October 4, 2023

REGEN BIOPHARMA, INC.

(OTC – RGBP, RGBPP)

Industry: BioPharma

Price Target: $5.00

REGEN BIOPHARMA, INC.

Underfollowed, Undervalued Autoimmune and Cancer Therapy Player

Rob Goldman
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COMPANY SNAPSHOT

Publicly-traded Regen BioPharma, Inc. is focused on the immunology, oncology and immunotherapy spaces. The Company's approach is to rapidly advance novel, autologous cell therapies through pre-clinical and Phase I and Phase II clinical trials. Regen is also focused on small molecule therapies for treating cancer and autoimmune disorders.

KEY STATISTICS

Price as of 10/3/23	$1.80
52 Week High – Low	$10.95 - $1.03
Est. Shares Outstanding	3.5M
Market Capitalization	$6.3M
Average Volume	6,553
Exchange	OTCPK

COMPANY INFORMATION

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La Mesa CA 91942

Web: www.RegenBiopharmaInc.com
Email: david.koos@regenbiopharma.com
Phone : 619.722.5505

INVESTMENT HIGHLIGHTS

Regen BioPharma may be an underfollowed and undervalued preclinical player today, but major steps on the R&D front could serve as a near-term catalyst for its stock. A recent set of experiments unearthed surprising results which could lead to a series of key milestone events.

The Company has a deep IP portfolio centered around a key validated target and a diverse preclinical product pipeline, with a focus on immune-oncology and autoimmune diseases. Regen's next-gen technology platforms have led to multiple IND submissions and an IND approval.

The Company's most recent study, led by a highly regarded CRO, provided strong results that have prompted a potential new major opportunity. Regen has evolved from primarily a cancer therapy product approach to a firm that now features autoimmune therapy development as well.

Upcoming milestones include new CRO confirmatory study results, animal studies, and an IND submission. The IND submission could lead to a Phase I clinical (human) trial in 18+ months.

Our 6-12-month price target is $5.00. This target represents a $17.5 million market cap, which we believe is fair and typical for a preclinical firm with deep IP, next-gen tech, multiple target therapy markets, and one with a potential product on a clinical trial path.

COMPANY OVERVIEW

The View from 30,000 Feet

Tracing its roots to 2012, **Regen BioPharma, Inc. (OTCPK: RGBP, RGBPP)** is a publicly traded biotechnology company focused on developing innovative treatments using autologous cell therapies, RNA and DNA-based immunotherapy and small molecules in the immune-oncology and autoimmune disease spaces. Leveraging an impressive array of IP, the Company plans to rapidly advance novel technologies through pre-clinical and Phase I/ II clinical trials. At present, Regen is advancing cellular therapies, including CAR-T cells, for treating cancer and autoimmune disorders by modulating the immune checkpoint NR2F6. The Company also has additional potential products in its pipeline, including a product with an FDA-cleared IND (Investigational New Drug) application.

Recent Tests Results a Potential Gamechanger

The first phase of in vitro experiments seeking to validate its DuraCAR CAR-T cell therapeutics successfully synthesized and expressed in transfected cells the chimeric antigen receptor (CAR) construct targeting CD19 and NR2F6. However, a second set of experiments yielded unexpected results whereby siRNAs designed to suppress NR2F6 mRNA expression yielded the opposite result. The Company has engaged a contract research organization (CRO) that is independent of the CRO which performed the second set of experiments to determine if these surprising findings are reproducible in a confirmatory study. If confirmed, these results could lead to the development of a therapy whereby T-Cells that suppress autoimmunity can be created---a potentially major development. If the results are confirmed, RGBP is poised to initiate a Phase I clinical trial.

The autoimmune therapeutic segment is massive and impacts millions of sufferers around the world. According to Future Market Insights, this segment is projected to grow from an estimated $71.5 billion in 2023 to $123.5 billion in 2033. Autoimmune disorders (ADs) are a family of more than 100 chronic, and often disabling, illnesses broadly characterized by immune system dysfunction leading to the loss of tolerance to self-antigens, presence of increased level of auto-antibodies, inflammatory and mediatory cells and resulting chronic inflammation. ADs affect up to 9% of the population and are of considerable personal and public health burdens.

