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Zacks Small-Cap Research

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ABVC BioPharma (ABVC-NASDAQ)

ABVC: Several Potential Paths to Achieving Near-Term Milestones

ABVC has several potential paths to achieving 2023 milestones as it advances its portfolio of therapeutic treatments and devices, we believe. The FDA recently approved the IND submission for ABVC's subsidiary BioKey to proceed with the clinical study of ABV-1519 for the treatment of non-small cell lung cancer.

Current Price (1/17/23)	$0.81
Valuation	**$2.02**

OUTLOOK

ABV-1519 is being co-developed by BioKey & Rgene Corp., in which ABVC holds a minority stake. BioKey expects to receive a $600k milestone payment and is eligible to garner additional payments for other co-development projects with Rgene. BLEX 404, which is extracted from the Maitake mushroom, is the primary active ingredient in ABV-1519. The Maitake mushroom has been shown to have immunological benefits, as demonstrated in two Phase I/II clinical studies conducted at Memorial Sloan Kettering Cancer Center. The development of ABV-1519 is consistent with ABVC's strategy to leverage plant based and natural ingredients for treating a range of conditions.

SUMMARY DATA

52-Week High	**$3.23**
52-Week Low	**$0.50**
One-Year Return (%)	**-73.7**
Beta	**0.30**
Average Daily Volume (sh)	**801,721**
Shares Outstanding (mil)	**33**
Market Capitalization ($mil)	**$26**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**1**
Insider Ownership (%)	**50**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2022 Estimate	**N/A**
P/E using 2023 Estimate	**N/A**

Risk Level	**High,**
Type of Stock	**N/A**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020	0 A	0 A	0 A	0 A	0.5 A
2021	0.3 A	0 A	0.1 A	-0 A	0.4 A
2022	0.0 A	0.3 A	0.0 A	0.0 E	0.4 E
2023	0.0 E	0.3 E	0.3 E	0.0 E	0.7 E

EPS / Loss Per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020	-$0.06 A	-$0.09 A	-$0.09 A	-$0.24 A	-$0.50 A
2021	-$0.05 A	-$0.08 A	-$0.07 A	-$0.32 A	-$0.51 A
2022	-$0.20 A	-$0.06 A	-$0.11 A	-$0.19 E	-$0.56 E
2023	-$0.05 E	-$0.06 E	-$0.04 E	-$0.05 E	-$0.20 E

Quarters might not sum due to rounding & share counts

Disclosures on page 15

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KEY POINTS

Several potential paths to near-term milestones…

- ABVC has **s**everal potential paths to achieving 2023 milestones as it continues to advance its portfolio of therapeutic treatments and devices. For example, the FDA recently approved the IND submission from ABVC's subsidiary BioKey, Inc. that enables the company to proceed with the clinical study of ABV-1519 for the treatment of non-small cell lung cancer, which represents a multibillion dollar market.

- The treatment is being co-developed by BioKey, Inc. and Rgene Corporation, which together have three co-development projects underway. BioKey expects to receive a $600,000 milestone payment and is eligible to garner payments aggregating $3.0 million over three years. ABVC holds a minority stake in Rgene.

- BLEX 404 is the primary active ingredient in ABV-1519. BLEX 404 is extracted from the Maitake mushroom, an edible mushroom with immunological effects that have been demonstrated in two Phase I/II clinical studies performed at Memorial Sloan Kettering Cancer Center (MSKCC) with breast cancer and myelodysplastic syndromes (MDS) patients. The development of ABV-1519 is consistent with the company's strategy to leverage plant based and natural ingredients for treating a range of conditions.

… With important milestones anticipated in 2023

- Separately, the company has several other clinical trials underway, with potential milestones expected in 2023. For example, ABVC's Phase II Part 2 clinical study of ABV-1505, its ADHD medicine, is expected to be completed in 3Q23.

- In 2023, ABVC also expects to complete Vitargus® Phase II trials in Thailand, Australia and Taiwan. Vitargus, or ABV-1701, is a biodegradable hydrogel vitreous substitute needed for vitrectomy surgery to treat problems of the retina and vitreous.

- ABVC believes that Vitargus® has several advantages compared to existing vitreous substitutes, including that it minimizes medical complications and lowers the risk of a patient requiring additional surgeries. ABVC is optimistic about Vitargus and believes the revenue prospects for Vitargus could begin to be realized fairly shortly after the trial is completed.

MULTIPLE CLINCIAL RESEARCH EFFORTS UNDERWAY

California-based ABVC BioPharma (NASDAQ: ABVC), a biopharma and medical device company developing therapies for a range of conditions focused on oncology / hematology, central nervous system (CNS) and ophthalmology, has a varied pipeline of therapies to treat challenging diseases, including in the oncology area and depression.

The company continues to advance its portfolio of therapeutic treatments and devices. For instance, the FDA recently approved the IND submission from ABVC's subsidiary BioKey, Inc. that enables the company to proceed with the clinical study of ABV-1519[1] for the treatment of non-small cell lung cancer. Reflecting the prevalence of the disease, the global non-small cell lung cancer (NSCLC) market is a multibillion dollar one.

[1] A Phase I/II, Open Label Study to Evaluate the Safety and Efficacy of BLEX 404 Oral Liquid Combined with Pemetrexed + Carboplatin Therapy in Patients with Advanced Inoperable or Metastatic EGFR-Mutated Non-Small Cell Lung Cancer Patients.

