

# Zacks Small-Cap Research

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## ABVC BioPharma (ABVC-NASDAQ)

### ABVC: Lead Products Move Closer To Potential Approval; Important Clinical Studies Advancing

ABVC is a biopharma and medical device company developing a diversified portfolio of therapies for a range of conditions. The company currently has multiple drugs, dietary supplements and a medical device under development, with two lead assets (discussed in this report) moving through in advanced stages of development.

Current Price (3/7/22) **\$2.26**  
Valuation **\$9.50**

### OUTLOOK

Among ABVC's 2022 goals, the company is implementing a Part 2 ADHD clinical study on ABV-1505, which is a plant-based drug treatment that targets ADHD symptoms in adults. The study's principal investigator meeting was held recently, with participants from medical centers of UCSF and five sites in Taiwan. ABVC is also launching a pivotal trial for Vitargus®, the company's bio-degradable vitreous substitute, which ABVC believes has several competitive advantages. Vitargus® received the 2021 "National Innovation and Renewal of Diligence" award from IBMI of Taiwan and was also presented at the 14th Asia-Pacific Vitreo-Retina Society Congress. ABVC notes that several pharmaceutical companies have indicated potential interest in collaborating on Vitargus.

### SUMMARY DATA

52-Week High **\$6.03**  
52-Week Low **\$1.95**  
One-Year Return (%) **-48.64**  
Beta **0.41**  
Average Daily Volume (sh) **211,460**

Shares Outstanding (mil) **29**  
Market Capitalization (\$mil) **\$65**  
Short Interest Ratio (days) **N/A**  
Institutional Ownership (%) **0**  
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 2021 Estimate **N/A**  
P/E using 2022 Estimate **N/A**

Zacks Rank **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)
2018	0 A	0 A	0 A	0 A	0 A
2019	0 A	0 A	0 A	0 A	1 A
2020	0 A	0 A	0 A	0 A	0.5 A
2021	0.3 A	0 A	0.1 A	0.2 E	1 E

#### EPS / Loss Per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	\$0.00 A				
2019	-\$0.05 A	-\$0.03 A	-\$0.06 A	-\$0.06 A	\$0.21 A
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	-\$0.04 E	-\$0.23 E

Quarters might not sum due to rounding & share counts

Disclosures on page 16

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## KEY POINTS

- ABVC is implementing a Part 2 ADHD clinical study on ABV-1505, which is a plant-based drug treatment that targets Adult Attention Deficit Hyperactivity Disorder (ADHD) symptoms in adults. The study is a randomized, double-blind, placebo-controlled study that is expected to enroll about 100 patients in the U.S. and Taiwan. The principal investigator meeting for the study was held last month, with principal investigators from the University of California San Francisco Medical Center and five Taiwan medical centers participating.
- The company expects ABV-1505 to be equally or even more effective than many of the medications currently available to relieve ADHD sufferers, including that if patients experience any side effects from the ABV-1505, they will be mild to moderate.
- ABVC is also launching a pivotal trial for Vitargus®, the company's bio-degradable vitreous substitute that ABVC believes has several advantages compared to existing vitreous substitutes, including that it minimizes medical complications and lowers the risk of a patient requiring additional surgeries. The objective of the study is to demonstrate the safety and efficacy of Vitargus as compared to SF6 Gas OE, which is a standard of care for retina re-attachment.
- Vitargus® received the 2021 "National Innovation and Renewal of Diligence" award from the Institute for Biotechnology and Medicine Industry (IBMI) of Taiwan. Moreover, in December of 2021, Vitargus® was presented at the 14th Asia-Pacific Vitreo-Retina Society Congress by Dr. Andrew Chang, the Medical Director of the Sydney Retina Clinic and head of the retinal unit at the Sydney Eye Hospital. Dr. Chang is the principal investigator of the Vitargus study.
- Early clinical studies indicate that Vitargus has unique properties that eliminate the need for post-surgery patient face-down positioning and significantly improves the patient's recovery, comfort and visual acuity compared to existing products.
- ABVC also has indicated that Vitargus has received collaboration inquiries from several pharmaceutical companies. The company expects the growing Vitargus clinical study database to facilitate potential partnerships.