Valuation

In our view, RGBP's shares are undervalued relative to its diverse product development, deep patent portfolio (9 granted) and a product with a cleared IND. Moreover, with potential confirmatory autoimmune study data on the near-term horizon, we believe that RGBP's market value could enjoy exponential gains in the next 6-12 months. Our $5.00 price target reflects a roughly $17.5 million market cap, four times the stock's recent price. Based on our historical coverage of biopharma companies, this figure represents a fair and typical valuation for a Company in RGBP's development stage, which includes multiple, large therapy markets and a core product with a clinical trial path.

AUTOIMMUNE: A PRIMER

Definition, Types

Although investors may be familiar with the term autoimmune diseases or disorders, many are unfamiliar with how pervasive these diseases have taken over our society. This arena may not carry the type of mortality rates as cancer; however, the chronic, debilitating nature of autoimmune diseases dramatically impact sufferers and families, as many have no cure.

An autoimmune disease is the result of the immune system attacking one's body instead of protecting it. Autoimmune diseases can affect many types of tissues and nearly any organ in the body. They may cause a variety of symptoms including pain, fatigue, rashes, nausea, headaches, dizziness and more. Specific symptoms depend on the exact disease.

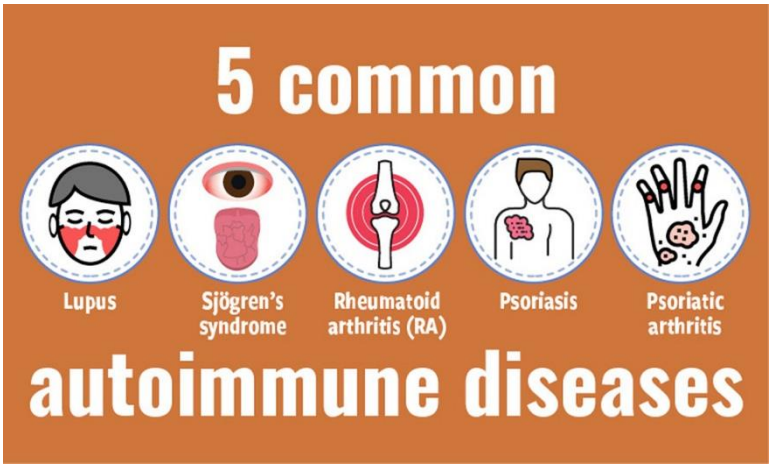
There are over 100 known autoimmune diseases and common ones include lupus, rheumatoid arthritis, Crohn's disease and ulcerative colitis. Many autoimmune diseases are more common in women than in men. It is estimated that 78% of all autoimmune sufferers are women. The diseases are common — 1 in 12 people in the U.S. (25 million people) have an autoimmune disease, according to the National Institutes of Health. One million people in the U.S. have lupus and 1.4 million have Crohn's disease or ulcerative colitis.

Autoimmune Disease Categories & Common Disorders

Joints/Muscles	Digestive	Endocrine	Skin	Nervous System	Other
Lupus	Chron's	Grave's Disease	Psoriasis	Multiple sclerosis	Type 1 Diabetes
Rheumatoid Arthritis	Celiac	Addison's Disease	Dermatomyositis	Guillian-Bare	Vasculitis
	Colitis				

Source: Cleveland Clinic

Diagnosing an autoimmune disease usually takes healthcare providers longer than it does to diagnose other diseases. This is because many autoimmune diseases have similar symptoms with each other and with other diseases. It is not uncommon for sufferers to have multiple disorders.



Treatment depends on the type and severity of the condition. Nonsteroidal anti-inflammatory drugs (NSAIDs) and immunosuppressants are often used. Intravenous immunoglobulin may also occasionally be used. While treatment usually improves symptoms, they do not typically cure the disease. Traditional treatment options include immunosuppressant drugs to reduce the immune response against the body's own tissues, such as NSAIDs to reduce inflammation, glucocorticoids to reduce inflammation, disease-modifying anti-rheumatic drugs (DMARDs) to decrease the damaging tissue and organ effects of the inflammatory autoimmune response.