The proposed clinical investigation is of BLEX 404, which is the primary active ingredient in ABV-1519, for advanced inoperable or metastatic EGFR-mutated non-small cell lung cancer. The treatment is being co-developed by BioKey, Inc. and Rgene Corporation. The latter submitted the IND to the FDA on November 30, 2022. ABVC holds a minority interest in Rgene; it would not surprise us if ABVC elected to waive portions of the expected milestone payments in exchange for an increased stake in Rgene.

BioKey has three co-development projects focused on oncology programs with Rgene, following their June 2022 expanded co-development partnership agreement. At that time, BioKey entered into an agreement with Rgene to guide three Rgene drug products through completion of Phase II clinical studies under U.S. FDA IND regulatory requirements. These assets are:

- RGC-1501 for the treatment of non-small cell lung cancer (NSCLC)
- RGC-1502 for the treatment of pancreatic cancer and
- RGC 1503 for the treatment of colorectal cancer patients

BioKey expects to receive a $600,000 milestone payment and is eligible to garner payments aggregating $3.0 million over three years. The RGC-1501 study will initially be conducted at Taipei Veterans General Hospital in Taiwan.

Natural ingredient- based therapies minimize potential side-effects

BLEX 404 is extracted from the Maitake mushroom (Grifola frondosa), an edible mushroom that has been shown to have immunological benefits that have been demonstrated in two Phase I/II clinical studies performed at Memorial Sloan Kettering Cancer Center (MSKCC) with breast cancer and myelodysplastic syndromes (MDS) patients. The development of RGC-1501 is consistent with ABVC's strategy to leverage plant based and natural ingredients for treating a range of conditions.

In fact, ABVC's other products are also derived primarily from plants. ABVC believes that its focus on botanical sourcing in drug development distinguishes its asset portfolio from that of many other biopharma companies. The company believes that plant-derived medicines can have substantial therapeutic benefits and simultaneously minimize potential side-effects compared to therapies developed from animals or chemicals. Aspirin, for example, is derived from shrubs that contain salicylic acid, which is found in jasmine, beans, peas, clover and certain grasses and trees.

The natural botanical active ingredients that form the company's assets have minimal to no significant side effects and generally are well tolerated by patients. Moreover, the active ingredients in ABVC's formulations have already demonstrated successful therapeutic effects in Asia with minimal to no side effects, reflecting that the therapies are derived from plants and other natural components. ABVC therefore believes its pipeline is well positioned to attain regulatory approval with the FDA and other regulators in international markets.

SEVERAL CLINICAL STUDIES ADVANCING

Separately, the company's Phase II Part 2 clinical study of ABV-1505, its ADHD medicine, is being conducted at five medical centers in Taiwan. The study is a randomized, double-blind, placebo-controlled study that is expected to enroll about 100 patients in Taiwan and the U.S. Results of the first subject treated in Taiwan were reported on May 10, 2022 and 30 subjects subsequently have been enrolled in the study from a total of 43 subjects screened. ABVC anticipates that enrollment for the study will accelerate substantially, and worldwide we are expecting to complete the Part 2 study in 3Q23.

The University of California, San Francisco (UCSF) Medical Center recently joined the study. Part 1 of the Phase II study of ABV-1505 was conducted at UCSF from January 2020 through July 2020 and was accepted by the US Food & Drug Administration in October of 2020.

Results from the Part 1 study support further clinical development of ABV-1505 for the treatment of ADHD. The Part 1 study found that the active ingredient of ABV-1505, PDC-1421, was safe, well-tolerated and efficacious during the treatment and follow-up period with six adult patients. For the primary endpoints, the percentages of improvement in Adult Attention-Deficit/Hyperactivity Disorder Rating Scale-Investigator Rated-IV (ADHD-RS-IV) score from baseline through eight weeks of treatment were 83.3% (N=5) in the Intention-To-Treat (ITT) population and 80.0% (N=4) in the Per-Protocol (PP) population. Both low and high doses of PDC-1421 met the primary end points by passing the required 40% population in ADHD-RS-IV test scores.

In 2023, ABVC expects to complete Vitargus Phase II trials in Thailand, Australia and Taiwan, conclude discussions with the FDA to derive an acceptable protocol for Phase III trials for MDD and advance its program for oncology drugs, among other goals.

ABV-1505 clinical trial – treating ADHD with minimal (to no) side effects

ABVC continues to enroll participants in its Phase II part 2 clinical study of ABV-1505 for Adult Attention Deficit Hyperactivity Disorder (ADHD). ABV-1505 is a plant-based drug treatment that targets ADHD symptoms in adults. The active ingredient in ABV-1505 is PDC-1421. The FDA approved ABV-1505 Phase II clinical trial for the treatment of ADHD in 2016, enabling ABVC to move forward in its clinical studies of this lead asset. ABVC also recently hired two doctors to provide consulting services on its clinical study activities related to major depression disorder (MDD) and ADHD.

Earlier in 4Q22, Cedars-Sinai Medical Center joined ABVC's Phase I Clinical Study of its Phase I study of ABV-1601 for treating depression in cancer patients. The Phase I study is open label and will be conducted with 12 cancer patients with moderate to severe depressive symptoms. The main objective of the study is to evaluate the safety of PDC-1421, the primary active ingredient in ABV-1601. The second objective is to determine the most effective dosages for a randomized, double-blind, non-inferiority Phase II trial of PDC-1421 that ABVC expects to initiate in 2023. The company intends to compare results of the Phase II study of ABV-1601 to Wellbutrin XL, a commonly used medicine to treat cancer patients suffering with depression.

