UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): July 11, 2023

Blue Water Biotech, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-41294**	**83-2262816**
(State or other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

201 E. Fifth Street, Suite 1900 Cincinnati, Ohio	**45202**
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code: **(513) 620-4101**

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	**Trading Symbol(s)**	**Name of Each Exchange on Which Registered**
Common Stock, par value $0.00001 per share	BWV	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

On July 11, 2023, Blue Water Biotech, Inc., a Delaware corporation (the "Company"), issued a press release announcing that it has entered into an agreement with Advantage Point Solutions, LLC to support the Company's market access strategy for its commercial pharmaceutical portfolio (the "Press Release"). The Press Release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1	Press Release, dated July 11, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Blue Water Biotech, Inc.

Date: July 11, 2023

By: /s/ Joseph Hernandez
Joseph Hernandez
Chief Executive Officer

Exhibit 99.1

Blue Water Biotech Teams with Advantage Point Solutions to Provide Healthcare Payer Coverage Support

Pharmaceutical consulting firm to provide Blue Water with access to healthcare payers and PBMs

CINCINNATI, OH, July 11, 2023 - Blue Water Biotech, Inc. ("Blue Water" or the "Company") (Nasdaq: BWV), a biotechnology and pharmaceutical company focused on developing and commercializing transformational therapies to address significant health challenges globally, today announced the signing of an agreement with Advantage Point Solutions, LLC ("APS") to support Blue Water's market access strategy for its commercial pharmaceutical portfolio.

Since the purchase of the approved product ENTADFI® in April and additional approved therapies purchased in June, Blue Water has made significant progress in the advancement of its commercial strategy through the establishment of key relationships and agreements. Blue Water's agreement with APS follows its recently announced agreements with IQVIA for the development of its medical sales representative team to market products to physicians and bfw Advertising ("bfw") for marketing and advertising services. Most recently, Blue Water was granted a license to operate as a pharmaceutical wholesaler in its home state of Ohio and will look to expand its licenses nationwide in the future. With these agreements in place, Blue Water believes it is assembling the key pieces to commercially launch and drive revenue from its approved product portfolio.

APS will support market access for ENTADFI®, including assistance in formulary negotiations with key healthcare payers and pharmacy benefit managers ("PBM") in the commercial and government sectors. With its robust network of relationships, APS helps commercial stage pharmaceutical companies build long-term relationships with payers with the goal of maximizing access and reimbursement for approved pharmaceutical products. APS also has decades of experience advising companies on product launches across a broad spectrum of therapeutic areas.

"Establishing proper payer and PBM coverage is critical to the success of any product launch, as well as continued coverage throughout the product life cycle to make sure patients can access affordable therapy," said Joseph Hernandez, Chairman and Chief Executive Officer of Blue Water. "As we progress towards the launch of ENTADFI®, we will look to secure placement on key formularies to enable the execution of our commercialization strategies and aim to expand existing formulary coverage for the newly acquired products. APS, with their proven track record of success in the market access space, will be an invaluable partner for us as we move through the commercial landscape. Moreover, we are grateful that industry veterans like APS, IQVIA and bfw are joining with us and validating our commercial plans."

About Blue Water Biotech

Blue Water Biotech, Inc. is a biotechnology and pharmaceutical company focused on developing and commercializing transformational therapies to address significant health challenges globally. Headquartered in Cincinnati, OH, the Company 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 benign prostatic hyperplasia without the negative sexual side effects typically seen in patients on finasteride alone. The Company is also in the process of acquiring the approved therapies from WraSer, LLC, and Xspire Pharma, LLC, including ZONTIVITY® (reduction of thrombotic cardiovascular events in patients with myocardial infarction or with peripheral arterial disease), OTOVEL® (acute otitis media with tympanostomy tubes), CETRAXAL® (acute otitis externa), CONJUPRI® (hypertension), TREZIX™ (moderate to severe pain) and NALFON® (NSAID treatment for pain and inflammation). The Company also has a robust vaccine pipeline. Blue Water 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 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 S&P nanoparticle versatile virus-like particle 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. For more information about Blue Water, visit www.bwbioinc.com.

About Advantage Point Solutions (APS)

APS launched in 2012 with a singular focus: to help pharmaceutical manufacturers bring new products to market in an ever-changing and complex payer environment. Our team has extensive real-world payer experience, which enables us to define ground-breaking clinical, formulary, coverage, contracting and financial strategies, as well as pull-through initiatives.

APS has extensive experience assisting pharmaceutical manufacturers to optimize their U.S. market access through effectively planning the payer pre-launch, launch and post-launch strategies, resulting in successful outcomes for our clients. APS can help manufacturer's looking to outsource their managed care account facing teams by working on behalf of our clients directly with payers on the full complement of formulary access and positioning responsibilities including the following: development of the pricing and contracting strategies as well as the planning and execution of the payer engagement to achieve the optimal access possible. For more information about APS, visit www.apsconsulting.com.

Cautionary Note Regarding 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 (including, without limitation, the anticipated benefits of the Company's agreement with APS and the anticipated results of the Company's sales and market efforts, each as described herein) 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 acquisitions of ENTADFI®, ZONTIVITY®, OTOVEL®, CETRAXAL®, CONJUPRI®, TREZIX™ and NALFON®; risks related to Blue Water's ability to expand its business scope, commercialize ENTADFI® and integrate the assets and commercial operations being acquired from WraSer into Blue Water's business; risks related to Blue Water's ability to attract, hire and retain skilled personnel and establish an effective sales team; risks related to Blue Water's ability to establish, maintain and optimize key third party commercial collaboration agreements (such as those with IQVIA, APS and bfw); risks related to the Company's present need for capital to close its asset acquisitions, commercially launch the Company's acquired products and have adequate working capital; risks related to the development of Blue Water's vaccine candidates; the failure to obtain FDA clearances or approvals and noncompliance with FDA regulations; risks related to the timing and progress of clinical development of our product candidates; 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 commercial-stage pharmaceutical product or any product candidate under clinical development, there are significant risks in the development, regulatory approval and commercialization of pharmaceutical 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.

Media Contact Information:
Blue Water Media Relations
Telephone: (646) 942-5591
Email: Nic.Johnson@russopartnersllc.com

Investor Contact Information:
Blue Water Investor Relations
Email: investors@bwbioinc.com