UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): October 26, 2020

KIROMIC BIOPHARMA, INC.

(Exact name of registrant as specified in its charter)

Delaware	001-39619	46-4762913		
(State or other jurisdiction of incorporation)	(Commission File Number			
	7707 Fannin, Suite Houston, TX, 770 (Address of principal executive o	054		
Reg	istrant's telephone number, including	g area code (832) 968-4888		
Check the appropriate box below if the Form 8-K provisions (see General Instruction A.2. below):	filing is intended to simultaneously	satisfy the filing obligation of the registrant under any of the following	wing	
☐ Written communications pursuant to Rule 425 und	er the Securities Act (17 CFR 230.42	25)		
☐ Soliciting material pursuant to Rule 14a-12 under	the Exchange Act (17 CFR 240.14a-1	12)		
☐ Pre-commencement communications pursuant to F	Rule 14d-2(b) under the Exchange Ac	ct (17 CFR 240.14d-2(b))		
☐ Pre-commencement communications pursuant to F	Rule 13e-4(c) under the Exchange Act	et (17 CFR 240.13e-4(c))		
Securities registered pursuant to Section 12(b) of	the Act:			
Title of Each Class	Trading Symbol(s) KRBP	Name of Each Exchange on Which Registered The Nasdaq Stock Market LLC		
Common Stock, \$0.001 par value	KRBP	The Nasdaq Stock Market LLC		
Indicate by check mark whether the registrant is Rule 12b-2 of the Securities Exchange Act of 193		fined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapt	er) or	
Emerging growth company ⊠				
If an emerging growth company, indicate by che revised financial accounting standards provided p		and not to use the extended transition period for complying with any nange Act. \Box	ew or	

Item 7.01 Regulation FD Disclosure.

Kiromic BioPharma, Inc. intends to conduct meetings with third parties in which its corporate slide presentation will be presented. A copy of the presentation material is attached as Exhibit 99.1 to this Form 8-K.

The information in Item 7.01 of this Current Report on Form 8-K and Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section. This information shall not be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference therein.

Item 9.01 Financial Statements and Exhibit

(d) Exhibits.

The following exhibit is filed with this Current Report on Form 8-K:

Exhibit					
Number	Description				
<u>99.1</u>	Corporate Presentation of Kiromic BioPharma, Inc.				

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Kiromic BioPharma, Inc.

Date: October 26, 2020

By: /s/ Maurizio Chiriva Internati
Maurizio Chiriva Internati
Chief Executive Officer



Disclaimer



This presentation is provided by Kiromic BioPharma, Inc. (the "Company") for the express purpose of giving prospective investors, bankers, employees, consultants, and corporate affiliations information regarding the Company to assist the recipient in evaluating a potential formal association with the Company. While the information contained herein or in any other materials that may be provided by the Company is believed to be true, accurate and reasonable, the Company makes no such representation or warranty, express or implied, as to the veracity, accuracy, reasonableness or completeness of such information. The Company expressly disclaims any and all liability which may be based on such information, any errors therein or omissions

therefrom. This presentation does not imply an offering of Securities. This presentation may contain forward-looking statements within the meaning of applicable securities regulations. All statements other than statements of historical facts are forward-looking statements. In some cases, forward-looking statements may be identified by the use of words such as "anticipate," "believe," "plan," "estimate," "expect," "intend," "may," "will," "would," "could," "should," "might," "potential," or "continue" and variations or similar expressions. Readers should not unduly rely on these forward-looking statements, which are not a guarantee of future performance. There can be no assurance that forward-looking statements will prove to be accurate, as all such forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause actual results or future events to differ materially from the forward-looking statements. Such risks include, but may not be limited to: general economic and business conditions; technology changes; competition; changes in strategy or development plans; governmental regulations and the ability or failure to comply with governmental regulations; the timing of anticipated results; and other factors referenced in the Company's business materials and prospectuses.