In earlier studies, ABV-1505 has been shown to achieve 40% or greater improvement in the ADHD rating scale at both low-dose and high-dose treatments, with no severe adverse events (SAEs) occurring. PDC-1421 is the active ingredient of ABV-1505.

ABV-1505 advantages

The company expects ABV-1505 to be equally or even more effective than many of the medications currently available to relieve ADHD sufferers. ABVC expects that if patients experience any side effects from the ABV-1505, they will be mild to moderate. The prevalence of adult ADHD has increased significantly in the U.S. over the past decade. According to the Journal of the American Medical Association (JAMA), the diagnosis of ADHD in adults continues to rise. A study published in JAMA observed a 43% rise in the rate of adults being diagnosed with ADHD over the decade. The increased diagnosis supports the need to improve assessment and treatment of ADHD in adults, according to JAMA.

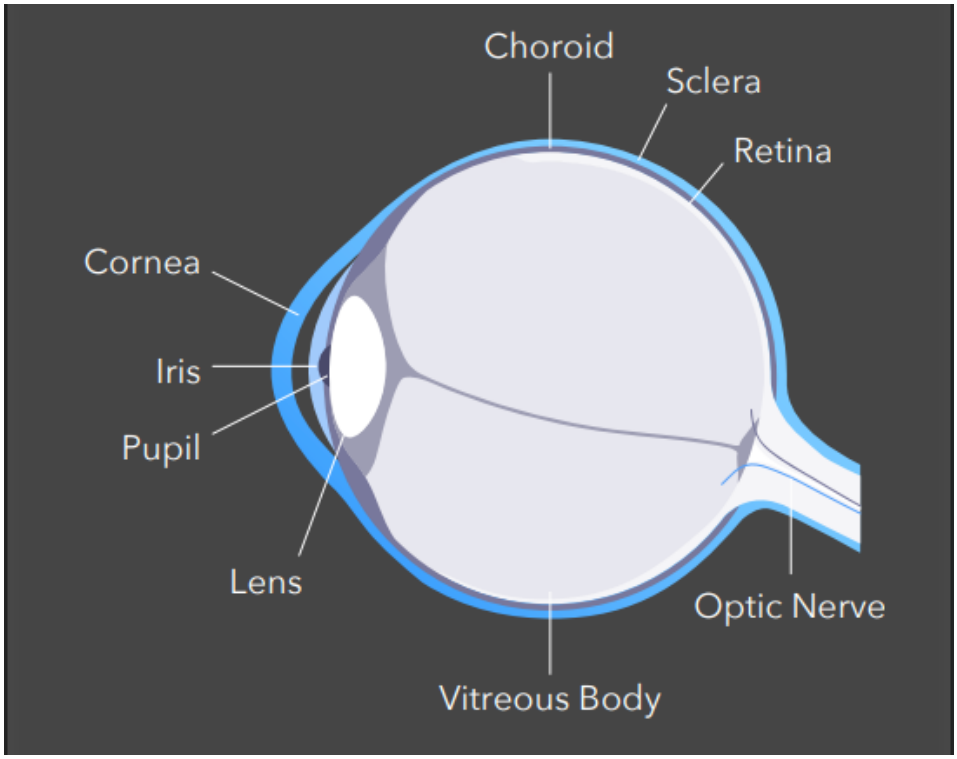
The U.S. is a major region for ADHD treatment, reflecting expanding diagnosis of ADHD patients and expansion in the number of medical sites offering therapy, according to the National Resource Center (NRC) on ADHD. These metrics suggest potentially strong demand for ABVC s therapies, we believe. The climbing diagnosis of ADHD is expected to lead to growth in the size of the therapy market. Grand View Research puts the global ADHD market at roughly $16.4 billion in 2018 and estimates that it will grow at a 6.4% CAGR through 2025, driven by worldwide drug product approvals, among other factors. This expected growth is consistent with the trend observed over the past three decades. According to the National Institute of Health (NIH), from 1993 through 2003 the global use of ADHD medications increased threefold.

… AND VITARGUS, ABV-1701, IS ANOTHER LEAD PRODUCT

Vitargus – strong demonstrated advantages

Vitreous is a gel-like fluid that attaches to the retina and fills the human eye. Vitargus®, or ABV-1701, is a biodegradable hydrogel vitreous substitute. Vitrectomy surgery is conducted to treat problems of the retina and vitreous. The surgery involves the removal of all or some of the vitreous from the middle of the eye and the substitution of a replacement fluid. Vitargus® is a bio-degradable vitreous substitute.

ABVC believes that Vitargus® has several advantages compared to existing vitreous substitutes, including that it minimizes medical complications and lowers the risk of a patient requiring additional surgeries. Vitargus® allows a patient unrestricted post-surgery movement or activity, as it sets as a stable semisolid gel that adheres to the retina, which means that the patient does not need to remain face-down after surgery in order for Vitargus® to maintain its retinal location during and immediately following vitrectomy surgery. ABVC is optimistic about Vitargus and believes the revenue prospects for Vitargus could begin to be realized fairly shortly after the trial is completed.



Source: Company presentation

Early clinical studies indicate that Vitargus has unique properties that eliminate the need for post-surgery patient face-down positioning and significantly improves recovery period patient comfort and visual acuity compared to existing products.

