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M. Marin
312-265-8211
mmarin@zacks.com

scr.zacks.com

10 S. Riverside Plaza, Chicago, IL 60606

American BriVision (ABVC-OTC)

ABVC: Developing a Growing Portfolio Of Therapies With Strong Prospects

ABVC is a biopharma and medical device company developing a diversified portfolio of therapies for a range of conditions. The company currently has six drugs and one medical device under development, with two lead assets moving through in advanced stages of development.

Current Price (1/21/21)	$5.05
Valuation	**$9.50**

OUTLOOK

ABVC's strategy is to find new products that have already shown efficacy in Asia-Pacific countries and introduce them to other international markets under licensing arrangements. The company has two lead assets and has moved drug candidate ABV-1505 through phase II part I clinical trials for treatment in adult attention deficit hyperactivity disorder (ADHD), which was completed with a Clinical Study Report (CSR) issued on October 24, 2020. Moreover, ABVC is also expanding the active ingredient in ABV-1505, PDC-1421, into trials evaluating its efficacy in treating major depressive disorder (MDD) in cancer patients. An important factor that distinguishes ABVC's product portfolio from those of many other biopharma companies is that ABVCs assets primarily are derived from botanical sources.

SUMMARY DATA

52-Week High	**$5.65**
52-Week Low	**$2.00**
One-Year Return (%)	**N/A**
Beta	**0.31**
Average Daily Volume (sh)	**1,584**
Shares Outstanding (mil)	**24**
Market Capitalization ($mil)	**$121**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**63**
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 2020 Estimate	**N/A**
P/E using 2021 Estimate	**N/A**
Zacks Rank	**N/A**

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

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 E	1 E
2021					1 E

Price/Sales Ratio (Industry = 2.5x)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	$0.00 A	$0.00 A	$0.00 A	$0.00 A	$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	-$0.09 E	-$0.34 E
2021					-$0.24 E

Quarters might not sum due to rounding & share counts

Disclosures on page 15

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KEY POINTS

- **We are initiating coverage of American BriVision**, a biopharma and medical device company developing therapies for a range of conditions focused on oncology/hematology, central nervous system (CNS) and ophthalmology. ABVC's strategy is to find new products that have already shown efficacy in the Asia-Pacific region and introduce them to other international markets via licensing arrangements. The company is developing several clinical and business initiatives that management believes hold the potential for important milestones and catalysts.

- American BriVision currently has six drugs and one medical device under development, with two lead assets that are in advanced stages of development in multiple programs. One important factor distinguishing ABVC's products from those of many other drug candidates is that all of the company's products are derived primarily from plants. ABVC has a growing pipeline of assets.

- ABV-1505 is one of ABVC's two lead assets. The company has moved ABV-1505 through a phase II part I clinical trial for treatment in adult attention deficit hyperactivity disorder (ADHD), which was completed with a Clinical Study Report (CSR) issued on October 24, 2020. Moreover, given the observed improvements in patients enrolled in the trial, ABVC is expanding the active ingredient of ABV-1505, PDC-1421, into trials evaluating its efficacy in treating major depressive disorder (MDD) in cancer patients.

- Vitargus, ABVC's other primary asset, is a device that is used to replace vitreous in the eye during surgery. In 4Q20, ABVC issued a full CSR report of its Vitargus® first-in-human phase I clinical trial that 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.

- We are optimistic about the chances of ABV-1505 and Vitargus receiving FDA approval and of the subsequent commercial demand of these treatment therapies. We estimate rapid growth for both once they are commercialized.

COMPANY OVERVIEW

Two Lead Drug Candidates; Potentially Multiple Programs

California-based American BriVision (OTC: 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. The company has a diversified drug asset portfolio. Among ABVC's active pipeline of six drugs and one medical device (ABV-1701/Vitargus®) under development, two lead products – ABV-1505 and Vitargus – are in advanced stages of development and also have the potential for multiple programs. For instance, in addition to ABV-1505, which ABVC has moved through phase II part I clinical trials for treatment in adult attention deficit hyperactivity disorder (ADHD), ABVC is also expanding the program to study the active ingredient in ABV-1505, PDC-1421, in trials evaluating its efficacy in treating MDD. The company's other lead asset is its medical device Vitargus®, which has completed phase I clinical trials.

ABVC Drugs & their 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-1702
			MYELODYSPLASTIC SYNDROME

Source: Company reports Grey shading indicates two lead assets

Expanding Product Portfolio

The company also has ABV-1702, ABV-1501, ABV-1601 and ABV-1703 in earlier stages of development. 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 expects to initiate an ABV-1601 phase II part 1 clinical trial for the treatment of MDD in cancer patients at Cedars-Sinai Medical Center in Los Angeles in 1Q 2021 and to finalize the CSR by year-end 2021.