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KIROMIC

CEO Director Maurizio Chiriva-Internati, PhD

Mr. Chiriva-Internati is an associate professor at MD Anderson Cancer Center. He has spent the past 28 years studying cancer targets and is the founder of Kiromic Artificial Intelligence Neural Network. He has published +160 articles (+peer reviews) on cancer targeting and on the use of Al to expedite the search for these targets. He holds PhD in immunology (U of Nottingham), PhD in morphological science (Milan), and a Certificate in Artificial Intelligence - M.I.T.

CFO Tony Tontat

COO Director Mr. Tontat brings to Kiromic over 2 decades of business experience from public (NASDAQ: SRNE, NK) and privately held biotechs. He had been healthcare analysts at specialist healthcare investment funds in New York, and Connecticut. He was also an investment banker at HSBC Securities in their New York, London, and Paris offices. Bachelor of Arts in Economics - Harvard University.

CSIO

Director

Gianluca Rotino Chief Strategy, Innovation Officer Mr. Rotino held CEO and Chairman roles in several Italian companies specializing in high-tech, and corporate consulting. He also worked at law firms in Milan where he specialized in M&A, intellectual property prosecution and corporate law. He holds a business development degree and bachelor of science (electronics) - EBD Academy in London, and completed the drug discovery, develop. and commercialization - U.C. San Diego.

CMO Scott Dalhbeck, MD, PharmD

Dr. Dalhbeck was a radiation oncologist and was an adjunct professor of internal medicine, pathology, and urology at Texas Tech. He has also patented, manufactured, and commercialized IP and has more than a decade of experience in medical and oncology commerce. He holds an MD - Texas Health Science Center, and a PharmD - U of Nebraska. His residency was at Kaiser Permanente of Los Angeles.

NASDAQ: KRBP

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We are connecting the dots in cancer research by using AI and machine learning to connect silos of informations and arrive at cancer targets which will be more effective vs. classic development, saving man-years and billions in development dollars.



Non-Viral Genome edit and delivery

Our single-cut gene edits carry a lower mutagenesis risk vs. classic double-cut gene edits.

Our CAR receptors will also have higher safety with an on-demand cut-off switch vs. classic CAR therapies with no off-switch.

Kiromic at a Gla

Revolutionizing Next-Gen Allogenic CAR Therapy for Solid Tumors



Gamma Delta T-cell Immune Cell Type

Our CAR Therapy will be using off-the-shelf Gamma-Delta T-cells and will have a higher yield and significantly lower yield variability vs. classic CAR-T therapies.



Our CAR Therapies will be able to access the micro tumor environment due to our chPD-1 check-point activator vs. classic CAR-T therapies.

Classic CAR-T are limited to hematologic indications.

Micro Tumor Environment

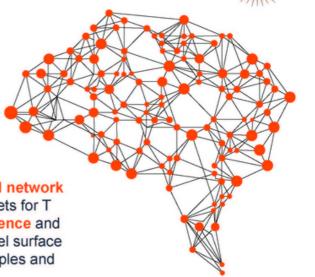
Solid Tumor



Artificial Intelligence Neural Network

for Target Selection

Diamond is a computational platform and a neural network that can identify new cancer immunological targets for T cells and B cells. Diamond is an artificial intelligence and machine learning approach that can identify novel surface tumor targets. It uses public and proprietary samples and can expand into the tumor target space.



ADVANCING CAR through A.I.