Growing market for ocular surgery underscores commercial potential of Vitargus

Driven partially by the aging of the global population, market research suggests strong growth in the market for ocular surgery, including for vitreo-retinal procedures. Market intelligence and research firm Fior Markets, for instance, expects the worldwide vitreo-retinal surgery devices market to reach $2.5 billion by 2027, up from about $1.6 billion in 2019. Studies from other market research firms suggest similar growth trajectories and support forecasts that the market can reach or exceed the roughly $2.0+ billion level over this period. From 2012 to 2030, the number of vitrectomy cases is expected to increase from 1.26 million to 4.0 million, which represents a nearly 7% CAGR.

The growing occurrence of eye disorders, usually more common in older patients, boosts general awareness of eye health and, in turn, likely contributes to expected market growth. The rising incidence of other disorders such as diabetes also might sometimes be a contributing factor, as well, according to the World Health Organization.

Phase II clinical study of Vitargus moving forward…

ABVC intends to advance its clinical study of Vitargus. The Vitargus® Phase II Clinical Study Protocol has been approved by the Thailand Food and Drug Administration (FDA). Import licenses for the Vitargus medical device and SF6-Gas used as a comparator in the clinical study were issued to both TH001 and TH002 study sites in Thailand on November 2, 2022. Vitargus medical devices and SF6-Gas comparators will be shipped to Ramathibodi Hospital, Mahidol University located in Bangkok (TH001) and Srinagarind Hospital, Khon Kaen University located in Khon Kaen Province (TH002) in preparation for the Site Initiation Visit (SIV) of the study.

The study is expected to enroll a total of at least 20 patients undergoing vitreo-retinal surgery. The company expects two Australian sites to receive the green light from the Australian Therapeutic Goods Administration (TGA) in time to enable the company to move ahead with the Australian study in early 2023. The Vitargus Phase II study plan was approved by the Australian Bellberry Human Research Ethics Committee (HREC) on September 29, 2022. A Clinical Trial Notification (CTN) was submitted to the Australian Therapeutic Goods Administration (TGA) subsequently. The Phase II study will be conducted in Thailand as well as Australia and will include a total of at least 20 subjects. ABVC expects to commence the study in early 2023 and to add additional study sites in 2023.

A prior study found that Vitargus® was well-tolerated as a vitreous substitute without any apparent toxicity to ocular tissues and no indication of an increased safety risk. The enrolled patients also showed improvement in visual acuity compared to other vitreous substitutes. The company believes that the safety and preliminary efficacy findings from this study, combined with the unique properties of Vitargus® (BFC-1401), support further development for its use during vitrectomy surgery in patients requiring vitreous replacement. Early clinical studies indicate that Vitargus can eliminate the need for positioning patients face-down post-surgery, which generally results in improving patient post-surgery comfort and visual acuity during recovery compared to other products that are than currently available.

Clinical studies to-date indicate that Vitargus® eliminates the need for post-surgery patients to remain in a face-down position and also significantly improves the patient's recovery period, comfort and visual acuity compared to existing therapeutic products. The objective of the Phase II study[2] is to demonstrate the safety and efficacy of Vitargus® compared to Sulphur Hexafluoride (SF6) Gas OE, which currently is a standard of care used for retina re-attachment.

The company has secured Dr. Andrew Chang to be the principal investigator, as noted, to conduct Vitargus Phase II clinical trials in Australia. As of January of 2022, two clinical sites in Thailand had been selected to participate in the Phase II clinical study of Vitargus®. The new sites are at the Ramathibodi

[2] The study is titled, "A Prospective Multi-Site Randomized Controlled Clinical Investigation of the Safety and Effectiveness of the ABV-1701 Ocular Endotamponade (OE)"

Hospital at Mahidol University and the Srinagarind Hospital at Khon Kaen University. Two Australian medical centers are also participating in the study.

Improved patient recoveries

According to ABVC citing data from medical journals, the incident of retinal detachment by age 85 is about 3% and 1% in Thailand and Australia, respectively. The company continues to select sites to participate in the study. Earlier this month, ABVC announced a new clinical site in Australia at the Sydney Eye Hospital, which will join East Melbourne Eye Group in East Melbourne, Victoria, Australia and Ramathibodi Hospital and Srinagarind Hospital in Thailand to participate in the study. The Sydney Eye Hospital has more than 10 years of clinical trial experience, including 23 completed and 22 on-going ophthalmology studies, according to ABVC.

EXPANDING TARGETED TREATMENT AREAS

Leveraging assets for multiple treatment programs extends reach…

We would not be surprised to see the company's targeted treatment areas expand as the drug portfolio grows. Moreover, the company is also leveraging its assets for multiple programs and. For instance, Both ABV- 1505, which is in an advanced stage of development, and ABV-1504 are derived primarily from the plant-based compound PDC-1421. The company's optimistic outlook for PDC-1421 also has positive implications for ABV-1504, which is in earlier stages of development. Thus, in addition to moving ABV-1505 forward through phase II part II clinical trials for treatment in ADHD, ABVC is also expanding the program to study PDC-1421 in trials evaluating its efficacy in treating MDD.

Moreover, given the relatively low percentage of drugs that receive FDA regulatory approval for commercialization, we believe the company also increases the potential to gain approval for its therapies by expanding the number of conditions they address. Citing research by external researchers, ABVC notes that some 85+% of drugs engaged in clinical trials do not obtain regulatory approval from the FDA for a variety of reasons, including failure to demonstrate effective outcomes with little to no adverse side effects and / or poorly conducted trials.