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## ABVC'S DIVERSIFIED PRODUCT PORTFOLIO INCLUDES LEAD PRODUCT ABV-1505...

### [\*Moving Part 2 ADHD ABV-1505 Study Forward\*](#) [ABV-1505 – potential to treat ADHD with minimal to no side effects](#)

California-based ABVC BioPharma (NASDAQ: ABVC) is a biopharma and medical device company developing therapies for a range of conditions focused on oncology / hematology, central nervous system (CNS) and ophthalmology. Among ABVC's active pipeline of six drugs, one medical device (ABV-1701/Vitargus®) and dietary supplements under development, ABV-1505 is one of two lead products. The other is Vitargus. Both are in advanced stages of development.

The company is implementing a Part 2 ADHD clinical study on ABV-1505, a plant-based drug treatment that targets Adult Attention Deficit Hyperactivity Disorder (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. The company subsequently launched the Phase II Part I clinical study to evaluate the tolerability and efficacy of ABV-1505 in treating adult patients with ADHD with the University of California San Francisco (UCSF).

The open label trial for ABV-1505 was designed for the enrollment of six adult ADHD patients and was conducted at UCSF Medical Center. It was a dose escalation study during which each of the six patients received a low-dose treatment (380 mg) three times a day for 28 days, followed by a high-dose treatment (760 mg) three times daily for a subsequent 28 days. The primary objective of this study was to determine the effective doses and treatment period of ABV-1505 in adult patients with ADHD. The secondary objective was to evaluate the safety of ABV-1505 in patients receiving the drug at various dose levels. At both low-dose and high-dose treatments, ABVC studies have shown that ABV-1505 achieves 40% or greater improvement in the ADHD rating scale, which is the primary end point of the ADHD clinical trial. No severe adverse events (SAEs) occurred.

The phase II part I clinical trial for ABV-1505 in ADHD was completed on July 22, 2020 and ABVC issued an update on it in 4Q20. The Part 1 study found PDC-1421, the active ingredient of ABV-1505, was safe, well-tolerated and effective. 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 achieved the primary endpoints, passing the required 40% population in ADHD-RS-IV test scores. A Clinical Study Report (CSR) was issued on October 24, 2020 and submitted to and accepted by the FDA.

The Part 1 results demonstrated the therapeutic value of PDC-1421 and, ABVC believes, support further clinical development of ABV-1505 for the treatment of ADHD. ABVC has received Taiwan Central Institutional Review Board (CIRB) approval to begin the phase II part 2 study at five medical centers<sup>1</sup> in Taiwan. ABVC expects to advance into the phase II part 2 study at UCSF, as well as at medical centers in Taiwan. The study is expected to be completed by year-end 2022.

The study is a randomized, double-blind, placebo-controlled study expected to enroll about 100 patients in Taiwan and the U.S. The company anticipates that the Phase II Part 2 study data will demonstrate preliminary proof of ABV-1505's efficacy and safety.

The principal investigator meeting for the study was held last month, with principal investigators from the UCSF medical center and five Taiwan medical centers participating to discuss potential further improvement to the study protocol prior to initiation.

### **Growing prevalence of ADHD; 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

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Likely participants: National Taiwan University (NTU) Hospital, Cheng Hsin General Hospital, Linkou Chang Gung Memorial Hospital, Kaohsiung Chang Gung Memorial Hospital & Taipei Veterans General Hospital.

National Institute of Health (NIH), from 1993 through 2003 the global use of ADHD medications increased threefold.

