, individuals afflicted with cancer, doctors who take care of cancer patients, and laboratory providers involved in identifying cancer.

MARKET AND COMMERCIALIZATION STRATEGY

The Company is serving the global liquid biopsy market that is expected to reach an estimated $8.6B by 2027 with a CAGR of 14.5% from 2022 to 2027. EPISEEK, the Company's first product, is a multi-cancer early detection test that can detect more than 20 different cancer types at various stages from a peripheral blood specimen. In April of 2024, in partnership with TruDiagnostic (a clinical laboratory in Lexington, Kentucky), Precision Epigenomics entered the commercial liquid biopsy, early multi-cancer screening market as a clinical reference laboratory.

TECHNICAL AND COMPETITIVE ADVANTAGE

EPISEEK is the second commercially available, molecular, blood test for multi-cancer screening in the United States. Advantages of EPISEEK test include price, costs, turnaround time, and strong diagnostic test performance characteristics. Precision Epigenomics has DNA methylation biomarkers for almost every cancer type and robust bioinformatics/data analysis software capabilities. Finally, the Company has ongoing R&D activities with biofluids other than blood.

REGULATORY STRATEGY AND INTELLECTUAL PROPERTY

EPISEEK was introduced into the market as a laboratory developed test (LDT) before the new FDA rule became final. However, Precision Epigenomics, together with Next Step Biotech, will chart an FDA regulatory pathway for EPISEEK and other forthcoming liquid biopsy intended uses. The United States PTO issued a patent for the technology and approach in 2024.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
July 2024	Completed Series A1 fund raise
April 2024	Launched EPISEEK as a LDT in the liquid biopsy market place
April 2024	Awarded the Company's second NCI SBIR Grant to develop another molecular test
December 2023	USPTO issued United States 11,851,711 B2 to Precision Epigenomics
July 2021	Awarded NCI SBIR Phase I Grant

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2024	Dilutive Funding Series A1	Funding for infrastructure of the Company	$1.5M
2024	Non-Dilutive Funding	NCI Direct to Phase II Grant to develop a liquid biopsy test in the diagnostic space	$2M
2024	Non-Dilutive Funding	Flinn Foundation Bioscience Entrepreneurship Program	$30K
2023	Non-Dilutive Funding	Seed funds to develop a melanoma diagnostic test	$8K
2022	Non-Dilutive Funding	NCI Phase I SBIR Grant	$397K
2022	Non-Dilutive Funding	NCI R21	$412K
2020	Non-Dilutive Funding	Sponsorship into the University of Arizona Center for Innovation Incubator	$30K

USE OF PROCEEDS

Precision Epigenomics is planning a Series A2 round to:

1. Recruit scientific, clinical, and business personnel to the Company
2. Develop product marketing and sales for EPISEEK screening test and other intended uses
3. Establish an insurance payor approval strategy for the liquid biopsy tests
4. Seek FDA regulatory approval
5. Continue research & development efforts for new liquid biopsy applications

KEY TEAM MEMBERS

Richard Bernert, M.D. (Vice President & COO): Certified in dermatopathology, anatomic, and clinical pathology; significant diagnostic business management experience.

Matthew Miller, C.P.A. (CFO): An Arizona certified public accountant with more than 35 years of healthcare experience.

Joshua Routh, M.D. (Laboratory Medical Director): Board certified in molecular pathology, anatomic, and clinical pathology; diagnostics and commercial product development expertise.

Stem Pharm

Drug Development Tool

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COMPANY OVERVIEW

Stem Pharm is a neurological drug discovery company developing small molecule drugs using a human-first approach. The Company's proprietary platform is based on human 3D neural organoids that feature microglia and model neuroinflammation. Stem Pharm uses the platform to discover and validate targets and therapeutics for their internal programs in glioblastoma, Alzheimer's disease, and epilepsy, and for the Company's biopharma partners' programs. The Company has used $5.8M in grant funding, residency in Illumina and Merck Accelerators, and projects with multiple pharmaceutical companies to develop and validate the platform. Stem Pharm is raising $2M to develop disease models with validated therapeutic targets for their internal programs.

MARKET AND COMMERCIALIZATION STRATEGY

Stem Pharm is developing a therapeutic pipeline through internal developments and external pharma collaborations focused on neuroinflammation. Small molecule drug candidates discovered by Stem Pharm utilizing the Company's neural organoid models and developed through Stem Pharm's pre-clinical development efforts will be out-licensed for clinical development and commercialization. Stem Pharm will also offer access to their drug discovery platform through partnership-based projects for disease modeling, target discovery and validation, and phenotypic screening during hit and lead compound stages. The Company recently announced research collaboration with Verge Genomics on Parkinson's disease.