ABVC Drugs / potential therapies			
ADHD	**RETINAL VITRECTOMY**	**DEPRESSIVE DISORDERS**	**ONCOLOGY**
ABV-1505	Vitargus® – ABV-1701	ABV-1504	ABV-1501
ADULT ADHD	*VITREOUS REPLACEMENT*	*MDD*	*TRIPLE NEGATIVE BREAST CANCER*
		ABV-1601	ABV-1703
		DEPRESSION IN CANCER PATIENTS	*PANCREATIC CANCER*
	ABV-2001, ABV-2002		ABV-1702
	OPHTHALMOLOGY		*MYELODYSPLASTIC SYNDROME*

Source: Company reports Grey shading indicates lead asset

The company has also expanded its development collaboration agreement with affiliate BioFirst to include potential corneal storage and intraocular irrigation solutions during corneal transplant and other ocular procedures. This program is being developed as ABV-2002. Moving this program forward is a 2022 goal, as noted.

ABVC has filed new PCT (Patent Cooperation Treaty) applications for its PDC-1421-based medicines that treat MDD and ADHD. ABVC has completed a Phase II Part II study for MDD of 60 patients with moderate to severe MDD treated with PDC-1421 three times a day for six weeks. The study was a randomized, double-blind, placebo-controlled, multi-center trial that found that PDC-1421 met the pre-specified primary endpoint.[3] The company believes the PCT filings can help extend its global market exclusivity until about 2040-2041, if subsequent national phase applications are granted.

Earlier in 4Q22, ABVC received a Notice of Allowance for ABV-1504 from the U.S. Patent and Trademark Office for a patent, entitled *Polygala Extract for the Treatment of Major Depressive Disorder*, which outlines a method for treating MDD by oral administration of ABV-1504. In addition to the United States, the patent was also filed in China, Taiwan and under the Patent Cooperation Treaty (PCT). The PCT patent application was published on January 27, 2022, and subsequently was filed in Japan, Australia and with the European Patent Office (EPO). The new patent substantially extends the existing patent life of ABV-1504 to the year 2041 in the U.S., according to ABVC. The company also expects it will be granted in China, Taiwan, Japan, Australia and in several European markets.

The key active ingredient in ABV-1504 is PDC-1421, a composition containing Radix Polygalae (Polygala tenuifolia Willd). The polygala extract was orally administered to healthy volunteers and proved to be safe and well-tolerated for a daily dose from 380 mg to 3800 mg in a study that indicated that the drug can be administered chronically over at least 25 days with the daily dose administered once per day, twice per day, or three times per day, wherein each dose contains from 380 mg to 760 mg of the botanical extraction.

Depression: A Growing Problem

Depression is a growing problem globally. According to the World Health Organization (WHO), the prevalence of diagnosed mental health conditions is increasing worldwide. Primarily reflecting demographic changes, there has been a 13% increase in mental health conditions and substance use disorders noted in the ten years leading up to 2017. Reflecting the importance of addressing depression, WHO launched a special initiative for mental health in 2019. Depression is an important health area that ABVC's asset portfolio addresses.

Specifically related to oncology, there is a wide range in Rates of depression in cancer patients. Roughly 40% to 60% of all cancer patients suffer emotional distress needing clinical attention and a formal diagnosis of psychiatric disorder can be made in about 25% to 30%, according to Annals of Oncology.

PDC-1421

The active ingredient of ABV-1505, ABV-1504 and ABV-1601 is PDC-1421, which is a botanical investigational new drug (IND). Through its subsidiary BioLite, ABVC has completed a phase II study of the PDC-1421 capsule to evaluate its safety and efficacy in treating patients with MDD. The study, conducted at Stanford University, found the PDC-1421 capsule to be safe and well-tolerated in effectively treating six enrolled adult patients.

Both low and high doses of the PDC-1421 capsule passed the required 40% population in ADHD-RS-IV test scores, thus meeting the primary end points of the study. The percentages of improvement in adult attention deficit/hyperactivity disorder rating scale score from baseline through eight weeks of treatment were 83.3% in the Intention-To-Treat (ITT) population and 80.0% in the per-protocol (PP) population,

[3] Patients exhibited no severe adverse events.

which support further clinical development of ABV-1505 / PDC-1421 for the treatment of adult ADHD and MDD.

ABVC clinical trial for the treatment of MDD in cancer patients studying ABV-1601 at Cedars-Sinai Medical Center in Los Angeles has been posted on the CSMC website under the working title *ABV-1601 Polygala Phase I*. ABVC also expects to form a commercial partnership in the U.S. to collaborate the development of ABV-1504 for the treatment of MDD. The company believes that ABV-1504, ABV-1505 and ABV-1601 have strong prospects to treat depression and ADHD disorders and obtain better therapeutic outcomes with fewer serious side-effects compared to current standard of care therapies such as SSRIs (selective serotonin reuptake inhibitors), which are frequently prescribed antidepressants, MAO (monoamine oxidase) inhibitors and TCAs (tricyclic antidepressants).

For example, SSRIs that are widely used for depressive disorders sometimes lead to anxiety, sleep disruptions and weight gain. ABVC believes that its plant-based therapies address these disorders without similar negative side effects.