### **Other ABVC 2022 Goals; Financial Flexibility**

In addition to moving the Part 2 study forward, the company's other 2022 goals to advance its growth strategy include:

- Seeking a Phase III partner to advance its MDD treatments
- Launching a self-funded pivotal trial for Vitargus, targeting 2024 U.S. FDA Premarket Approval (PMA)
- Advancing other development programs, including corneal storage media and Maitake mushroom-based dietary supplements, among others
- Raising capital to support continued Phase II clinical trials for oncology and ADHD indications and to expand its existing portfolio

The company recently raised over \$7.0 million through an equity offering of 1.1 million units consisting of shares and warrants. ABVC also received about \$4.245 million of incremental gross proceeds from the exercise of warrants, bringing total proceeds to about \$11.1 million (as of November 9, 2021) to support its growth strategies. The proceeds enhance ABVC's financial position and flexibility to continue advancing its portfolio of drugs and therapies towards regulatory approval and commercialization, in our view.

As of the end of 3Q21, the company had about \$3.7 million of cash and equivalents plus about \$0.7 million of restricted cash. With the funds generated by the issuance and warrant exercise, management believes the company has enough cash to support its growth strategy through mid-2023. ABVC contemplates another potential capital raise in 2022 to ensure its liquidity for advancing its product development plans.

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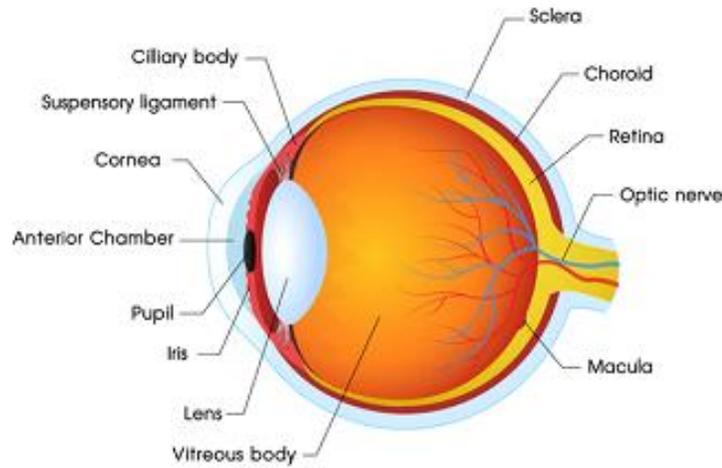
## **... AND VITARGUS, ABV-1701, IS ANOTHER LEAD PRODUCT**

### **Vitargus – Strong commercial potential**

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® 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.

## Eye Anatomy



Source: [www.shutterstock.com](http://www.shutterstock.com)

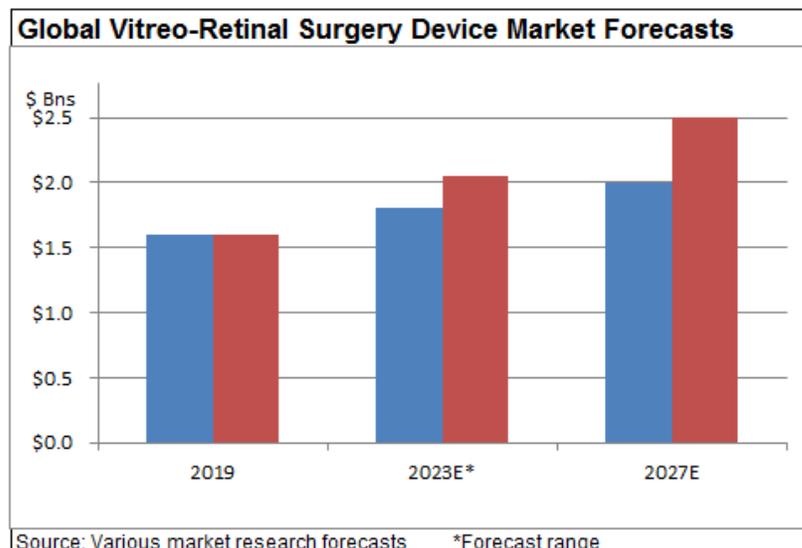
In fact, Vitargus® received the 2021 “National Innovation and Renewal of Diligence” award from the Institute for Biotechnology and Medicine Industry (IBMI) of Taiwan. Moreover, in December of 2021, Vitargus was presented at the 14th Asia-Pacific Vitreo-Retina Society Congress by Dr. Andrew Chang, MD, Ph.D., the medical director of the Sydney Retina Clinic and head of the retinal unit at the Sydney Eye Hospital. Dr. Chang is the principal investigator of the Vitargus Phase I first-in-human clinical study.

