

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 7.01 Regulation FD Disclosure.

On December 7, 2020, VBI Vaccines Inc. (the “Company”) and Syneos Health (Nasdaq: SYNH) issued a press release announcing a partnership for the commercialization of the Company’s 3-antigen prophylactic hepatitis B (HBV) vaccine in the United States, Europe, and Canada, pending regulatory approvals. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

The Company undertakes no obligation to update, supplement or amend the materials attached hereto.

The information in this Current Report on Form 8-K (including Exhibit 99.1 attached hereto) is being furnished pursuant to Item 7.01 and shall not be deemed to be filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise be subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof and regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated December 7, 2020 (furnished pursuant to Item 7.01)
104	Cover Page Interactive Data File (formatted as Inline XBRL)

SIGNATURES

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

Date: December 7, 2020

By:*/s/ Jeff Baxter*

Jeff Baxter

President and Chief Executive Officer

VBI Press Release

VBI Vaccines Selects Syneos Health as Commercialization Partner for Prophylactic 3-Antigen Hepatitis B Vaccine

- VBI and Syneos Health partner to prepare for commercial launch of VBI's 3-antigen hepatitis B vaccine in the U.S., Europe, and Canada, pending regulatory approvals
- Syneos Health selected for their robust and innovative commercialization experience and deep vaccine expertise, including successful partnerships with leading vaccine manufacturers
- The BLA was submitted to FDA (U.S.) on November 30, 2020 and the MAA was submitted to EMA (Europe) on November 20, 2020

CAMBRIDGE, M.A. and Morrisville, N.C. (December 7, 2020) – VBI Vaccines Inc. (Nasdaq: VBIV) (VBI), a biopharmaceutical company developing next-generation infectious disease and immuno-oncology vaccines, and Syneos Health (Nasdaq: SYNH), the leading Contract Commercialization Organization (CCO) and the longest-tenured U.S. provider of outsourced sales teams, today announced a partnership for the commercialization of VBI's 3-antigen prophylactic hepatitis B (HBV) vaccine in the United States, Europe, and Canada, pending regulatory approvals. VBI and Syneos Health have been working together on the pre-launch strategy and activity since the fourth quarter of 2019. The companies have expanded their relationship to build the leadership team and field teams dedicated to VBI and incorporate full service commercialization solutions.

Jeff Baxter, VBI's President and CEO commented, "We are excited to announce this partnership with Syneos Health, which represents an innovative, flexible, and integrated approach to vaccine commercialization. VBI is committed to addressing significant unmet medical needs and we believe this vaccine could be an important additional public health intervention for healthcare providers as they work to address the increasing disease burden of hepatitis B in the U.S., Europe, and Canada. Over the last year, we have made significant progress on our roadmap to commercialization with Syneos Health and we move into 2021, and beyond, with a clear, joint mission and action plan to do so."

Michelle Keefe, President, Syneos Health Commercial Solutions, further commented, "This collaboration brings together robust expertise, experience, and networks from two impressive organizations. We believe this full service commercial engagement provides the insights and best-in-class capabilities needed to support a public health-centered launch of VBI's vaccine. Our focus is on reaching all adults who need safe and effective protection against HBV infection."

VBI will access Syneos Health's fully-integrated, outsourced commercial capabilities and proven delivery model to accelerate launch performance. The cross-functional Syneos Health team will create and execute a comprehensive commercialization strategy including market research, communications, field teams, and operations across Medical Affairs, Market Access, and Sales and Marketing. The commercial program will be powered by Syneos Health's Kinetic™ omnichannel capability, aimed at ensuring the right messages reach the right stakeholders at the right time, to drive product adoption and uptake. Syneos Health also brings a demonstrated track record of successfully commercializing vaccines in the North American and European markets with more launches, sales team creations, and recruiting experience than any other biopharmaceutical solutions company.

John Dillman will serve as the Syneos Health Commercial Lead for VBI, orchestrating Syneos Health's vast commercial capabilities to drive brand performance. Mr. Dillman previously spent 17 years at Sanofi Pasteur, the human vaccines business of the Sanofi Group, in a variety of commercial sales and marketing leadership roles. His most recent role was Vice President of Sales, responsible for direction and oversight of the sales force, marketing and sales training, and telesales organization, with full P&L responsibility delivering over \$3 billion of sales annually. During his tenure, Mr. Dillman was also responsible for all segment, consumer, and digital marketing activities, and spent three years as the General Manager of VaxServe, a Sanofi Pasteur company and a leading specialty distributor of vaccines.

About VBI's 3-Antigen Hepatitis B Vaccine

This vaccine is a 3-antigen hepatitis B vaccine, comprised of the S, pre-S1, and pre-S2 surface antigens of the hepatitis B virus, and is approved for use and commercially-available in Israel, under the name Sci-B-Vac®. In December 2017, VBI initiated a global Phase 3 clinical program that consisted of two concurrent pivotal studies: PROTECT, a safety and immunogenicity study, and CONSTANT, a lot-to-lot consistency study. Data from both the PROTECT study and the CONSTANT study, which were announced in June 2019 and January 2020, respectively, comprise the basis for the regulatory submissions in the U.S., Europe, and Canada.

To learn more about VBI's 3-antigen Hepatitis B vaccine, visit: <https://www.vbivaccines.com/sci-b-vac/>

About VBI Vaccines Inc.