Big Data Science

meets

Target Identification



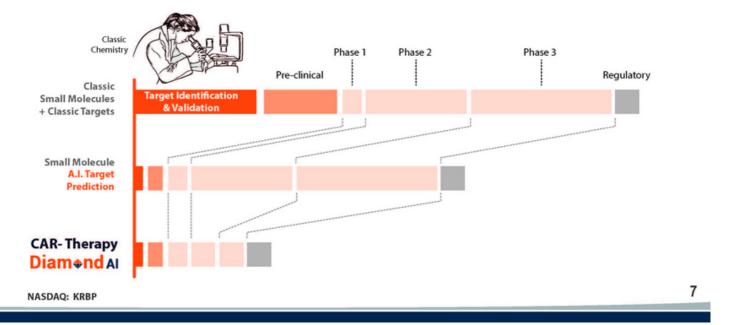
dramatically compressing

Man-Years and Billions of Drug Development Dollars

to develop a live drug

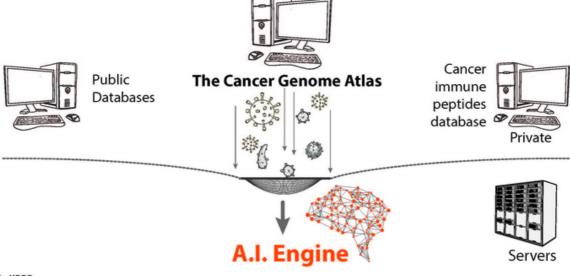
Artificial Intelligence Engine's

Compression of Time & Costs for live drug development



Step 1

Big Databases

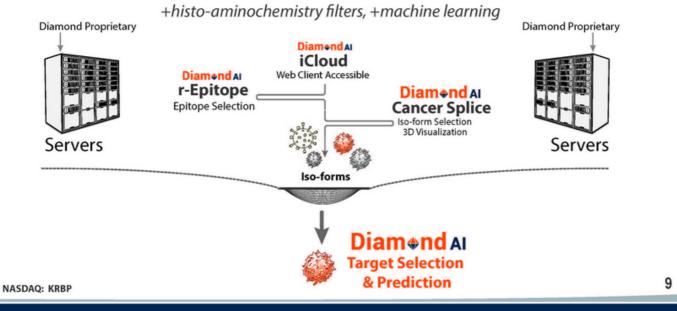


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Step 2

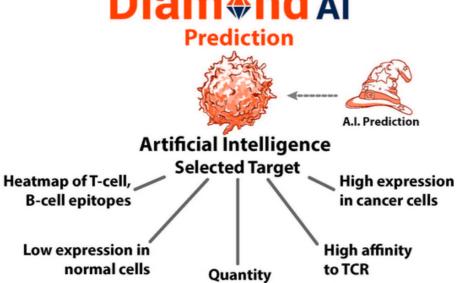


Artificial Intelligence Engine





Step 3 Diam nd AI



expression signature 10 NASDAQ: KRBP

surface antigen

Step 4



Target Validation

We rigorously validate all targets from our A.I. Prediction Engine Internal validations and then external validation





Baylor University University of Rome Humanitas Research Hospital (Milan)







Diam*nd AI Processes

non-exhaustive list of functions being applied by A.I. Engine

Prioritizing T and B Cell Targets

Diamond generates a prioritized list of cancer immunological targets for T cells and B cells.

These targets can be used to create therapies such as antibody therapies, T cell therapies, T cell receptor therapies, CAR T cell therapies and vaccine therapies.

Identify Highly Expressed Genes

Diamond's cognitive and deep learning capabilities extract information from our extensive digital library consisting of clinical studies, genomic and proteomic datasets.

Diamond harmonizes all the raw data and creates datasets which allows us to screen for cancer targets.

Diamond will identify and prioritize lists of genes (biomarkers, wild type, mutant, isoform, neoepitope, etc.) that are highly and specifically expressed in the disease of interest while providing its distribution and methylation status across the entire patient population.

It also maps out the exact portion of the gene that will elicit an immune response.

Perform Meta Analysis

Diamond performs meta-analysis and convolution studies while standardizing and normalizing data across multiple and variable experimental platforms, then allows for the visualization of consistent and accurate results in a user-friendly fashion.

Predict Isoform Targets

Cancer cells will down regulate or shed targets in order to avoid detection and destruction by T cells (the immune system).

These variations are known as isoforms.

CancerSplice also shows a box plot by tissue of expression of the isoform in normal cancer genome atlas tissues and a box plot of the matching isoform in genotype-tissue expression program normal data.

The sequence of amino acids that are specific for the selected cancer isoforms are then directly fed to Diamond's artificial neural capsule network for peptide design and prioritization.



Diam⊕nd Aı CancerSplice ™

A key A.I. Engine

Target isoforms are protein variants of the same targets that occur during the normal processing of immature gene transcripts to the mature form.

Target isoforms include variations in their primary amino acid sequence that can change both the final folded form of the target plus their ability to be recognized by modified T cells (autologous/allogeneic) and other cells, such as NK or invariant NKT cells (often used in the allogeneic setting).