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. The objective of the Australian study is to demonstrate the safety and efficacy of Vitargus as compared to SF6 Gas OE, which is a standard of care for retina re-attachment.

### ***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 launch a self-funded study of Vitargus in 2022 in the U.S., Thailand, Australia and potentially other markets. In 4Q20, the company issued a full CSR of its Vitargus® first-in-human phase I clinical trial. The study was an open label trial conducted at a single facility in Sydney, Australia, with 11 participants enrolled who were diagnosed with either a:

- Complex or rhegmatogenous retinal detachment or chronic retinal detachment with failure of gas or silicone oil treatment or
- Vitreous hemorrhage requiring vitrectomy surgery.

The 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.

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<sup>2</sup> 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 Hospital at Mahidol University and the Srinagarind Hospital at Khon Kaen University. Two Australian medical centers are also participating in the study.

ABVC expects the first patient enrollments are likely to begin in 2Q22. According to ABVC citing data from medical journals, the incident of retinal detachment by age 85 is about 3% and 1% in Thailand and

<sup>2</sup> The study is titled, “A Prospective Multi-Site Randomized Controlled Clinical Investigation of the Safety and Effectiveness of the ABV-1701 Ocular Endotamponade (OE)”

Australia, respectively. By year-end 2022, the company hopes to have at least four countries participating in the Vitargus Phase II study. The company continues discussions with the U.S. FDA to include U.S. patients in the study.

Moreover, ABVC has noted that it has received indications of potential interest in collaborating on Vitargus from several regional and global pharmaceutical companies. ABVC also has indicated that Vitargus has received collaboration inquiries from several regional and global pharmaceutical companies. The company expects the growing Vitargus database to facilitate a potential partnership.

## EXPANDING ASSETS & IP TO MULTIPLE PROGRAMS

The company is also leveraging its assets for multiple programs. 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. This is a goal for 2022.

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.

### ***Plant-based therapies - minimizes potential side-effects***

Importantly, ABVC's products are 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.

## ABVC Near-Term Pipeline

MEDICAL CONDITION	ABVC DRUG	PIPELINE STATUS	CLINICAL PARTNER
Major Depressive Disorder (MDD)	ABV-1504	Phase II Completed	Stanford University Medical Center, Taipei Veterans General Hospital
Adult Attention Deficit Hyperactivity Disorder (ADHD)	ABV-1505	Phase II Part I Completed	University of California San Francisco (UCSF), School of Medicine
Myelodysplastic Syndrome (MDS)	ABV-1702	Phase II	TBD
Advanced Inoperable or Metastatic Pancreatic Cancer	ABV-1703	Phase II	TBD

Source: [ABVC Winter 2021 Presentation](#)

ABVC recently filed new PCT (Patent Cooperation Treaty) applications for its PDC-1421-based medicines that treat MDD and ADHD. ABVC recently 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.<sup>3</sup> The company believes the PCT filings can help extend its global market exclusivity until about 2040-2041, if subsequent national phase applications are granted.

### 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.

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

<sup>3</sup> PDC-1421 demonstrated a 13.2-point reduction in the Montgomery-Åsberg Depression Rating Scale (MADRS) total score by Intention-To-Treat (ITT) analysis, averaged over the 6-week treatment period from baseline, compared to 9.2-point reduction of the placebo group. By Per-Protocol (PP) analysis, PDC-1421 showed a dose dependent efficacy toward MDD in which high dose (2 x 380 mg) gave 13.4-point reduction in MADRS total score from baseline and low dose (380 mg) gave 10.4-point reduction as compared to 8.6 in the placebo group. The patients exhibited no severe adverse events.

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. Importantly, 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. 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.