Expanding the product / asset portfolio

ABVC's strategy is to find new products that have already shown efficacy in the Asia-Pacific region and Introduce these assets to other international markets via licensing arrangements. In order to obtain new products, ABVC works with partners in Taiwan, where it has an office.

ABVC monitors new medical discoveries and/or device technologies to select candidates to license for its portfolio. Once ABVC decides that an asset can enhance its portfolio and obtained the licensing rights to it, the company then works with various research institutions primarily in the U.S., Australia and Taiwan to advance the asset through clinical trials towards FDA and other regulatory approvals. The company's strategy is to then license its growing portfolio of drug candidates and medical devices to major pharmaceutical companies for phase III and pivotal clinical trials and subsequent commercialization.

The company continues to seek products to add to its growing asset portfolio. In 4Q21, ABVC restructured its BioLite Japan JV with privately-held Tokyo-based Lucidam to jointly identify early-stage opportunities in drug development, digital health, and medical device technology to expand its product portfolio. Following successful pre-clinical studies, the JV will transfer the rights to ABVC for further clinical development, regulatory approvals and commercialization in exchange for royalties and/or milestone payments, as well as seek potential licensing partners for ABVC's current pipeline of drugs and medical devices. The company expects the JV to improve its ability to identify early-stage opportunities, particularly in Japan.

The company has many other assets in earlier stages of development in its portfolio, including ABV-1702, ABV-1501, ABV-1601 (noted earlier) and ABV-1703. ABVC intends to launch a phase II part 1 clinical trial of ABV-1703 in oral liquid format for the treatment of metastatic pancreatic cancer and biliary tract cancer at Cedars-Sinai Medical Center in Los Angeles. Depending on the outcome of the part 1 study, ABVC would conduct phase II part II as a multi-nation, multi-site study.

ABVC also intends to focus on dietary supplements derived from the maitake mushroom and intends to produce these dietary supplements in both tablet and liquid forms. Memorial Sloan Kettering and other medical centers have noted that the maitake mushroom has been found to reduce cholesterol and improve cardiovascular health, strengthen the immune system and lower blood glucose levels. ABVC estimates the global dietary supplements market at about $140.3 billion in 2020 based on market research, and expected to grow at a nearly 9% CAGR from 2021 to 2028.

VALUATION

ABVC share price declined from the $5 level to the $2 range in 2H21 and subsequently have remained under pressure. The 2H21 drop reflected, among other factors, dilution from securities offerings and restructuring of certain agreements with related parties that led ABVC to waive expected loan repayments, We attribute subsequent share price pressure primarily to market fluctuations, economic uncertainty and general concerns that current conditions could delay timelines for early stage development companies. Nevertheless, we remain optimistic about the chances of ABV-1505, Vitargus and potentially other assets receiving regulatory approval and of the subsequent commercial demand of these treatment therapies. We note that both Vitargus and ABV-1505 address areas of large need where the current cost of standard care is high.

Nevertheless, we believe the difficulty of ascertaining the revenue arc for ABVC at this stage will continue to weigh on the shares. We therefore assign a confidence factor of about 0.6x in our valuation analysis. Given the multiple therapies in development, the growing size of the company's target markets and the ability of ABVC's treatment therapies to produce results with lower side effects, we believe ABVC could attain product revenue of $14.5 million to $16 million in 2025-2027 time period. Applying a peer-benchmarked 12x multiple (down from the prior 14x multiple as valuations of clinical development / clinical stage companies have declined) to the lower end of this revenue forecast range and discounting back to the present at 10%/year results in a present value of about $119 million or about $3.54 per share. Applying the above-noted 0.6x confidence factor yields a near-term valuation of $2.02.

ABVC reaching additional milestones could lead us to our raise our confidence factor. Moreover, we would anticipate multiple expansion as the company continues to advance its candidates. However, any delay or failure in clinical development or regulatory approval could cause the share price to decline and represent a potential risk to our valuation but we believe the risk / reward ratio could be attractive for investors who have a higher than average risk tolerance and longer time horizon.

RECENT NEWS

- On January 5, 2023, ABVC announced that the FDA approved an IND submission allowing the company to move forward with a clinical study of ABV-1519 for the treatment of non-small cell lung cancer.
- ABVC BioPharma provided an update on its Vitargus® study on November 17, 2022.
- On November 14, 2022, ABVC BioPharma reported 3Q22 results.
- ABVC received a Notice of Allowance from the USPTO for ABV-1504 for MDD on November 7, 2022.
- Cedars-Sinai Medical Center joined ABVC's Phase I Clinical Study of Medication for Treating Depression in Cancer Patients on November 2, 2022.
- On October 5, 2022, ABVC announced that its Vitargus® Phase II study plan was approved by HREC in Australia.
- ABVC announced UCSF Institutional Review Board approval and provided an update on the ADHD Phase II Part 2 clinical study on September 23, 2022.
- ABVC issued a letter to shareholders on September 13, 2022.

RISKS

Risks to ABVC achieving its objectives, and to our valuation, include the following.

- The company might not obtain regulatory approval for its therapies.
- ABVC might need to raise additional capital earlier than expected.
- COVID-19 might delay the company's clinical and commercialization timelines.
- The company might not find strategic partners to help advance and commercialize its assets.
- The company might not obtain licenses for additional drug or medical device candidates.
- Production of critical components of its various drugs, including of polygala tenuifolia, could be disrupted.
- Clinical trials might not generate results that support further development efforts of some of the company's assets.