VBI Vaccines Inc. (Nasdaq: VBIV) is a commercial-stage biopharmaceutical company developing a next generation of vaccines to address unmet needs in infectious disease and immuno-oncology. VBI is advancing the prevention and treatment of hepatitis B, with: (1) the only 3-antigen hepatitis B vaccine, which is approved for use and commercially available in Israel, under the name Sci-B-Vac®, and recently completed its Phase 3 program in the U.S., Europe, and Canada; and (2) an immunotherapeutic in development for a functional cure for chronic hepatitis B. VBI's enveloped virus-like particle (eVLP) platform technology enables development of eVLPs that closely mimic the target virus to elicit a potent immune response. VBI's lead eVLP programs include a vaccine immunotherapeutic candidate targeting glioblastoma (GBM), a prophylactic cytomegalovirus (CMV) vaccine candidate, and two prophylactic coronavirus vaccine candidates. VBI is headquartered in Cambridge, MA, with research operations in Ottawa, Canada, and research and manufacturing facilities in Rehovot, Israel.

Website Home: <http://www.vbivaccines.com/>

News and Insights: <http://www.vbivaccines.com/wire/>

Investors: <http://www.vbivaccines.com/investors/>

About Syneos Health

Syneos Health (Nasdaq:SYNH) is the only fully integrated biopharmaceutical solutions organization. Our Company, including a Contract Research Organization (CRO) and Contract Commercial Organization (CCO), is purpose-built to accelerate customer performance to address modern market realities. We bring together approximately 24,000 clinical and commercial minds with the ability to support customers in more than 110 countries. Together we share insights, use the latest technologies and apply advanced business practices to speed our customers' delivery of important therapies to patients. To learn more about how we are shortening the distance from lab to life®, visit syneoshealth.com.

(VBI) Cautionary Statement on Forward-looking Information

Certain statements in this press release that are forward-looking and not statements of historical fact are forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and are forward-looking information within the meaning of Canadian securities laws (collectively, “forward-looking statements”). The Company cautions that such statements involve risks and uncertainties that may materially affect the Company’s results of operations. Such forward-looking statements are based on the beliefs of management as well as assumptions made by and information currently available to management. Actual results could differ materially from those contemplated by the forward-looking statements as a result of certain factors, including but not limited to, the impact of general economic, industry or political conditions in the United States or internationally; the impact of the ongoing COVID-19 pandemic on our clinical studies, manufacturing, business plan, and the global economy; the ability to establish that potential products are efficacious or safe in preclinical or clinical trials; the ability to establish or maintain collaborations on the development of therapeutic candidates; the ability to obtain appropriate or necessary governmental approvals to market potential products; the ability to obtain future funding for developmental products and working capital and to obtain such funding on commercially reasonable terms; the Company’s ability to manufacture product candidates on a commercial scale or in collaborations with third parties; changes in the size and nature of competitors; the ability to retain key executives and scientists; and the ability to secure and enforce legal rights related to the Company’s products. A discussion of these and other factors, including risks and uncertainties with respect to the Company, is set forth in the Company’s filings with the SEC and the Canadian securities authorities, including its Annual Report on Form 10-K filed with the SEC on March 5, 2020, and filed with the Canadian security authorities at sedar.com on March 5, 2020, as may be supplemented or amended by the Company’s Quarterly Reports on Form 10-Q. Given these risks, uncertainties and factors, you are cautioned not to place undue reliance on such forward-looking statements, which are qualified in their entirety by this cautionary statement. All such forward-looking statements made herein are based on our current expectations and we undertake no duty or obligation to update or revise any forward-looking statements for any reason, except as required by law.

(Syneos Health) Forward Looking Statements

Except for historical information, all of the statements, expectations, and assumptions contained in this press release are forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. Actual results might differ materially from those explicit or implicit in the forward-looking statements. Important factors that could cause actual results to differ materially include, but are not limited to: reliance on key personnel; principal investigators and patients; general and international economic, political, and other risks, including currency and stock market fluctuations and the uncertain economic environment; any inability to satisfy or any failure to waive the closing conditions related to our acquisition of SHCR Holdings Corporation (“Synteract”); any failure to realize the anticipated benefits of the acquisition of Synteract; risks related to the COVID-19 pandemic; the Company’s ability to adequately price its contracts and not overrun cost estimates; any adverse effects from the Company’s customer or therapeutic area concentration; the Company’s ability to maintain or generate new business awards; the Company’s ability to increase its market share, grow its business, and execute its growth strategies; the Company’s backlog not being indicative of future revenues and its ability to realize the anticipated future revenue reflected in its backlog; fluctuations in the Company’s operating results and effective income tax rate; risks related to the Company’s information systems and cybersecurity; changes and costs of compliance with regulations related to data privacy; risks related to the United Kingdom’s withdrawal from the European Union; risks related to the Company’s transfer pricing policies; failure to perform services in accordance with contractual requirements, regulatory requirements and ethical considerations; risks relating to litigation and government investigations; risks associated with the Company’s early phase clinical facilities; insurance risk; risks of liability resulting from harm to patients; success of investments in the Company’s customers’ business or drugs; foreign currency exchange rate fluctuations; risks associated with acquired businesses, including the ability to integrate acquired operations, products, and technologies in our business; risks related to the Company’s income tax expense and tax reform; risks relating to the Company’s intellectual property; risks associated with the Company’s acquisition strategy; failure to realize the full value of goodwill and intangible assets; restructuring risk; potential violations of anti-corruption and anti-bribery laws; risks related to the Company’s dependence on third parties; downgrades of the Company’s credit ratings; competition in the biopharmaceutical services industry; changes in outsourcing trends; regulatory risks; trends in the Company’s customers’ businesses; the Company’s ability to keep pace with rapid technological change; risks related to the Company’s indebtedness; fluctuations in the Company’s financial results and stock price; and other risk factors set forth in the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2019 as updated by the Company’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, and other SEC filings, copies of which are available free of charge on the SEC website at www.sec.gov. The Company assumes no obligation and does not intend to update these forward-looking statements, except as required by law.

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