### **Moving earlier stage assets forward & expanding the 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.

As noted, ABVC also intends to focus on dietary supplements derived from the maitake mushroom in 2022 and recently announced that it will 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. Through a subsidiary, BioKey, ABVC has entered into a three-year distribution agreement with a Taiwan-based pharmaceutical marketing company focused on sales of drugs, dietary supplements and medical products in the Asia-Pacific region, Define Biotech. Define Biotech has committed to purchase \$3.0 million worth of ABVC's new dietary product line over the three-year period and received the exclusive right to distribute the line in China and Taiwan.

BioKey will manufacture the supplements at its California production plant. The company also entered into a contract to grow organic maitake mushrooms. BioKey believes its extraction process creates a competitive advantage for the company's products. The company believes worldwide demand for immunity-boosting products has grown during the pandemic. 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

We are optimistic about the chances of ABV-1505 and Vitargus receiving FDA approval and of the subsequent commercial demand of these treatment therapies. If and when ABVC's assets are commercialized, we estimate rapid growth for both commencing in approximately 2023 – 2024. While it is difficult to know the revenue arc for ABVC at this stage, given the large need that both Vitargus and ABV-1505 address and the current cost of standard care, as well as the growing incidence of adult ADHD and vitreo-retinal procedures, we believe ABVC could attain product revenue of \$3.2 million in 2023 and \$14.5 million to \$16 million in 2024.

We believe these forecasts are supported by the growing size of the target markets and the ability of ABVC's treatment therapies to produce results with lower side effects. In fact, we believe that if the company maintains the timeline we expect and these candidates are commercialized by 2023, our forecast could prove conservative, particularly as the company continues to expand the applications of existing therapies and add new ones such as the dietary supplements noted earlier.

In our view, ABVC's differentiated products and programs imply that there are no direct publically traded peers. Moreover, we would also expect ABVC to have a higher growth rate in the early years of commercializing its drug candidates. In addition, the various other companies that are engaged in introducing new therapies and are at a similar stage of development have a wide range of price-to-revenue multiples on forward estimates. Nevertheless, we believe the average price-to-sales multiple of companies in this comparison of 14x provides a valuation benchmark for ABVC. The recent uplisting of ABVC shares to the Nasdaq is expected to boost awareness of the company and ABVC's prospects, as well as expand the pool of potential investors.

Therefore, applying a 14x multiple to our \$14.5 million to \$16 million 2024E revenue forecast and discounting back to the present at 10%/year results in a present value of nearly \$168 million to \$185 million for ABVC, or about \$9 to \$10 per share on a fully diluted basis. As the company expands the number of assets in its growing portfolio as it finds innovative therapies in the Asia-Pacific markets and introduces them in other geographies, our forecast could change.

We think the current share price does not reflect the fundamental value of the company's pipeline and prospects and would anticipate multiple expansion as the company continues to advance its candidates.

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.

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## RECENT NEWS

- On February 2, 2022, ABVC announced the principal investigator meeting for its Phase II Part 2 ADHD clinical study.
- On January 5, 2022, ABVC provided an update on additional Vitargus phase II Study sites.
- Vitargus was presented at the 14th APVRS Congress on December 22, 2021.
- ABVC BioPharma introduced a maitake mushroom-based dietary supplement and entered into a \$3.0 million distribution agreement on December 9, 2021.
- ABVC reported 3Q21 results on November 15, 2021.
- The company completed its recent offering on August 6, 2021 and on November 11, 2021, announced an incremental \$4.2 million from the exercise of warrants.
- ABVC announced Central IRB approval for ABV-1505 Phase II Part II in Taiwan sites on October 27, 2021.
- On October 12, 2021, ABVC restructured its JV to facilitate identifying new candidates to expand its portfolio.
- ABVC completed the site selection for its ABV-1505 ADHD Phase II Part 2 study on September 13, 2021.
- ABVC announces new PCT filings for MDD and ADHD treatments on September 1, 2021.
- The company's name change became effective on May 3, 2021.