More advanced therapies which aim to be less toxic to the patient and have more specific targets include monoclonal antibodies that can be used to block pro-inflammatory cytokines. Newer, antigen-specific immunotherapy allows immune cells to specifically target the abnormal cells that cause autoimmune disease. In addition, this approach can include a co-stimulatory blockade that works to block the pathway that leads to the autoimmune response. T-cell therapy utilizes this special type of T cell to suppress the autoimmune response.

It is in the advanced therapies where RGBP stands to potentially emerge as a leading therapeutic player.

THE REGEN ADVANTAGES

Regen BioPharma focuses on creating immune checkpoint medicines. An immune checkpoint is a mechanism by which certain cells of the immune system, typically T cells, are kept from being fully activated. This type of restraint on the immune system is important in the normal functioning of the immune system. However, it is now well-established that many cancers have an ability to trick immune cells into up-regulating their checkpoints and thus shut down the ability of these immune cells to kill the tumor. Several drugs which target checkpoints, termed checkpoint inhibitors, are currently used as standard of care in certain cancers. Regen has been focusing its research on a novel immune checkpoint called NR2F6.

RGBP boasts platform technologies that have led to the development of cellular therapies (including CAR-T cells) as well as RNA and DNA technologies for the treatment of various cancers, and personalized stem cells for which the Company received IND clearance. It has submitted two other INDs for cancer therapies whose status are presently dormant but may be re-visited. Clearly, Regen has a valuable, diverse pre-clinical pipeline spanning cell therapies, RNA and DNA therapeutics and small molecule drugs. However, for the purposes of the Company's positioning and our valuation, we are focused on the DuraCAR platform.

NR2F6

NR2F6 can be defined as an intracellular immune checkpoint that suppresses adaptive anti-cancer immune responses. It may have properties that when targeted for next-generation immunological regimens, may delay cancer progression and help improve survival. Hence, the patents RGBP owns regarding NR2F6 and cancer therapies. For example, RGBP was granted patents on shRNA that is designed to inhibit NR2F6 expression in CAR-T Cells and make these CAR-T cells have long-term, durable effectiveness. Separately, blocking NR2F6 in CAR-T cells should also make these cells more effective at killing solid tumors.

In September 2023, RGBP engaged the CRO ProMab Biotechnologies to embark on a series of preclinical experiments using the Company's proprietary shRNA NR2F6-inhibiting technology. The objective was to validate its DuraCAR platform's approach whereby inhibition of this checkpoint protects CAR-T cells from exhaustion, a common problem of existing CAR-T cell therapies. "T cell exhaustion" means the T cells that are initially recruited to the tumor to kill it end up losing their effectiveness. The Company believes that NR2F6, a checkpoint that puts the brakes on T cell activity, is a key player in the T Cell exhaustion phenomenon. Inhibiting NR2F6 is expected to prevent these T cells from becoming dysfunctional.

(CAR-T cells are lymphoid cells that are genetically engineered in a laboratory. They have a new receptor so they can bind to cancer cells and kill them. Different types of cancers have different antigens. Each kind of CAR-T cell therapy is made to fight a specific kind of cancer antigen.)

The first phase of in vitro experiments seeking to validate its DuraCAR CAR-T cell therapeutics successfully synthesized and expressed in transfected cells the chimeric antigen receptor (CAR) construct targeting CD19 and NR2F6. However, a second set of experiments yielded unexpected results whereby siRNAs designed to suppress NR2F6 mRNA expression yielded the opposite result.

The Company has engaged a second CRO that is independent of the CRO which performed the second set of experiments to determine if these surprising findings are reproducible in a confirmatory study. If confirmed, these results could lead to the development of a therapy whereby T-Cells that suppress autoimmunity can be created---a potentially major development in autoimmune therapeutics.

Regen has identified and filed patents on small molecules that activate and inhibit NR2F6 which controls how the immune system reacts to cancer cells and to inflammatory responses and which dovetails with this new data. If the results are confirmed, RGBP is prepared to expedite animal studies, and determine which autoimmune indications may be low-hanging fruit.