PROJECTED FINANCIALS

ABVC BioPharma Income Statement & Projections (US $)

	2019	2020A	1Q21A	2Q21A	3Q21A	4Q21A	2021A	1Q22A	2Q22A	3Q22A	4Q22E	2022E	2023E
Revenues	$701,719	$483,045	$263,150	$31,441	$98,999	($37,793)	$355,797	$25,660	$312,860	$42,269	$26,438	$407,227	$697,754
COGs	20,137	18,716	1,245	646	393	2,802	5,086	1,896	8,367	10,741	1,983	22,987	18,335
Gross profit	681,582	464,329	261,905	30,795	98,606	(40,595)	350,711	23,764	304,493	31,528	24,455	384,240	679,419
Gross margin	97%	96%	100%	98%	99.6%	NM	98.6%	92.6%	97%	75%	92.5%	94.4%	97%
S,G&A	3,069,493	4,273,468	1,167,595	1,231,692	1,579,996	1,766,836	5,746,119	1,191,078	1,592,831	3,216,146	1,227,169	7,227,224	7,761,003
R&D	1,048,553	549,658	121,315	358,878	263,424	260,188	1,003,805	359,404	532,782	305,483	370,294	1,567,963	784,717
Stock-based compensation	22,314	4,146,979	225,740	475,740	225,740	4,379,535	5,306,755	4,692,003	225,740	225,740	4,834,175	9,977,658	485
Total operating expenses	4,140,360	8,970,105	1,514,650	2,066,310	2,069,160	6,406,559	12,056,679	6,242,485	2,351,353	3,747,369	6,431,639	18,772,846	8,546,205
Operating (loss)/profit	(3,458,778)	(8,505,776)	(1,252,745)	(2,035,515)	(1,970,554)	(6,447,154)	(11,705,968)	(6,218,721)	(2,046,860)	(3,715,841)	(6,407,184)	(18,388,606)	(7,866,787)
Interest income	23,344	71,045	52,529	10,722	9,333	(29,388)	43,196	40,175	39,015	48,164	41,392	168,746	151,298
Interest expense	(482,014)	(405,032)	(130,229)	(82,671)	(38,677)	24,367	(227,210)	(18,213)	(14,758)	(126,536)	(18,765)	(178,272)	(231,451)
Other income	(92,833)	(1,974,173)	84,098	162	37,987	556,908	679,155	22,277	(7,181)	21,911	22,952	59,959	23,935
Total other income / (expenses)	(551,503)	(2,308,160)	6,398	(77,005)	8,643	551,887	495,141	44,239	17,076	(56,461)	45,579	50,433	(56,218)
Pretax (loss)/income	(4,010,281)	(10,813,936)	(1,246,347)	(2,112,520)	(1,961,911)	(5,895,267)	(11,210,827)	(6,174,482)	(2,029,784)	(3,772,302)	(6,361,604)	(18,338,172)	(7,923,005)
Provision for income tax	(77,041)	(220,352)	(51,024)	(59,564)	(75,667)	1,011,279	825,024	(86,867)	(82,451)	4,222	(89,499)	(254,595)	(182,730)
Net loss	(3,933,240)	(10,593,584)	(1,195,323)	(2,052,956)	(1,886,244)	(6,906,546)	(12,035,851)	(6,087,615)	(1,947,333)	(3,776,524)	(6,272,105)	(18,083,577)	(7,740,275)
Noncontrolling interests	(291,464)	(802,420)	(66,818)	(81,390)	(79,756)	1,030,926	802,962	(92,175)	(88,336)	(71,660)	(94,968)	(347,139)	(988,992)
Net loss attributed to ABVC	(3,641,776)	(9,791,164)	(1,128,505)	(1,971,566)	(1,806,488)	(7,937,472)	(12,838,813)	(5,995,440)	(1,858,997)	(3,704,864)	(6,177,137)	(17,736,438)	(6,751,283)
FX	7,902	(98,893)	36,140	364,581	16,137	(442,058)	(25,200)	(113,339)	(123,221)	(190,019)	(116,773)	(543,352)	(69,408)
Comprehensive loss	(3,633,874)	(9,890,057)	(1,092,365)	(1,606,985)	(1,790,351)	(8,374,312)	(12,864,013)	(6,108,779)	(1,982,218)	(3,894,883)	(6,293,910)	(18,279,790)	(6,820,692)
Per share data													
LPS	($0.21)	($0.50)	($0.05)	($0.08)	($0.07)	($0.32)	($0.51)	($0.20)	($0.06)	($0.11)	($0.19)	($0.56)	($0.20)
Avg shares out	17,498,543	19,715,559	24,420,526	24,421,082	26,882,181	24,490,299	25,053,522	29,683,402	31,307,329	32,574,551	32,574,701	31,534,996	33,609,400

Source: Company reports & Zacks

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APPENDIX: CLINICAL TRIAL HIGHLIGHTS

Highlights of some institutions currently, recently or shortly conducting clinical trials in partnership with ABVC:

Drug: ABV-1701
Vitargus® in vitrectomy surgery, First-in-Human, Medical Device
Principal Investigator: Andrew Chang, MD, Ph.D.
Sydney Eye Hospital, Australia

Drug: ABV-1504
Major Depressive Disorder (MDD), Phase II, NCE drug
Principal Investigators: Charles DeBattista M.D. and Alan F. Schatzberg, MD
Stanford University Medical Center, Cheng-Ta Li, MD, Ph.D
Taipei Veterans General Hospital