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## 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 \$)

	2018	2019	1Q20	2Q20	3Q20	4Q20A	2020A	1Q21A	2Q21A	3Q21A	4Q21E	2021E
Revenues	\$6,956	\$701,719	\$78,786	\$226,513	\$115,553	\$62,193	\$483,045	\$263,150	\$31,441	\$98,999	\$195,289	\$588,879
COGs	185,280	20,137	3,959	4,236	8,619	1,902	18,716	1,245	646	393	13,135	15,419
Gross profit	(178,324)	681,582	74,827	222,277	106,934	60,291	464,329	261,905	30,795	98,606	182,154	573,460
Gross margin	nm	97%	95%	98%	93%	97%	96%	100%	98%	99.6%	93%	97%
S,G&A	1,588,718	3,069,493	1,152,889	1,277,133	1,262,199	581,247	4,273,468	1,167,595	1,231,692	1,579,996	2,534,694	6,513,977
R&D	988,721	1,048,553	92,790	139,082	134,501	183,285	549,658	121,315	358,878	263,424	11,735	755,352
Stock-based compensation	28,800	22,314	525	75	-	4,146,379	4,146,979	225,740	475,740	225,740	(701,020)	226,200
Total operating expenses	2,606,239	4,140,360	1,246,204	1,416,290	1,396,700	4,910,911	8,970,105	1,514,650	2,066,310	2,069,160	1,845,410	7,495,530
Operating (loss)/profit	(2,784,563)	(3,458,778)	(1,171,377)	(1,194,013)	(1,289,766)	(4,850,620)	(8,505,776)	(1,252,745)	(2,035,515)	(1,970,554)	(1,663,256)	(6,922,070)
Interest income	5,212	23,344	10,720	9,350	19,571	31,404	71,045	52,529	10,722	9,333	38,294	110,878
Interest expense	(462,751)	(482,014)	(131,517)	(140,525)	(16,311)	(116,679)	(405,032)	(130,229)	(82,671)	(38,677)	(14,168)	(265,745)
Other income	(3,187,525)	(92,833)	(57,656)	(907,513)	(889,360)	(119,644)	(1,974,173)	84,098	162	37,987	(15,610)	106,637
Total other income / (expenses)	(3,645,064)	(551,503)	(178,453)	(1,038,688)	(886,100)	(204,919)	(2,308,160)	6,398	(77,005)	8,643	8,516	(53,448)
Pretax (loss)/income	(6,429,627)	(4,010,281)	(1,349,830)	(2,232,701)	(2,175,866)	(5,055,539)	(10,813,936)	(1,246,347)	(2,112,520)	(1,961,911)	(1,654,740)	(6,975,518)
Provision for income tax	(365,097)	(77,041)	(40,568)	(48,644)	(44,735)	(86,405)	(220,352)	(51,024)	(59,564)	(75,667)	(25,150)	(211,405)
Net loss	(6,064,530)	(3,933,240)	(1,309,262)	(2,184,057)	(2,131,131)	(4,969,134)	(10,593,584)	(1,195,323)	(2,052,956)	(1,886,244)	(1,629,590)	(6,764,113)
Noncontrolling interests	(489,151)	(291,464)	(61,724)	(334,760)	(285,085)	(120,851)	(802,420)	(66,818)	(81,390)	(79,756)	(543,056)	(771,020)
Net loss attributed to ABVC	(5,575,379)	(3,641,776)	(1,247,538)	(1,849,297)	(1,846,046)	(4,848,283)	(9,791,164)	(1,128,505)	(1,971,566)	(1,806,488)	(1,086,534)	(5,993,093)
FX	(87,912)	7,902	(6,451)	(10,568)	(25,384)	(56,490)	(98,893)	36,140	364,581	16,137	(443,804)	(26,946)
Comprehensive loss	(5,663,291)	(3,633,874)	(1,253,989)	(1,859,865)	(1,871,430)	(4,904,773)	(9,890,057)	(1,092,365)	(1,606,985)	(1,790,351)	(1,530,338)	(6,020,039)
<i>Per share data</i>												
LPS	(\$0.48)	(\$0.21)	(\$0.06)	(\$0.09)	(\$0.09)	(\$0.24)	(\$0.50)	(\$0.05)	(\$0.08)	(\$0.07)	(\$0.04)	(\$0.23)
Avg shares out	11,607,103	17,498,543	19,484,542	19,488,168	19,488,168	20,401,358	19,715,559	24,420,526	24,421,082	26,882,181	26,883,181	25,651,743