We believe that diseases such as lupus and rheumatoid arthritis, which are chronic disorders that carry heavy disease burden for millions of sufferers may emerge as two of the potential candidates, as NR2F6 has shown to induce an anti-inflammatory signal in the T-cell compartment. Once indications are determined and pre-clinical studies are completed, RGBP will file an IND, and initiate a Phase I clinical trial in 18 months. While it is early to ascertain the primary objectives aside from safety and tolerability, some limited inflammation reduction may be in the cards.

It should be noted while the autoimmune space may be the Company's current primary target therapy, it continues to further develop cancer programs focusing on solid tumors. There are two INDs which could be refiled on the cancer front as well. Plus, RGBP's HemaXellerate product, for which an IND has been cleared by

the FDA, may also be the recipient of further development. HemaXellerate is a personalized cellular therapeutic product designed to stimulate blood production in patients whose bone marrow is not properly functioning.

Looking Ahead

Developmental milestones over the coming months are clear, as outlined above, in our view. What may not be clear are RGBP's inherent advantages, relative to most firms focused on the pre-clinical R&D arena.

- RGBP has a deeper, more diverse IP portfolio than its peers and focused on a validated target
- RGBP has leveraged the IP in building core technology platforms
- RGBP is focused on two of the largest therapeutic categories: cancer and autoimmune
- The Company is focused on next-generation therapies
- The Company has access to capital to take products to the clinic (more on this below)
- Management has experience in filing approved INDs
- Interim Phase I results could attract Big Pharma partnerships

THE REGEN LEADERSHIP TEAM

David Koos, PhD, DBA, Chairman, Chief Executive Officer

Over 30 years experience investment banking and venture capital. Co-Founder of Regen BioPharma Inc., and founder of numerous public and private corporations. Extensive background in public market reporting/ compliance and corporate finance. Financial instruments including equity and debt financing, contract negotiations. Also, several peer reviewed publications.

Harry Lander, Ph.D., Chief Scientific Consultant

Dr. Lander has over 30 years of professional scientific, business and financial management experience related to biomedical research. As a trained biochemist and immunologist, Dr. Lander bridges the gap between science and business. He has had extensive experience in establishing the Sidra Medical and Research Center in Qatar as well as establishing Weill Cornell Medical College – Qatar and has deep experience with growing biotechnology/pharmaceutical companies. Dr. Lander is currently a Managing Partner of Dyo Biotechnologies, LTD where he oversees strategic consulting for biotechnology projects in Southeast Asia. Dr. Lander was President and Chief Scientific Officer of Regen BioPharma, Inc. . Formerly he has served as Research Chief / Administration for Sidra Medical and Research Center (Doha, Qatar) and Assistant Provost for Weill Cornell Medical College (Cornell University). He has extensive managerial and financial experience running complex organizations and establishing new ones. He founded, managed and sold The Gramercy Group, LLC, a NASDAQ market making firm in 2003 (currently Chardan Capital Management) and had multiple SEC licenses.

Scientific Advisory Board Members

Ravinder Reddy, Ph.D.: Dr. Reddy is currently a Professor of Radiology and the Director of the Center for Advanced Metabolic Imaging in Precision Medicine at the University of Pennsylvania. His research interests are in the mechanisms of CAR T-cell toxicities as well as ways to monitor immunotherapy effectiveness. He is the recipient of several prestigious awards, has more than 200 peer-reviewed papers and 15 patents.

Mohammad Haris, Ph.D.: Dr. Haris is an Associate Professor in the Department of Radiology at the University of Pennsylvania. His research focuses on improving outcomes for patients with cancer. With more than 100 peer reviewed publications and multiple patents, Dr. Haris has extensive expertise in examining and understanding the mechanisms of cancer growth and the tumor microvasculature.