If they are the predominate form on the cell surface, these isoforms can make it impossible for T cells to outright bind the targets on cancer cells.

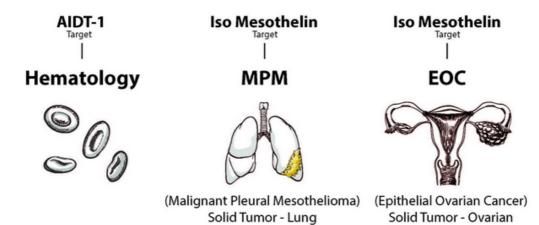
No binding or insufficient binding to the isoform results in no killing of cancer cells.

Our CancerSplice accurately predicts the most appropriate isoforms for T cells to bind and destroy cancer cells.



Targets Which We Have Identified

How our identified targets are developed into therapies for live drugs to treat cancer



Indications: By the Numbers





Ovarian Cancer

300,000

Worldwide number of patients American Cancer Society

21,750

2018 new cases in the USA American Cancer Society 2018

\$1.2 BLN in 2018 Grand View Research (July 2019)



MPM - Lung Cancer

43,000

Worldwide number of patients American Cancer Society

3,000

Annually in the USA American Cancer Society 2018

\$300 M by 2025 Persistent Market Research, Jul 2017



Hematological Cancers

200,000

Worldwide number of patients American Cancer Society

30,000

Annual Diagnosis in the USA American Cancer Society 2018

\$4.6 BLN by 2025 BIS Research, Nov 2019



Our Pipeline







	In vitro validation	Pre clinical	IND	Phase 1	Phase 2	Phase 3
Alexis (γδ-T cells) Allogenic / Iso-Mesothelin EOC (Solid, Ovarian)						
Alexis (γδ-T cells) Allogenic / Iso-Mesothelin MPM /Pleural mets (Solid, Pleural)						
Alexis (γδ-T cells) Allogenic / AIDT-1 (Hematologic Indications)						
chPD-1 check point activator (Solid Tumors)						

chPD-1 Check-Point Activation

Checkpoint inhibitors block PD-1 and PD-L1.

Our chPD-1 (chimeric PD-1) takes it one step further by converting PD-1 and PD-L1 from an inhibitory signal to an activation signal.

This pivotal CAR transformation allows our CART-cells to then kill solid tumors and TME (tumor micro environment).

Isoform Mesothelin

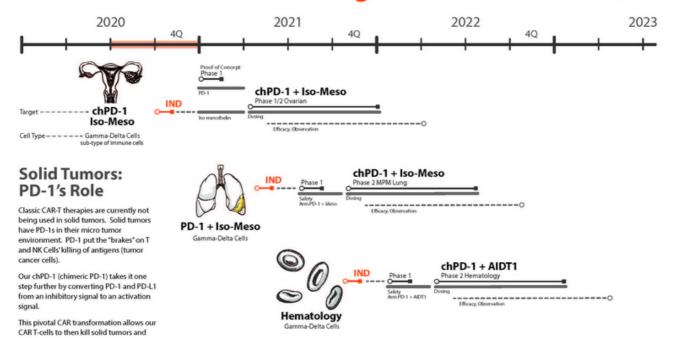
This is our lead target candidate which came out of our Artificial Intelligence Prediction Engine.

Isoform targets are highly expressed on cancer cells while very lighly expressed on normal (healthy) cells.

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Clinical Programs





TME (tumor micro environment).

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ADVANCING CAR through A.I.