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.

Focus on Botanical Sources

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. In 2021, ABVC intends to focus on establishing a secure supply chain of medicinal plants from international sources, including China and possibly Canada.

Partnership Prospects

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.

ABVC completed Phase I and Phase II clinical trials of ABV-1504 in 2013 and intends to seek a Big Pharma partner to complete a Phase III study, submit the New Drug Application (NDA) to the FDA, and commercialize the drug upon approval by the FDA and the Taiwanese regulatory authorities. Based on early discussions with potential Big Pharma licensing partners for the manufacture and distribution of ABV-1504, ABV-1505 and ABV-1601, ABVC is optimistic about the prospects of a partnership opportunity and also that they can demonstrate the availability of a secure and consistent supply source for the botanical active ingredient, *polygala tenuifolia*. ABVC also intends to seek a commercialization partner for Vitargus® in 2021 (see below).

In addition to signing new partners to help finance and accelerate the development of products in its portfolio, ABVC also intends to strengthen its internal management team in order to support clinical trials and expand its product pipeline. The company has indicated that it is also considering additional financing in 2021 to support growth.

ADVANCING TWO LEAD ASSETS, ABV-1505 & VITARGUS

Two Lead Asset Candidates; Multiple Programs

The company believes that both of its clinical programs for ABV-1505 and Vitargus address markets with sizable needs and provide an avenue of potential regulatory approval from the FDA. Both have already gone through phase II clinical trials and are moving forward towards advanced studies.

The open label trial for ABV-1505 was designed for the enrollment of six adult ADHD patients and was conducted at University of California San Francisco (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 company expects ABV-1505 to be equally or even more effective than many of the medications currently available to relieve ADHD sufferers. Additionally, the company expects that if patients experience any, side effects from the ABV-1505, they will be mild to moderate. Both ABV-1504 and ABV-1505 are derived primarily from the plant-based compound PDC-1421.

The phase II part I clinical trial for ABV-1505 in adult attention deficit hyperactivity disorder (ADHD) was completed on July 22, 2020. A Clinical Study Report (CSR) was issued on October 24, 2020 and submitted to the FDA. ABVC expects to advance into a phase II part II study of ABV-1505 in 2Q 2021 at UCSF, as well as at medical centers in Taiwan. Additionally, the company is optimistic that discussions with Big Pharma companies for funding for phase III clinical trials and distribution will also move forward.

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.

Vitargus

Clinical Study Report for Vitargus First-in-Human Phase I Clinical Trial

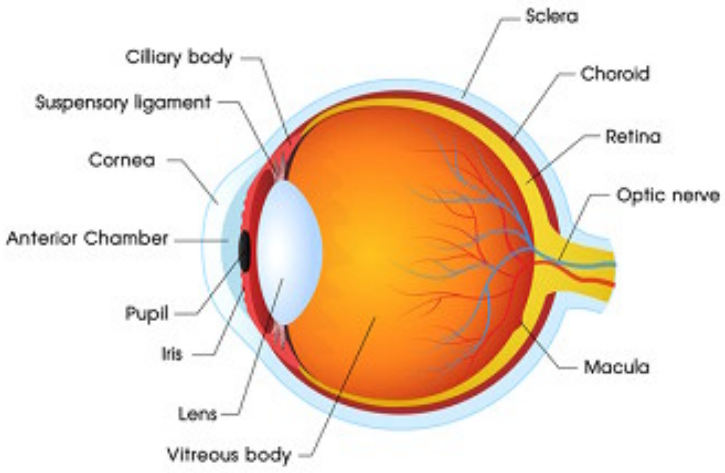
Vitreous is a gel-like fluid that attaches to the retina and fills the human eye. Vitargus®, or ABV-1701, is a biodegradable hydrogel vitreous substitute. In 4Q20, the company also issued a full CSR of its Vitargus® first-in-human phase I clinical trial. The study was an open label trial conducted at 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.

Eye Anatomy



Source: www.shutterstock.com

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. As a result of the trial, the company has been in discussions with several potential distribution partners seeking to work together for the upcoming pivotal trial phase, as well as the marketing and commercialization of Vitargus.