Drug: ABV-1505, Adult Attention-Deficit Hyperactivity Disorder (ADHD), Phase II, NCE drug
Principal Investigators: Keith McBurnett, Ph.D. and Linda Pfiffner, Ph.D.,
University of California San Francisco (UCSF), School of Medicine

Drug: ABV-1601, Major Depression in Cancer Patients, Phase I/II, NCE drug
Principal Investigator: Scott Irwin, MD, Ph.D.
Cedars Sinai Medical Center (CSMC)

Drug: ABV-1703, Advanced Inoperable or Metastatic Pancreatic Cancer, Phase II, NCE drug
Principal Investigator: Andrew E. Hendifar, MD
Cedars Sinai Medical Center (CSMC)

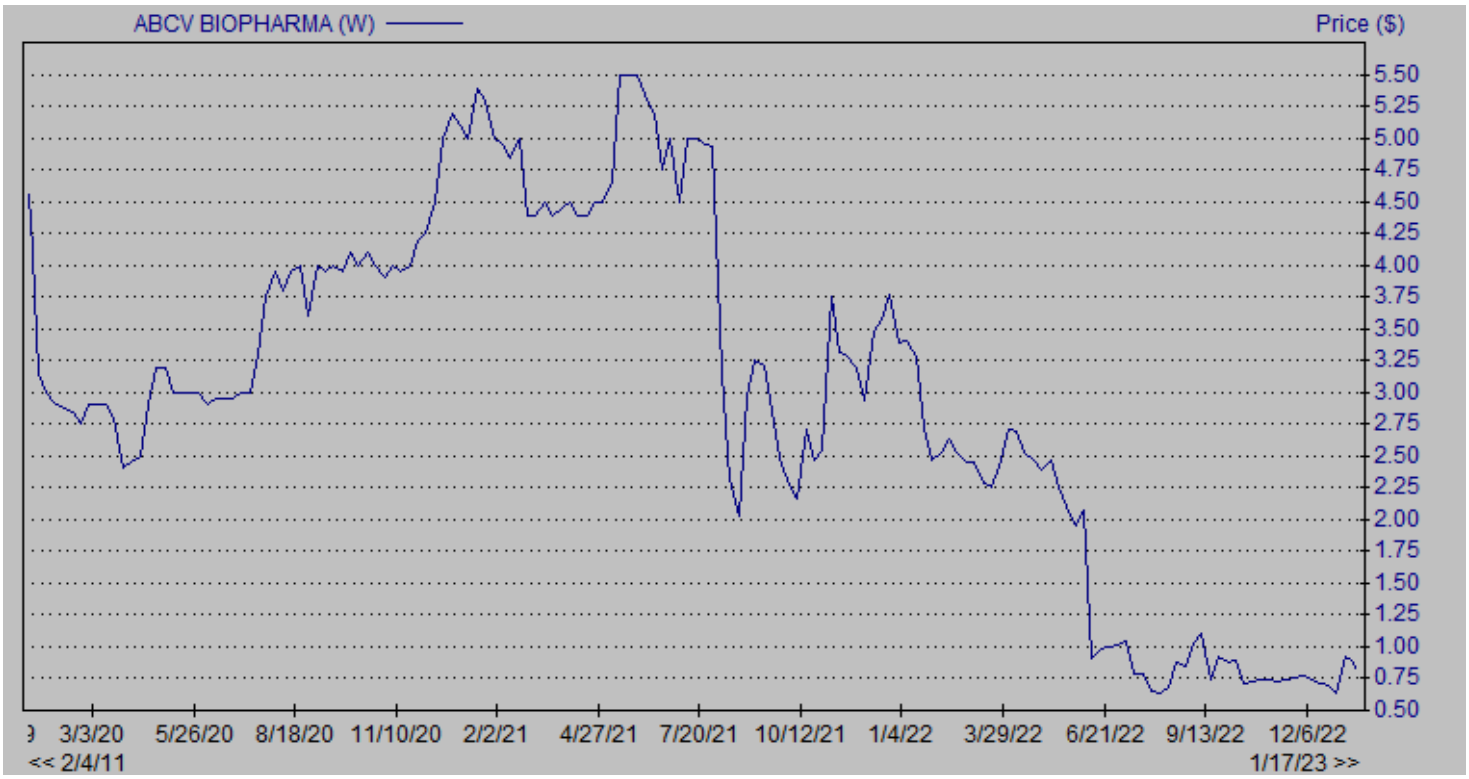
Drug: ABV-1702, A Phase II Study of BLEX 404 Oral Liquid to Evaluate the Safety and Infection Control in Patients with International Prognostic Scoring System (IPSS) Intermediate-1, Intermediate-2 or High-Risk Myelodysplastic Syndrome (MDS) and Chronic Myelomonocytic Leukemia (CMML)

Drug: PDC-1421, A Phase II Study of PDC-1421 Capsule to Evaluate the Safety and Efficacy in Patients With Major Depressive Disorder
Study Director: Richard King, Ph.D.
Stanford University, Stanford Depression Research Clinic
Taipei Veterans General Hospital

Drug: ABV-1519, A Phase I/II, Open Label Study to Evaluate the Safety and Efficacy of BLEX 404 Oral Liquid Combined with Pemetrexed + Carboplatin Therapy in Patients with Advanced Inoperable or Metastatic EGFR-Mutated Non-Small Cell Lung Cancer Patients.

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