Our Therapeutic Products

Allogenic CAR

Immuno CAR-GD-T Therapy

in solid tumors

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CAR = chimeric antigen receptors



Allogenic Engineered Immune Therapy

Step 01: Fractionation



Screening shows donor has healthy Gamma-Delta T cells



Whole Blood



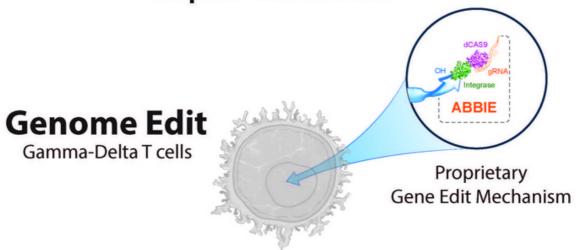
Fractionation

Gamma-Delta T cells extracted



Allogenic Engineered Immune Therapy

Step 02: Genome Edit





ABBIE Gene Editing Technology

Linear Non-viral Template



Figure 1. Our ABBIE gene-editing technology begins with the transgene template plasmid. Plasmid DNA is cut with restriction enzyme, Scal, liberating the transgene template along with the retroviral-derived long-terminal repeats (LTRs), which is purified away from the plasmid DNA and Scal protein.



Figure 2. The ABBIE integrase, derived from HIV, is added, which binds to the LTRs and exposes a reactive 3'-OH group on each end.

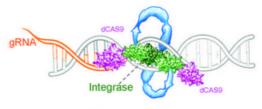


Figure 3. The guide RNA (gRNA) tethers ABBIE-bound template to the target site via DCas9, and Integrase helps to attach the exposed 3'OH groups to the target site on both strands without causing a dsDNA break.

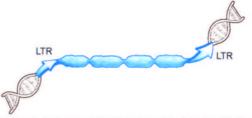
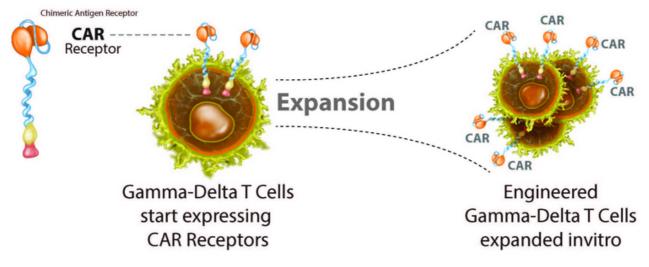


Figure 4. Following stable integration of the template into the target DNA locus, a short DNA duplication is present on each end.



Allogenic Engineered Immune Therapy

Step 03: Gamma-Delta T Cells expanded invitro

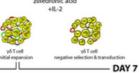


How We Know: GD-T cell Expansion Works





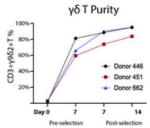






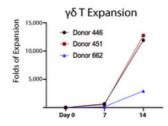


A large fold of expansion of highly pure $\gamma\delta$ T cells during in vitro stimulation, culture, isolation and expansion process.

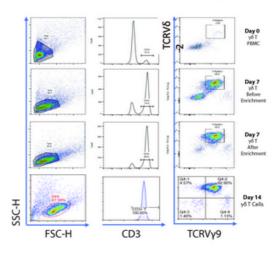


The percentage of CD3+ γ 9+ δ 2+ T cells over 14-day culture.

NASDAQ: KRBP



The expansion fold of CD3+ γ 9+ δ 2+ T cells with our method.



CONCLUSION

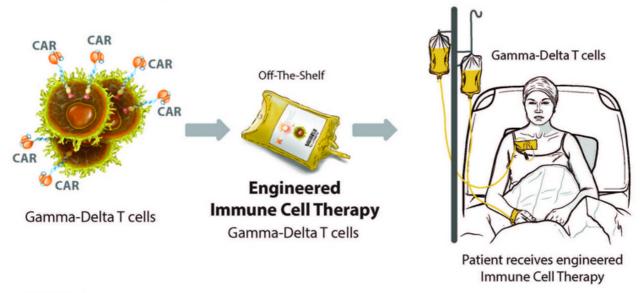
Our method of $\gamma\delta$ T expansion yield highest 12,000-fold expansion of $\gamma\delta$ T cells, which is over 95%purity for positive for CD3, Vy9, and V\delta2.

This has potential to produce enough number $\gamma\delta\,T$ for clinical use.