ABVC expects approval from the Australia Therapeutic Goods Administration (TGA) could come in 1Q 2021, which would enable the company to move forward with the pivotal clinical trial for Vitargus®. ABVC also intends to seek a commercialization partner for Vitargus® in 2021, as noted. With the assistance of a partner to fund the trial and expected subsequent commercialization, ABVC believes the revenue prospects for Vitargus® could begin to be realized fairly shortly after the trial is completed.

Extending Applicability Moreover, 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.**

ABVC targets execution of a licensing agreement with a Chinese pharmaceutical company in 1H 2021 to distribute the corneal storage solution in China. Any licensing agreement would require the Chinese partner to:

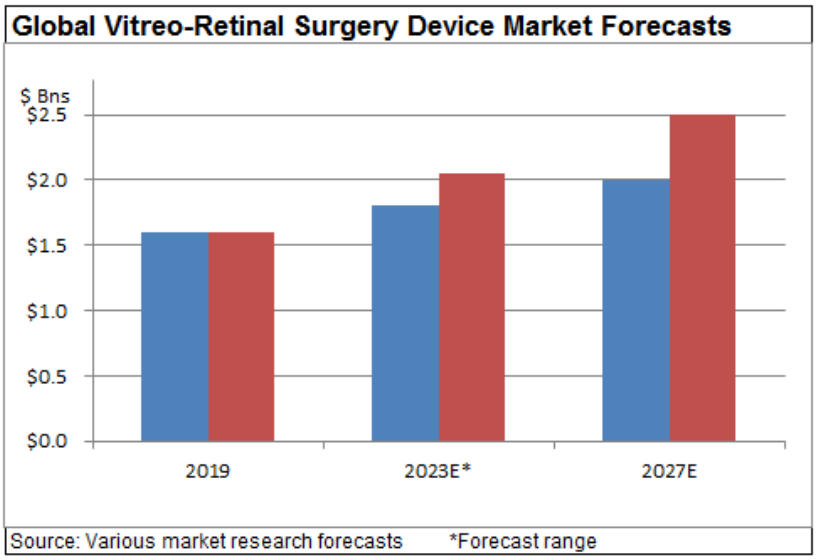
- finance the successful process to obtain regulatory approval for marketing in China;
- pay ABVC milestone payments beginning in 1H 2021

The company also intends to submit a premarket notification 510(K) submission to the FDA and the Taiwanese regulatory authority by year-end 2021 to demonstrate that ABV-2002 is at least as safe and effective as existing products currently on the market.

LEAD CANDIDATES: ADDRESSABLE MARKETS

Vitargus

Driven in part 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.

ADHD

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.

GROWING IP PORTFOLIO

American BriVision continues to pursue patent protection for its assets. For instance, ABVC subsidiary BioLite utilizes has patents on Yukiguni Maitake Extract 404, the API in ABV-1702, ABV-1703 and ABV-1501, which is patented in Japan and China.

Separately, the company recently announced that it had filed two new patents with the US Patent and Trademark Office (USPTO) for the treatment of MDD and ADHD. Patent # US 16/936,032, *Polygala Extract for the Treatment of Major Depressive Disorder,* outlines a method for treating MDD by the patient's oral administration of a composition containing Radix Polygalae (Polygala tenuifolia Willd) extract (which is the main ingredient in PDC-1421). Patent # P200032-US, *Polygala Extract for the*

Treatment of Attention-deficit Hyperactivity Disorder (ADHD) outlines a method for treating ADHD by administering a composition comprising a Radix Polygalae (*Polygala tenuifolia* Willd) extract. PDC-1421 can be prepared into a solid dosage form in a gelatin capsule.

The company has also filed the patent applications in Taiwan and will be filed under the Patent Cooperation Treaty (PCT). This treaty extends the patent legal protection in other countries. ABVC believes that if the new patents are granted, they will enhance the company's existing patent portfolio of Polygala tenuifolia Willd extract (PDC-1421) by strengthening ABVC's worldwide IP position for the treatment of MDD and ADHD and provide product exclusivity through 2040.

MANAGEMENT

CEO

Dr. Howard Doong is ABVC's CEO. He was appointed CEO in September of 2017. He also serves as CEO and Chief Scientific Officer of LifeCode Biotechnology Company, which is a Taiwan company that conducts medical research and provides cancer-related and genetic testing services.

Prior to joining ABVC, Dr. Doong served as the CSO of Taiwan-based biotech company Cold Spring Biotech Corporation from 2014 to 2016 and before that was the director of the Taipei Veteran General Hospital Laboratory of Cancer Genomic Medicine, a CAP-certified medical laboratory, from 2011 to 2013.