TECHNICAL AND COMPETITIVE ADVANTAGE

Stem Pharm's drug discovery platform is based on human stem cell-derived 3D neuro-immune organoids that uniquely incorporate microglia, the brain's resident immune cells. These organoids reflect the complexity of cell types and important cell-to-cell interactions in the developing brain. This is the most comprehensive neural organoid developed for drug discovery and is particularly suited to model neuroinflammation. The platform is complemented with a rich toolbox of validated assays to assess the response of the organoids to candidate drugs. No other system offers the reproducibility, complexity, biologically relevant microglia, or breadth of readouts.

REGULATORY STRATEGY AND INTELLECTUAL PROPERTY

Stem Pharm's regulatory strategy is based on pursuing the United States regulatory pathway for small molecule development (IND, NDA) through FDA CDER. The Company will seek Accelerated, Breakthrough, and Fast Track status as appropriate during Phase I clinical studies, and will request Priority Review upon

FDA submission. Stem Pharm has a strong base of IP protection, including foundational IP (patents issued and pending) licensed from Wisconsin Alumni Research Foundation with additional patent filings from internal Stem Pharm developments. The IP portfolio covers four international patent families and is actively expanding with new innovations.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
December 2024	Glioblastoma Program: Establish organoid disease model POC (Phase I SBIR)
April 2025	Glioblastoma Program: Submit Phase II SBIR application
December 2025	Glioblastoma Program: Validate organoid disease model
March 2026	Glioblastoma Program: Complete first drug screen
December 2024	Alzheimer's Disease Program: Establish organoid disease model POC (Phase I SBIR)
January 2025	Alzheimer's Disease Program: Submit Phase II SBIR application
June 2025	Alzheimer's Disease Program: Validate organoid disease model
September 2025	Alzheimer's Disease Program: Complete first drug screen
June 2026	Alzheimer's Disease Program: ID lead candidates for optimization
September 2024	Epilepsy Program: Re-submit Phase I SBIR application (as required)
January 2026	Epilepsy Program: Validate organoid disease model
March 2025	Commercial: Close Seed Round
September 2026	Commercial: Close Series A Round

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	DESCRIPTION	AMOUNT
2015	Founders	Initial investment by Founders	$67K
2015–2017	Angel-Equity	Angel investments (multiple rounds)	$645K
2020, 2021	Venture/Angel-Convertible Note	Venture and Angel investments via convertible notes	$550K
2022, 2023, 2024	Venture/Angel-SAFE Notes	Venture and Angel investments via SAFE notes	$610K

USE OF PROCEEDS

Stem Pharm is raising a $2M seed round to progress their pipeline programs, specifically to validate the glioblastoma, Alzheimer's, and epilepsy organoid disease models and screening assays, establish proof-of-concept target engagement by performing focused screening of compounds with known anti-inflammatory activity, and hiring an experienced neuroscience drug hunter (VP/Director-level).

KEY TEAM MEMBERS

Steve Visuri, Ph.D. (CEO): 25 years of experience in developing therapeutics and medical devices, launched multiple startups and instrumental to two successful exits.

Connie Lebakken, Ph.D. (COO and Co-founder): Expert in cell-based assay development, extensive experience at world-class life science companies with senior roles in manufacturing, operations, and R&D.

Ryan Gordon, Ph.D. (CBO): 25 years of pharmaceutical industry experience, developed three FDA-approved drugs, commercialized first 3D neural organoids, 30+ business deals including a drug discovery joint venture.

Alara Imaging

Alara Imaging

Software Bioinformatics: QA/Treatment Planning Tool

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COMPANY OVERVIEW

Alara was founded to usher in a new wave of medical imaging advancements that improve patient outcomes. Alara's flagship product, the Alara Medical Imaging Gateway, redefines the informatics experience for health systems and technology companies so that they can more securely and transparently work together. Alara serves as measure steward and provides the software for use in new radiology measures within Centers for Medicare and Medicaid (CMS) quality payment programs. Alara's collaborations with NVIDIA and AWS, among other partners, provide a performant pathway to modern compute interfacing with radiology data at unprecedented scale.