Allogenic Engineered Immune Therapy

Step 04: GD-T Cells infused into Patient



24

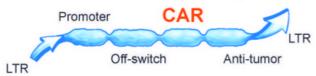


Up-Armoring

Accessory proteins can "up-armor" cellular therapies

Strategic choice of proteins to improve cellular function and neutralize anti-immune responses





- Activated signaling molecules chosen to enhance cell persistence by stimulating cytokine pathways
- * Targeting the immunosuppressive "reactive" stroma can enable tumor targeting by therapeutic cells while increasing anti-tumor efficacy







ACTIVATION Switch

A rapidly deployed activation switch can provide a survival and proliferation signal to the therapeutic cells to enhance their efficacy and persistence in vivo.



ATTENUATION Switch

A rapidly deployed attenuation switch can intercept activation signals transiently to minimize toxicity following successful anti-tumor interactions. Choice of two non-mutually exclusive Attenuation Switch approaches:

- (a) a protein-based switch that rapidly triggers attenuation of target cells in a dose-dependent fashion.
- a small molecule-based approach to rapidly and reversibly attenuate cell signaling.



SAFETY Switch

A rapidly deployed, protein-based safety switch can eliminate therapeutic cells in case of acute toxicity. The safety switch is designed to eliminate either:

- (a) essentially all active therapeutic cells.
- (b) only the most active cells, preserving a cohort of backup therapeutic cells for long-term control of residual relapsing tumor cells.

The Safety Switch will be co-expressed along with the bioactive chimeric activation receptor (CAR), the Activation Switch, and the Attenuation Switch.

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Our single-colourer mutage double-cut se

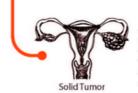
Value Drivers

Revolutionizing Next-Gen Allogenic CAR Therapy for Solid Tumors

Our CAR Therapy will be using off-the-shelf Gamma-Delta T-cells and will have a higher yield and significantly lower yield variability vs. classic CAR-T therapies.



Gamma Delta T-cell Immune Cell Type



Micro Tumor Environment

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Our CARTherapies will be able to access the micro tumor environment due to our chPD-1 check-point activator vs. classic CAR-T therapies.

Classic CAR-T are limited to hematologic indications.

Comparables

A.I. Targets + Small Molecules

SCHRÖDINGER

\$4.18 BLN

IPO Feb 2020

\$4.20 BLN

Public

DIAMOND THERAPEUTICS

\$1.14 BLN

IPO Jan 2020

NEKT

\$3.10 BLN



\$1.04 BLN

IPO Mar 2018

Kite Pharma

CAR-T and CAR-NK

\$11.9 BLN

Acquired



\$110.7 M IPO Jun 2020



\$9.0 BLN Acquired

28

NASDAQ: KRBP Market data as of 10/23/2020, Yahoo Finance closing





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ttontat@kiromic.com

Intellectual Property





Pending

PCT/US2016/025426: CAS 9 Retroviral Integrase and CAS 9 Recombinase Systems for Targeted Incorporation of a DNA Sequence into a Genome of a Cell or Organism

Switch Technology Pending

Provisional Patent Application No.: 63/039,364 -Tri Switch Technology for Multi-Dimensional Control of Cell Therapy



Granted

9149441: Nanospheres Encapsulating Bioactive Material and Method for Formulation of Nanospheres

Pending

15/731,143: Platform for Identification of Tumor-Associated Cancer/Testis Antigens

PCT/US20/35183: Methods for Identifying and Using Diseases-Associated Antigens

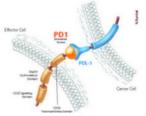
15/530,964: Anti-Human/Mouse Sperm Protein 17 (SP17) Antibody and Derivatives Thereo

PCT/US2017/022168: Compositions and Methods for Treating Cancers

15/932,396: CdS Quantum Dot-Chitosan-Anti-SP17 Nanohybrid as a Potential Cancer Biomarker

PCT/US2015/061703: Novel Nanoparticle—Based Vaccine Targeting Cancer/Testis Antigens (CTA) and its' Use in Solid and Hematological Malignancies

10004790: Nanospheres Encapsulating Bioactive Material and Method for Formulation of Nanospheres



Pending

PCT/US2018/052799: PD1-Specific Chimeric Antigen Receptor as an Immunotherapy

Gamma-Delta T-cells Pending

63/048,488. Mesothelin Isoform Binding Molecules and Uses Thereof

NASDAQ: KRBP





Tony Tontat Maurizio Chiriva-Internati, PhD Gianluca Rotino

Independent (Board Nominee)

Jerry Schneider, JD, MBA

Mr. Schneider has been nominated to serve on our Board of Directors.