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

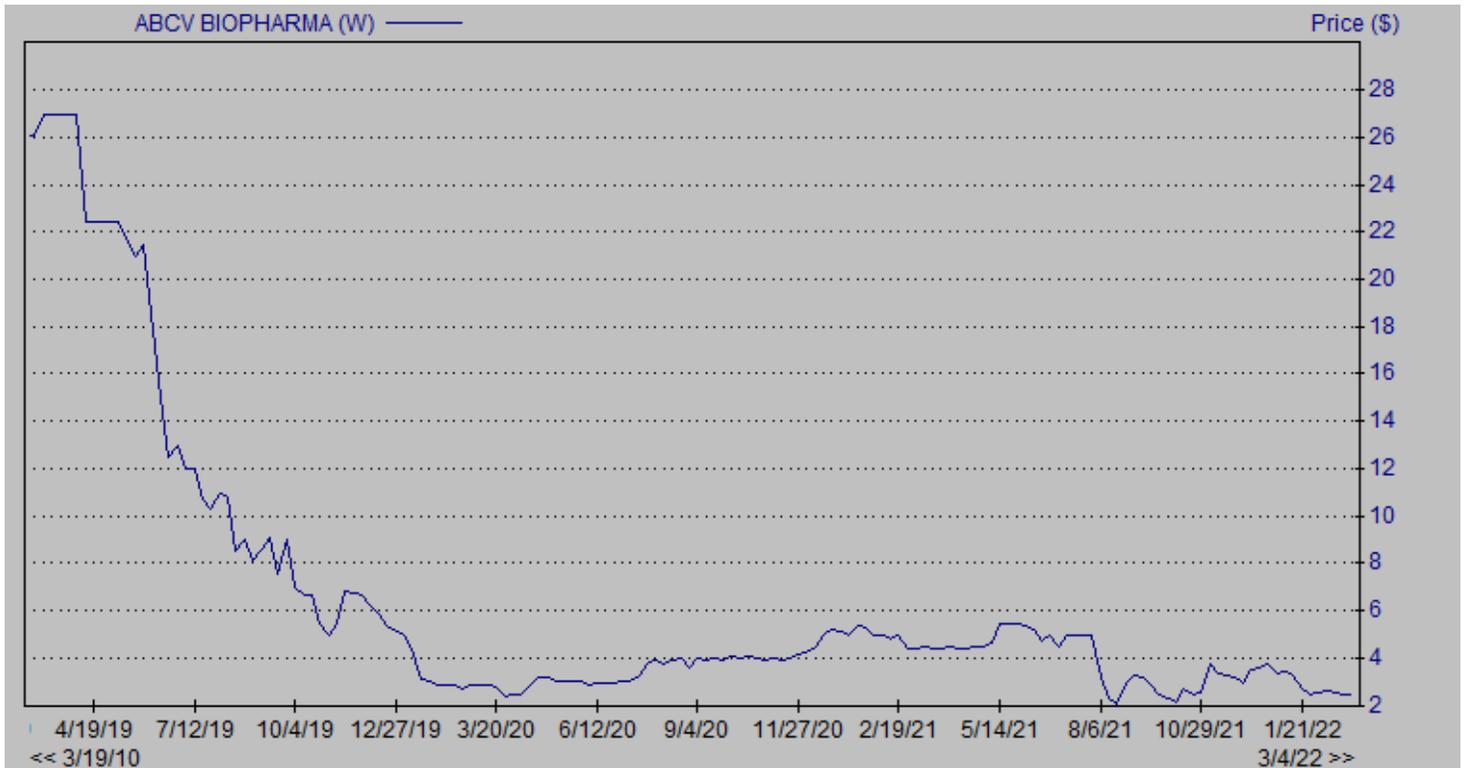
Principal Investigator: Andrew E. Hendifar, MD  
Cedars Sinai Medical Center (CSMC)

**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

## HISTORICAL STOCK PRICE



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