MARKET AND COMMERCIALIZATION STRATEGY

"Alara's solution at the time of Arterys' founding would have saved the Company $8M in development expense and eight years of development time." – John Axerio-Cilies, CEO & Co-founder of Arterys. According to PitchBook, there are now more than 1,600 medical imaging companies, each with a medical imaging gateway need as a prerequisite to dataflow and customer traction. Alara's "gateway-as-a-service" collapses the expense and time associated with medical imaging gateway development by providing the first secure, performant, "grab-and-go" software that accelerates technology adoption in health systems.

TECHNICAL AND COMPETITIVE ADVANTAGE

Alara's gateway has been architected with an "internet of medical things" (IoMT) approach that transforms the deployment, cost, performance, and security of medical imaging gateways. In the same way that Tesla invented the ability to push software upgrades to a car to improve its performance, Alara's gateway is the first of its kind and can be continuously updated and improved from a remote location without health system intervention required.

REGULATORY STRATEGY AND INTELLECTUAL PROPERTY

Alara is a measure steward for new radiology-focused electronic clinical quality measures (eCQMs) in three major CMS Quality Payment Programs. These measures provide clinical and financial incentive for more than 4,000 health systems in the United States to deploy Alara's software. Once deployed, health systems are able to benefit from Alara's software for improved security, superior interoperability, expanded access to compute, and improved financial performance.

Filed in 2023, Alara has a comprehensive patent portfolio under an international PCT filing that protects the novel aspects of the Company's unique medical imaging gateway software.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
November 2022	Alara announces collaboration with Amazon Web Services to transform medical imaging by enabling cloud-native radiology solutions
November 2023	Alara announces collaboration with NVIDIA to allow for heavy compute on premise within health systems
April and November 2023	Alara announced as measure steward for three new CMS Quality Payment Programs that motivate software adoption in over 4,000 United States health systems
February 2024	Dr. Jay Bronner, former Radiology Partners (RP) President and CMO, joins Alara as Director of Health Systems
August 2024	Bayer partners with Alara Imaging to standardize CT radiation doses

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	AMOUNT
2021	Seed Round	$3.1M
2023	Follow-on Round	$4.5M
2023	SBIR National Cancer Institute	$2M

USE OF PROCEEDS

Alara is rapidly deploying its software in health systems today. Additional proceeds will further accelerate health system deployments and technology vendor connections to those health system deployments. Proceeds will primarily be used to further expand Alara's distinguished and exceptional team.

TEAM MEMBERS

Nathan Mazonson, M.B.A. (Co-founder and CEO): Former company he co-founded, Plenty, is a unicorn

Andrew Bindman, Ph.D. (Co-founder): CMO of Kaiser Permanente

Jay Bronner, Ph.D. (Director of Health Systems): Former President and CMO of Radiology Partners, the largest radiology practice in the country

Marc Kohli, Ph.D. (Co-founder): Former chair of the Society for Imaging Informatics in Medicine

Jill Spear (VP of Operations): Former medical imaging GE sales and operations executive

GRADIENT HEALTH

Gradient Health

Bioinformatics Software: Algorithms & AI

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COMPANY OVERVIEW

Gradient Health breaks barriers in healthcare by de-identifying data at a large scale to make it available for teams building healthcare AI. To date, Gradient is fully commercialized and used by 50+ companies across the world. Gradient offers a subscription to data access as a SaaS product, and the Company also does large-scale data licenses for AI development.

MARKET AND COMMERCIALIZATION STRATEGY

Gradient Health already has 50+ customers across AI, medical device, and pharma. The Company is approaching $2M in ARR, and has received an SBIR to produce datasets and software for validating medical imaging AI. Gradient's market is composed of:

1. AI companies that develop AI to subsequently sell that AI
2. Hardware medical device companies building AI to validate and customize device installation
3. Radiology equipment companies looking to bundle AI with their devices

TECHNICAL AND COMPETITIVE ADVANTAGE

Gradient Health's advantage lies in:

1. The Company's network of hospitals that provide Gradient access to data
2. Gradient's ability to de-identify data at scale

Both of these combine to create typical market dynamics where customers beget more suppliers, etc.