He currently serves on the board of directors and audit committee for Cognex, a provider of vision systems, software, sensors, and industrial barcode readers used in manufacturing automation since 2016. Cognex (CGNX) is publicly traded on the Nasdaq stock exchange. He serves on other for-profit and non-profit boards. Mr. Schneider received his Juris Doctor from Loyola Law School, and a B.S. in Accounting from the University of California at Berkeley. He has experience of being a "financial expert" appointed by the U.C. Regents whilch oversee the University of California's budget of over \$30M.

Independent (Board Nominee) Michael Nagel

Mr. Nagel has been nominated to serve or our Board of Directors.

Mr. Nagel has over 30 years of sales and marketing experience in the medical device industry. Since 2012, Mr. Nagel has served as the President and CEO of Vomaria's Innovations, Inc, which specializes in wireless microcurrent-generating technologies that are focused on regeneration, healing, and recovery. Previously, Mr. Nagel served as the Chief Commercial Officer of Neomend, a biomaterial company that developed ProSei, a PMA approved surgical sealant for lung surgery. From 1997 to 2005, Mr. Nagel also served as Ce-Founder and Vice President of Worldwide Sales and Marketing at Vascular Solutions (WASC).

In addition to Mr. Nagel's executive experience, he also serves as a director for Franklin Mountain Medical, LLC an early stage company in the structural heart marker. Mr. Nagel holds both a B.A. in Business and a M.B.A. from the University of St. Thomas.

Independent

Americo Cicchetti, PhD

Dr. Cicchetti has served as a member of our board of directors since March 2020. Dr. Cicchetti has served as a Professor of Management at Universit's Cattolica del Sacro Cuore, Faculty of Economics, Rome since 2006. He is also currently the Director of the Graduate School of Health Economics and Management at Universit's Cattolica del Sacro Cuore. In addition to his cademic experience, Dr. Cicchetti was a member of the Price and Reimbursement Committee of the Italian National Drug Agency from 2009-2015. He is a member of the European Network of Health Technology Assessment, Member of the Innovation Steering Group of the National HTA Program for Medical Devices (Ministry of Health, Italy): Member of the National Immunization Technical Advisory Group at the Ministry of Health, Italy since 2019; Member of the Health and Research Commission of the Rome Foundation since 2007; and a Member of the Board of Directors of the Health and Research Foundation since 2017.

Furthermore, Dr. Cicchetti is the Chief Executive Officer and Director for Molipharma, whose core business is the research and development of new drugs and disignostics aimed at predicting, detecting and treating female oncological diseases. He also serves as an independent board member for Foundation Health and Research, and Leonida SICAF, a fixed capital investment company. He obtained his PhD in Management from University of Bologna, and his B.A. from University of Rome.

Independent

Pietro Bersani, CPA

Mr. Bersani has served as a member of our board of directors since June 2020. Since April 2020, Mr. Bersani is a Partner with 828 CFO Partners, LLC, which provides strategic management advisory services to owners of privately held companies. During October 2016 and July 2018, he served as the President, and Chief Executive Officer at K.P. Diamond Eagle, Inc., a consulting firm specialized in development of innovative commercial and private avisation business models. He also held the same positions at K.P. Diamond Eagle, Inc. between November 2019 and March 2020. He later served as a Senior Director within Alvarez & Massal's Private Equity Performance Improvement Practice, LLP between August 2018 and October 2019. Prior to those professional experiences, Mr. Bersani served as a the Chief Financial Officer of Fuel Systems Solutions, Inc. between April 2011 and October 2016.

Mr. Bersani is a Certified Public Accountant and is also a Certified Public Auditor and a Chartered Certified Accountant in Italy where he developed a significant knowledge of US GAAP and IFRS. Mr. Bersani earned a BA and MA in Business Economics from L. Bocconi University, Italy. Mr. Bersani was designated by certain holders of our Series B Preferred Stock. Except for the foregoing, there is no arrangement or understanding between any director or executive officer and any other person pursuant to which he was or is to be selected as a director.