Dr. Doong was also a professor at the University of Maryland Medical School and a researcher at National Cancer Institute of the National Institutes of Health (NIH). He was a VP of TrimGen Corp., a Maryland-based company that manufactures molecular diagnostic reagents and medical instruments. He was also a clinical research fellow at the Department of Surgery, University of Chicago Hospital and a researcher at the joint program of Harvard-MIT Health Sciences and Technology.

CFO

Chihliang An was appointed CFO on September 1, 2019. Prior to that, he was a managing director of Yinyai Investment in Hong Kong from September 2018 to June 2019 and before that, he was a Senior Director of Sales and Operations at Goertek in the U.S. from March 2017 to August 2018. From March 2015 through February 2017, he was the Director of Finance at ABVC's subsidiary BioKey, Inc.

Chief Science Officer

Dr. Chi-Hsin Richard King is ABVC's Chief Science Officer. From June 2005 to July 2017, he worked at Taiwan-based biotech company TaiGen Biotechnology Co., which develops therapeutics for infectious diseases, cancer and diabetes-related complications. He served in various positions at TaiGen, including SVP of R&D.

Prior to that, Dr. King was a director at Albany Molecular Research Inc. in New York state from 1997 through 2005 in various positions, including assistant director at the Medicinal Chemistry and Chemical Development departments.

Insiders collectively own about 63% of ABVC shares. This makes insider interests aligned with those of public shareholders and also makes ABVC a controlled company.

RECENT NEWS

- On January 6, 2021, ABVC issued a shareholder letter outlining its 2020 achievements and 2021 outlook.
- American BriVision issued an update on its phase II part I clinical trial for ABV-1505 in adult attention-deficit hyperactivity disorder (ADHD) on November 09, 2020.
- ABVC issued a Clinical Study Report for Vitargus first-in-human phase I clinical trial on September 9, 2020.
- On August 24, 2020, ABVC announced that it had filed a new patent for the treatment of major depressive disorder.
- ABVC reported that it had completed its ABV-1505 phase II part I clinical trial for the treatment of adult ADHD on Jul 28, 2020.

RECENT RESULTS AND FINANCIAL PROFILE

ABVC is largely pre-revenue at this stage. Most of ABVC's revenue comes from the CDMO business unit, which provides services such as pre-formulation studies and regulatory review of submission documents, among other services. Through September 30, 2020, the company generated 2020 revenue of $420,852 compared to $601,757 for the same period of 2019. The year-over-year decline primarily reflected the impact of COVID-19, as several of ABVC's clients postponed projects.

ABVC expects a potential licensing agreement for the clinical development and subsequent commercialization of Vitargus to be the first meaningful revenue it produces from its drugs and medical device portfolio.

Balance Sheet

As of the end of 3Q20, the company had about $136,000 of cash and equivalents. The company has focused on streamlining its capital structure and strengthening its balance sheet. In 2020, ABVC raised more than $8.0 million through the issuance of new equity and converted approximately $4.0 million of debt to equity. ABVC had debt of about $2.4 million at the end of 3Q20. In March of 2019, the company implemented a reverse 18:1 stock split.

The company has indicated that it is considering implementing additional financings in 2021 to support its growth efforts, as noted.

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. In terms of the potential commercial appeal for both programs, the dearth of effective therapies that have the limited side effects as these have, combined with high related healthcare costs of alternate existing treatments could translate, we believe, into high demand for ABVC's therapies following clinical studies.

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. Moreover, if ABVC is successful in signing well-capitalized partners for various assets, the company expects to receive milestone payments beginning as early as 1H 2021.

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.

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 of about $5.00 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.

RISKS

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

- 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.

PROJECTED FINANCIALS

American BriVision Income Statement & Projections (US $)