Rohit Duggal, Ph.D.: An experienced industry executive with specialization in establishing and advancing biotherapeutic products targeting cancer. Dr. Duggal has more than 23 years of industry experience that spans cellular immunotherapy, immuno-oncology, oncolytic virotherapy, translational oncology and antiviral drug discovery. Currently VP of Research at TRL, he was the head of R&D and site head of ONK Therapeutics Inc. Before that, Rohit led the primary lymphocyte product development program at NantKwest. At Sorrento Therapeutics he helped develop the immuno-oncology franchise that included antibodies in different formats. Rohit obtained his Ph.D. from Texas A&M University.

Hinrich Gronemeyer, Ph.D.: Research Director at the IGBMC in Strasbourg-Illkirch and Research Director (Class 'Exceptional') of the French National Institute of Health and Medical Research (INSERM). His nearly 200 publications received an average citation of 83.34. Hinrich Gronemeyer contributed to pioneering work on nuclear receptors and their therapeutic intervention by design of small molecule ligands.

Additional SAB members can be found on the Company website.

FINANCIALS SNAPSHOT

As evidenced by its quarterly financials, RGBP runs a lean ship, with very modest operating losses. Importantly, the Company has no long-term debt, which is somewhat unusual in this space. Perhaps that is why management was able to recently secure a favorable funding arrangement for general corporate purposes and R&D.

While this funding arrangement does entail issuance of common shares at a discount from market price the timing of sales and number of shares sold is controlled by Regen rather than the funder. This is in stark contrast to many commonly issued variable rate convertible securities which can be converted at the discretion of the holder rather than at the discretion of the Company. While a promissory note in the principal amount of $175,000 issued in connection with the financing arrangement is convertible at a discount at the option of the holder it only becomes convertible in the event of a default.

This arrangement reduces risk in these shares, in our opinion. Details can be found in the 8-K filed last month (https://www.otcmarkets.com/filing/html?id=16935686&guid=FG5-kF8sfHc8Kih).

RISK FACTORS

In our view, the Company's biggest near term risk is related to confirmatory testing results. Assuming the new tests elicit the same results, future development risks are related to the timing and execution of animal studies, autoimmune indication determination, IND filing and the launch of a Phase I clinical trial. With funding access now available, we believe that this major stumbling block affecting RGBP's preclinical company peers, reduces the risk for these shares. Competitive risks include the introduction of new, related products or technologies that may be on track to offer greater safety, tolerability or efficacy. The aforementioned risks could come from larger

competitors, existing firms, or new entrants. Still, these future concerns are consistent with firms of RGBP's size and standing. Moreover, we believe that RGBP's seasoned management team is prepared to overcome these hurdles.

Volatility and liquidity are typical concerns for microcap stocks that trade on the over the counter (OTC) stock market. Although the number of shares outstanding has been little changed in recent quarters, management is seeking to raise capital to fund corporate expansion and R&D. An overriding financial benefit as a public company is the favorable access to and the availability of capital to fund product launches, consistent marketing campaigns and other initiatives. Since the proceeds of any future funding would be used in large part to advance major business development, we believe that any dilutive effect from such a funding could be offset by related increases in market value.

CONCLUSION

Regen BioPharma may be an underfollowed and undervalued preclinical player today, but major steps on the R&D front could serve as a near-term catalyst for its stock. A recent set of experiments unearthed surprising results which could lead to a series of key milestone events. The Company has a deep IP portfolio and a diverse preclinical product pipeline centered around a validated target., with a focus on immune-oncology and autoimmune diseases. Regen's next-gen technology platforms have led to multiple IND submissions and an IND approval.

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RECENT TRADING HISTORY FOR RGBP

(Source: www.StockCharts.com)

SENIOR ANALYST: ROBERT GOLDMAN

Rob Goldman founded Goldman Small Cap Research in 2009 and has over 25 years of investment and company research experience as a senior research analyst and as a portfolio and mutual fund manager. During his tenure as a sell side analyst, Rob was a senior member of Piper Jaffray's Technology and Communications teams. Prior to joining Piper, Rob led Josephthal & Co.'s Washington-based Emerging Growth Research Group. In addition to his sell-side experience Rob served as Chief Investment Officer of a boutique investment management firm and Blue and White Investment Management, where he managed Small Cap Growth portfolios and *The Blue and White Fund*.

ANALYST CERTIFICATION

I, Robert Goldman, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report.

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