Artificial Intelligence Neural Network

162 Internal Publications



Chiriva-Internati M, Cobos E, Cannon MJ. Editorial: Prospects and Challenges for Immunotherapy of Ovarian Cancer-What Can We Learn from the Tumor Microenvironment? International Reviews of Immunology. 2011;30(2-3):67-70.



Cannon MJ, Goyne H, Stone PJB, Chiriva-Internati M. Dendritic cell vaccination against ovarian cancer - tipping the Treg/T(H)17 balance to therapeutic advantage? Expert Opinion on Biological Therapy. 2011;11(4):441-445.



Wachtel MS, Zhang Y, Xu T, Chiriva-Internati M, Frezza EE. Combined hepatocellular cholangiocarcinomas; analysis of a large database. Clin Med Pathol.1:43-7, 2008

Mirandola L, J Cannon M, Cobos E, Bernardini G, Jenkins MR, Kast WM,

Chiriva-Internati M. Cancer testis antigens: novel biomarkers and targeta-

ble proteins for ovarian cancer. Int Rev Immunol. Apr.-Jun;30(2-3):127-37.



Bumm K, Zheng M, Bailey C, Zhan F, Chirriva-Internati M, Eddlemon P, Terry J, Barlogie B, Shaughnessy JD Jr. CGO: utilizing and integrating gene expression microarray data in clinical research and data management. Bioinformatics. 2002 Feb;18(2):327-8.2002 Maurizio Chiriva-Internati, Leonardo Mirandola, Franco Marincola, Gianluca Rotino, Jose A. Figueroa, Fabio Grizzi, and Robert Bresalier The Quest for the Next-Generation of Tumor Targets: Discovery and Prioritization in the Genomics Era. Springer, Published 2019.{ chapter for a book "immune-Oncology: Cellular and Translational Approaches" 2019

Maurizio Chiriva-Internati & Adrian Bot. New Era in Cancer Immunotherapy: Discovering Novel Targets and Reprogramming the Immune System. International Reviews of Immunology, 34:2, 101-103, 2015

Grizzi F, Gaetani P, Tancioni F, Di Ieva A, Bollati A, Baena R, Dioguardi N, and Chiriva-Internati M. From Discovery to the Clinical Application In Nervo System Neoplasia. In: Tumor Associated Antigens, 2004.

Figueroa AJ, Pena C, Mirandola L, Reidy A, Payne D, Hosiriluck N, Suvorava N, Rahman LR, Whitlow AR, Verma R, Cobos E and Chiriva-Internati M. "Therapeutic Monoclonal Antibodies and Their Targets" by Wiley Production_Biosimilars of Monoclonal Antibodies: A Practical Guide to Manufacturing, Preclinical and Clinical Development, First Edition. Edited by Cheng Liu and K. John Morrow Jr. © 2017 John Wiley & Sons, Inc. Published 2017.

Grizzi F, Russo C, Portinaro N, Hermonat PL, Chirriva-Internati M. Complexity and cancer. Gastro-enterology. 2004 Feb;126(2):630-1; author reply 631-2. PubMed PMID: 14765401.2004

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ABBIE: Non-Viral Genome Editing Mechanism

ABBIE is a novel gene-editing system for inserting therapeutic genes safely into the genome of a host cell.

ABBIE technology comprises two main components,

- (i) a genome template (extracted from the ALEXIS plasmid), containing the therapeutic genes needed to retrain tumor-killing cells, and
- (ii) the gene-editing machinery required to safely insert this template into the genome of the therapeutic cells.

The ABBIE protein accompanies the CAR-containing genome template as it passes through the cell membrane into the nucleus and guides the template-flanking sequences (the "glue") safely into the target genome.

Due to this targeting ability, ABBIE can also be used to remove unwanted, inhibitory genes. CAR expression on the Gamma-Delta T cells allows them to detect and destroy the antigen-expressing targeted cells.

The OFF switch permits fast shutdown in the event of an unexpected toxicity. Additional Anti-tumor factors can help neutralize the toxic tumor microenvironment.