Blue Water Biotech Reports First Quarter 2023 Financial Results and Recent Business Highlights

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CINCINNATI, May 12, 2023 (GLOBE NEWSWIRE) -- Blue Water Biotech, Inc. (“Blue Water” or the “Company”), a biotechnology company spanning multiple sectors, today announced its financial results for the quarter ended March 31, 2023 and provided an update on recent business developments and Company progress. Blue Water Biotech is a biological and pharmaceutical technology company developing multiple preclinical vaccine candidates across various infectious diseases and owns the FDA-approved benign hyperplasia (“BPH”) asset, ENTADFI ®.

“Blue Water’s recent growth is highlighted by our acquisition of ENTADFI ®, as well as our subsequent rebranding initiative and name change to reflect our transition into a commercial-stage biotechnology company,” said Joseph Hernandez, Chairman and Chief Executive Officer of Blue Water. “We believe this product has the potential to be transformative for men suffering from BPH, and we are confident that our experienced management team will be the driving force behind ENTADFI®s anticipated success. We are also excited to bring in an approved asset to support the operations for our preclinical vaccine programs, including our *Streptococcus pneumoniae* vaccine candidate that is progressing towards clinical trials in the near term.”

Q1 2023 and Recent Corporate Developments

- In April 2023, Blue Water announced the acquisition of ENTADFI®, an FDA-approved treatment for BPH that counteracts negative sexual side effects seen in men on alternative BPH therapies.
    - Under the asset purchase agreement, Blue Water purchased ENTADFI® for a total consideration of up to $100 million, with $20 million upfront, paid in defined tranches through September 2024, and the possibility of an additional $80 million based on predetermined annual sales milestones.
    - Following this acquisition, Blue Water announced in April 2023 that the Company changed its corporate name to Blue Water Biotech, Inc. to reflect its transition into a commercial-stage company.
- In February 2023, Blue Water announced the appointment of seasoned commercial operations leader Frank Jaeger as Senior Vice President of Marketing and Business Development. Blue Water will leverage Mr. Jaeger’s experience, specifically in Men’s Health through his experience with JATENZO® and AndroGel 1.62%, in the official launch of ENTADFI® and its anticipated success within the BPH market.
- Throughout the first quarter of 2023 and beyond, Blue Water management presented its corporate overview and Company updates at key investor, financial, and scientific conferences to highlight the value story of the Blue Water pipeline and target leaders within the investment community.
    - In January 2023, Blue Water presented an overview of its vaccine candidate pipeline and progress at Biotech Showcase 2023 during the 41st annual J.P. Morgan Healthcare Conference Week in San Francisco, California. In addition, Blue Water management participated in the World Vaccine Congress in Washington D.C. in April 2023.
    - To promote ENTADFI® and connect with key leaders in the urology space, Blue Water management sponsored a booth at the American Urological Association Annual Meeting 2023 in Chicago, Illinois.

- In January 2023, Blue Water announced the appointment of seasoned public market and private equity investment leader, Timothy Ramdeen, to its board of directors. Mr. Ramdeen has nearly a decade of experience in private equity and hedge fund investing, capital markets, and company formation.

Q1 2023 and Recent Vaccine Candidate Developments

- In February 2023, Blue Water announced a partnership with AbVacc, Inc. (“AbVacc”) for the joint development of novel vaccine candidates targeting monkeypox and Marburg virus disease, among others. The vaccine candidates will utilize Blue Water’s norovirus shell and protrusion virus-like particle platform, which allows for the presentation of multiple antigens on the surface of either the S or P particle of a norovirus backbone. Under this partnership, Blue Water and AbVacc will work collaboratively to identify appropriate antigens to use within this platform and will work toward clinical development of vaccine candidates.
- In March 2023, Blue Water signed a sponsored research agreement with The University of Texas Health Science Center at San Antonio to initiate a non-human primate study for Blue Water’s live attenuated, orally delivered Chlamydia vaccine, BWV-401. In this study, non-human primates will be vaccinated with BWV-401 and subsequently challenged against Chlamydia to validate they hypothesis that this vaccine is both safe and efficacious in a human-like model.