REGULATORY STRATEGY AND INTELLECTUAL PROPERTY

Gradient's intellectual property is in the Company's pipelines that rapidly integrate into hospital systems and allow their data to be de-identified and presented as research-ready.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
September 2021	Reached ~$150K in revenue
May 2022	Raised a $2.2M Angel round
April 2023	Reached ~$700K in revenue
July 2023	Raised a $2.75M seed round
January 2024	Released SaaS product (Atlas)
May 2024	Reached ~$1.5M ARR

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	AMOUNT
2021	Note from Techstars	$300K
2022	Raised an Angel Round	$2.2M
2023	Raised a Seed Round	$2.75M

USE OF PROCEEDS

Gradient Health is raising $8-$10M to expand to deliver data at scale to foundation model companies. The Company has validated the market need for larger datasets, and will be tripling the size of their dataset to 10x their revenue.

KEY TEAM MEMBERS

Joshua Miller (CEO and Cofounder): Previously exited CEO with a 20x return at FarmShots

Ouwen Huang (CTO and Cofounder): Previously exited CTO from FarmShots

Rodrigo Greco (CRO and Cofounder): Previously CEO in Radiology

mPATH

Digital Health Educational Tool

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COMPANY OVERVIEW

mPATH is a B2B SaaS company that increases the uptake of life-saving preventive health services for healthcare organizations, insurers, and employers. mPATH was developed and founded by two academic physicians and board-certified clinical informaticists who wondered why major industries like travel and banking empowered people to manage their needs with technology, while healthcare did not. This inspired the creation of mPATH, a digital health program that combines automation with behavioral science to identify individuals overdue for routine health screenings, educate them about their options, and overcome barriers to care.

MARKET AND COMMERCIALIZATION STRATEGY

The Company sells mPATH to healthcare systems, federally-qualified health systems, and accountable care organizations (ACOs) under a Software as a Service subscription. Healthcare organizations are highly motivated to increase cancer screening rates because: 1) it increases revenue from completed tests and downstream care, and 2) it increases revenue from "quality bonus payments" that are tied to screening rates (in 2022, Medicare Quality Bonus Payments surpassed $10B). mPATH reaches customers with a direct sales force, marketing at national conferences, publication of research findings, and email campaigns.

TECHNICAL AND COMPETITIVE ADVANTAGE

mPATH's competitive advantage comes from the Company's intellectual property derived from more than 10 years of rigorous study and the Company's expertise incorporating behavioral science principles in digital health to encourage healthy behaviors. mPATH has more than 12 peer-reviewed publications in the nation's top medical journals documenting the effectiveness of mPATH. The Company has a patent pending for their process. As mPATH's database of users grows, the Company's AI algorithms for tailoring outreach and messaging will provide an additional competitive moat.

REGULATORY STRATEGY AND INTELLECTUAL PROPERTY

The mPATH digital health platform is HIPAA-compliant and SOC-2 certified. The Company falls short of meeting the criteria of Software as a Medical Device (SaMD), so they do not require FDA approval. As the platform grows, mPATH may pursue SaMD to increase their competitive advantage. The Company has registered trademarks for mPATH and a utility patent pending.

KEY MILESTONES

DATE/YEAR	DESCRIPTION
June 2022	Acquired exclusive worldwide license for mPATH from Wake Forest University
October 2022	Transferred technical stack from Wake Forest University to company cloud architecture
April 2023	Received STTR Phase I award
June 2023	Went live with first commercial customer
March 2024	Went live with second commercial customer
May 2024	Accepted into Flywheel/Atrium Health's Health Equity Innovation Challenge as the highest scoring company
June 2024	Received Letter of Intent from one of the five largest non-profit health systems in the United States to contract for mPATH
June 2024	Notified of approval to proceed to Phase II of STTR award

CAPITALIZATION HISTORY

YEAR	FUNDING TYPE	AMOUNT
2023	NCI Phase I STTR Grant	$397K
2023	OneNC Small Business Program Matching Award	$75K
2024	Convertible Note	$706K

USE OF PROCEEDS

mPATH is raising $1M to accelerate growth. Funds will be used to expand the technical team, allowing mPATH to develop additional modules for other preventive health needs more quickly. The Company will also expand their sales and customer success teams.

KEY TEAM MEMBERS

Dave Miller, M.D. (CEO): Nationally recognized cancer control researcher and digital health innovator with over $10M in NIH funding. mPATH inventor.

Ajay Dharod, M.D. (CTO): Computer & electrical engineering degree, experience in USPTO, and nationally recognized leader in clinical informatics. mPATH co-inventor.

Peter Kramer (Director of Operations):

Former Co-founder and COO of Abaqis (digital health software) that was acquired by Healthstream.

NATIONAL CANCER INSTITUTE | SBIR DEVELOPMENT CENTER

INVESTOR | INITIATIVES