	2018	1Q19	2Q19	3Q19	4Q19	2019	1Q20	2Q20	3Q20	4Q20E	2020E	2021E	2022E	2023E	2024E
Revenues	$6,956	$212,242	$191,782	$197,733	$99,962	$701,719	$78,786	$226,513	$115,553	$116,709	$537,561	$806,341	$886,975	$3,225,363	$14,514,134
COGs	185,280	1,499	13,352	2,797	2,489	20,137	3,959	4,236	8,619	7,625	24,439	28,962	23,307	1,451,413	6,451,533
Gross profit	(178,324)	210,743	178,430	194,936	97,473	681,582	74,827	222,277	106,934	109,083	513,121	777,379	863,668	1,773,950	8,062,602
Gross margin	nm	99%	93%	99%	98%	97%	95%	98%	93%	93%	95%	96%	97%	55%	56%
S,G&A	1,588,718	510,803	571,669	1,041,319	945,702	3,069,493	1,152,889	1,277,133	1,262,199	1,274,821	4,967,042	6,208,802	7,761,003	8,537,103	9,049,330
R&D	988,721	421,956	87,769	269,239	269,589	1,048,553	92,790	139,082	134,501	135,846	502,219	627,774	784,717	863,189	932,244
Stock-based compensation	28,800	8,550	7,800	-	5,964	22,314	525	75	-	-	600	540	485	435	390
Total operating expenses	2,606,239	941,309	667,238	1,310,558	1,221,255	4,140,360	1,246,204	1,416,290	1,396,700	1,410,667	5,469,861	6,837,116	8,546,205	9,400,727	9,981,964
Operating (loss)/profit	(2,784,563)	(730,566)	(488,808)	(1,115,622)	(1,123,782)	(3,458,778)	(1,171,377)	(1,194,013)	(1,289,766)	(1,301,584)	(4,956,740)	(6,059,737)	(7,682,537)	(7,626,777)	(1,919,362)
Interest income	5,212	189	1,066	6,024	16,065	23,344	10,720	9,350	19,571	19,767	59,408	62,378	65,497	68,772	72,210
Interest expense	(462,751)	(129,886)	(132,686)	(111,968)	(107,474)	(482,014)	(131,517)	(140,525)	(16,311)	(16,474)	(304,827)	(335,310)	(321,897)	(309,022)	(296,661)
Other income	(3,187,525)	(70,599)	(35,637)	(59,564)	72,967	(92,833)	(57,656)	(907,513)	(889,360)	(898,254)	(2,752,783)	(550,557)	(275,278)	(264,267)	(253,696)
Total other income / (expenses)	(3,645,064)	(200,296)	(167,257)	(165,508)	(18,442)	(551,503)	(178,453)	(1,038,688)	(886,100)	(894,961)	(2,998,202)	(823,488)	(531,679)	(504,517)	(478,147)
Pretax (loss)/income	(6,429,627)	(930,862)	(656,065)	(1,281,130)	(1,142,224)	(4,010,281)	(1,349,830)	(2,232,701)	(2,175,866)	(2,196,545)	(7,954,942)	(6,883,226)	(8,214,216)	(8,131,294)	(2,397,509)
Provision for income tax	(365,097)	(57,545)	(40,798)	48,555	(27,253)	(77,041)	(40,568)	(48,644)	(44,735)	(45,182)	(179,129)	(180,921)	(182,730)	(184,557)	(186,403)
Net loss	(6,064,530)	(873,317)	(615,267)	(1,329,685)	(1,114,971)	(3,933,240)	(1,309,262)	(2,184,057)	(2,131,131)	(2,151,362)	(7,775,812)	(6,702,305)	(8,031,486)	(7,946,737)	(2,211,106)
Noncontrolling interests	(489,151)	(81,646)	(56,877)	(114,826)	(38,115)	(291,464)	(61,724)	(334,760)	(285,085)	(287,936)	(969,505)	(979,200)	(988,992)	(998,882)	(1,008,871)
Net loss attributed to ABVC	(5,575,379)	(791,671)	(557,576)	(1,214,859)	(1,077,670)	(3,641,776)	(1,247,538)	(1,849,297)	(1,846,046)	(1,863,426)	(6,806,307)	(5,723,105)	(7,042,494)	(6,947,855)	(1,202,235)
FX	(87,912)	(86,786)	61,061	(61,061)	94,688	7,902	(6,451)	(10,568)	(25,384)	(25,638)	(68,041)	(68,721)	(69,408)	(70,103)	(70,804)
Comprehensive loss	(5,663,291)	(878,457)	(496,515)	(1,275,920)	(982,982)	(3,633,874)	(1,253,989)	(1,859,865)	(1,871,430)	(1,889,064)	(6,874,348)	(5,791,826)	(7,111,903)	(7,017,957)	(1,273,039)
Per share data															
LPS	($0.48)	($0.05)	($0.03)	($0.06)	($0.06)	($0.21)	($0.06)	($0.09)	($0.09)	($0.09)	($0.34)	($0.24)	($0.29)	($0.29)	($0.05)
Avg shares out	11,607,103	14,965,665	17,422,988	19,020,824	18,584,695	17,498,543	19,484,542	19,488,168	19,488,168	21,000,000	19,865,220	24,000,100	24,000,300	24,000,500	24,000,700

Source: Company reports & Zacks

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APPENDIX: CLINICAL TRIAL HIGHLIGHTS

Highlights of some institutions currently or recently 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

*Planned launch in 2021

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