Q1 2023 Financial Highlights

- **Cash Position:** Cash was $20.3 million as of March 31, 2023, as compared to $25.8 million as of December 31, 2022. The decrease was primarily due to an increase in various business activities to support company growth, as well as increased research and development activities.
- **Research and Development Expenses:** For the three months ended March 31, 2023, research and development expenses increased by approximately $0.6 million compared to the same period in 2022. The increase was primarily attributable to an increase in preclinical development activities of approximately $0.3 million mainly related to BWV-101 and BWV-201, and an increase in research and development personnel costs.
- **General and Administrative Expenses:** For the three months ended March 31, 2023, general and administrative expenses increased by $0.2 million compared to the same period in 2022. The increase was mainly due to an increase in professional fees and an increase in various business activities related to company growth and development, such as business advisory services, travel, and rent expenses. These increases were offset by a decrease in employee compensation, as well as a non-recurring expense in the three months ended March 31, 2022 to early terminate an agreement with an underwriter, with no similar expense in the current period.
- **Other Income:** Other income relates to the change in fair value of the contingent warrant liability, which was incurred at the close of the Company’s private placements in April and August 2022. There was no other income or expense during the three months ended March 31, 2022.
- **Net Loss:** Net loss was approximately $2.8 million for the three months ended March 31, 2023, as compared to $2.1 million for the same period in 2022. The increase is primarily due to research and development of preclinical vaccine candidates.

Condensed Balance Sheets

	March 31, 2023	December 31, 2022
ASSETS	**(Unaudited)**	
Current assets		
Cash	$ 20,255,803	$ 25,752,659
Restricted cash	1,000,000	—
Prepaid expenses and other current assets	780,173	469,232
Deferred offering costs	366,113	—
Receivable from related parties	70,302	35,850
Total current assets	22,472,391	26,257,741
Prepaid expenses, long-term	15,500	38,617
Property and equipment, net	14,210	14,089
Total assets	**$ 22,502,101**	**$ 26,310,447**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 1,503,262	$ 1,499,296
Accrued expenses	1,292,951	2,409,128
Contingent warrant liability	12,406	14,021
Total current liabilities	2,808,619	3,922,445
Total liabilities	**2,808,619**	**3,922,445**
Commitments and Contingencies		
Stockholders' equity		
Preferred stock, $0.00001 par value, 10,000,000 shares authorized at March 31, 2023 and December 31, 2022; 0 shares issued and outstanding at March 31, 2023 and December 31, 2022	—	—
Common stock, $0.00001 par value, 250,000,000 shares authorized at March 31, 2023 and December 31, 2022; 16,371,597 and 15,724,957 shares issued at March 31, 2023 and December 31, 2022, respectively; 15,879,230 and 15,265,228 shares outstanding at March 31, 2023 and December 31, 2022, respectively	164	157
Additional paid-in-capital	42,516,726	42,331,155
Treasury stock, at cost; 492,367 and 459,729 shares of common stock at March 31, 2023 and December 31, 2022, respectively	(600,264)	(566,810)
Accumulated deficit	(22,223,144)	(19,376,500)
Total stockholders' equity	19,693,482	22,388,002
Total liabilities and stockholders' equity	**$ 22,502,101**	**$ 26,310,447**

BLUE WATER BIOTECH, INC.
Condensed Statements of Operations
(Unaudited)

	Three Months Ended March 31, 2023	Three Months Ended March 31, 2022
Operating expenses		
General and administrative	$ 1,766,022	$ 1,615,569
Research and development	1,082,237	455,092
Total operating expenses	2,848,259	2,070,661
Loss from operations	(2,848,259)	(2,070,661)
Other income		
Change in fair value of contingent warrant liability	(1,615)	—
Total other income	(1,615)	—
Net loss	**$ (2,846,644)**	**$ (2,070,661)**
Cumulative preferred stock dividends	—	96,359
Net loss applicable to common stockholders	(2,846,644)	(2,167,020)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.18)	$ (0.34)
Weighted average number of common shares outstanding, basic and diluted	15,910,415	6,339,435

About ENTADFI®

ENTADFI® is an oral, once daily treatment for BPH that combines finasteride, a 5α-reductase inhibitor, and tadalafil, a phosphodiesterase 5 (PDE5) inhibitor, offering a more effective treatment option compared to other available therapies. Clinical trials have shown that ENTADFI® is more effective in treating BPH symptoms, including urinary frequency, urgency, weak stream, and difficulty initiating or maintaining urination, compared to finasteride monotherapy. Additionally, ENTADFI® has demonstrated a favorable safety profile, with fewer adverse sexual side effects compared to finasteride. ENTADFI® reduces potential for adverse sexual side effects, making it a preferred choice for men seeking relief from BPH symptoms without compromising their sexual health. ENTADFI® has received FDA approval for the indication of initiating treatment of the signs and symptoms of BPH in men with an enlarged prostate for up to 26 weeks. More information about BPH and full ENTADFI® prescribing information can be found on the product website at https://entadfipatient.com/.

About Blue Water Biotech

Blue Water Biotech, Inc. is a biological and pharmaceutical technology company focused on developing and providing transformational therapies to address significant health challenges globally. Headquartered in Cincinnati, OH, the Company holds the rights to proprietary technology developed at the University of Oxford, Cincinnati Children's Hospital Medical Center, St. Jude Children's Hospital, and The University of Texas Health Science Center at San Antonio. Blue Water is developing a Streptococcus pneumoniae vaccine candidate, designed to specifically prevent highly infectious middle ear infections, known as acute otitis media (AOM), in children, and prevention of pneumonia in the elderly. The Company is also developing a universal flu vaccine that will provide protection from all virulent strains in addition to licensing a novel norovirus (NoV) S&P nanoparticle versatile virus-like particle (VLP) vaccine platform from Cincinnati Children's to develop vaccines for multiple infectious diseases, including Marburg and monkeypox, among others. Additionally, the Company is developing a Chlamydia vaccine candidate with UT Health Science Center San Antonio to prevent infection and reduce the need for antibiotic treatment associated with contracting Chlamydia disease. Outside of its vaccine franchise, Blue Water owns ENTADFI®, an FDA-approved, once daily pill that combines finasteride and tadalafil for the treatment of benign prostatic hyperplasia. This combination allows men to receive treatment for their symptoms of BPH without the negative sexual side effects typically seen in patients on finasteride alone. For more information about Blue Water, visit www.bwbioinc.com.

Forward-Looking Statements

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking words such as "anticipate," "believe," "forecast," "estimate," "expect," and "intend," among others. These forward-looking statements are based on Blue Water's current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, risks related to Blue Water's ability to realize the benefits of its acquisition of ENTADFI ®, risks related to BWV's ability to expand its business scope and its ability to commercialize ENTADFI®, risks related to the development of Blue Water's vaccine candidates; the failure to obtain FDA clearances or approvals and noncompliance with FDA regulations; delays and uncertainties caused by the global COVID-19 pandemic; risks related to the timing and progress of clinical development of our product candidates; our need for additional financing; uncertainties of patent protection and litigation; uncertainties of government or third party payor reimbursement; limited research and development efforts and dependence upon third parties; and substantial competition. As with any vaccine under development, there are significant risks in the development, regulatory approval and commercialization of new products. Blue Water does not undertake an obligation to update or revise any forward-looking statement. Investors should read the risk factors set forth in Blue Water's Annual Report on Form 10-K, filed with the Securities and Exchange Commission (the "SEC") on March 9, 2023 and periodic reports filed with the SEC on or after the date thereof. All of Blue Water's forward-looking statements are expressly qualified by all such risk factors and other cautionary statements. The information set forth herein speaks only as of the date thereof.

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