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): March 24, 2023

VACCITECH PLC

(Exact name of registrant as specified in its charter)

England and Wales	**001-40367**	**Not Applicable**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

Vaccitech plc
Unit 6-10, Zeus Building Rutherford Avenue,
Harwell, Didcot, OX11 0DF
United Kingdom
(Address of principal executive offices, including zip code)

+44 (0) 1865 818 808
(Registrant's telephone number, including area code)

(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	Trade Symbol(s)	Name of each exchange on which registered
American Depositary Shares	VACC	The Nasdaq Global Market
Ordinary shares, nominal value £0.000025 per share*		

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. ☐

*American Depositary Shares may be evidenced by American Depositary Receipts. Each American Depositary Share represents one (1) ordinary share. Not for trading, but only in connection with the listing of the American Depositary Shares on The Nasdaq Global Market. The American Depositary Shares represent the right to receive ordinary shares and are being registered under the Securities Act of 1933, as amended, pursuant to a separate Registration Statement on Form F-6. Accordingly, the American Depositary Shares are exempt from the operation of Section 12(a) of the Securities Exchange Act of 1934, as amended, pursuant to Rule 12a-8.

Item 2.02. Results of Operations and Financial Condition.

On March 24, 2023, Vaccitech plc announced its financial results for the full year ended December 31, 2022. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Form 8-K (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1	Press Release dated March 24, 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 duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Vaccitech plc

Date: Mach 24, 2023

By: /s/ William Enright
William Enright
Chief Executive Officer

Vaccitech Reports Full-Year 2022 Financial Results and an Update on Corporate Developments

OXFORD, United Kingdom, March 24, 2023 (GLOBE NEWSWIRE) -- Vaccitech plc (NASDAQ: VACC) (the Company, we or us), a clinical-stage biopharmaceutical company engaged in the discovery and development of novel immunotherapeutics and vaccines for the treatment and prevention of infectious diseases, autoimmunity and cancer, today announced its financial results for year end 2022 and an overview of the Company's progress.

"2022 represented an extremely active year at Vaccitech in which the company continued to advance its exciting pipeline and strengthen the infrastructure necessary to support this and future growth. We announced the completion of enrollment of three clinical trials, and initiated dosing in three new trials. This, combined with the announcement of new, state-of-the-art laboratories and offices in the US and the UK, and a 121% increase in staff focused on R&D, clinical and manufacturing activities, highlights Vaccitech's progress towards our goal of becoming a global leader in immunotherapies that leverage T cell immune responses," said Bill Enright, Vaccitech's Chief Executive Officer. "2023 is shaping up to be an even more exciting year with Dr. Nadège Pelletier joining us as our new Chief Scientific Officer, key data readouts anticipated in the first and fourth quarters, and additional milestones to come beyond that. We continue to invest strategically in our programs to ensure that we are focused on reaching successful outcomes, both clinically and financially."

"Our clinical programs have advanced substantially in 2022, and we have already seen promising interim data from VTP-200 in our persistent HPV program in the first quarter of 2023, where we are working to clear HPV infection before it causes cancer. We also expect to see final data from VTP-300, our chronic Hepatitis B program, where we are seeking a component to a functional cure, before the end of the quarter," commented Meg Marshall, Vaccitech's Chief Medical Officer. "Moving forward we expect to see first patient first visit (FPFV) for VTP-850, our prostate cancer program, in the near term, as well as additional data for VTP-300 later in the year. We believe 2023 is going to be a big year for Vaccitech as we continue to advance our pipeline."

2022 Corporate Developments

License revenue

- In April 2022, we announced the commencement of milestone and royalty payments to the Company relating to commercial sales of Vaxzevria® by AstraZeneca. The Company's share of milestone and royalty payments received by Oxford University Innovation (OUI) from AstraZeneca which were recognized as revenue for the year ended December 31, 2022 amounted to $43.7 million.

Clinical developments

- In January 2022, Cancer Research UK, Vaccitech and the Ludwig Institute for Cancer Research (Ludwig), announced the first patient dosed in the MAGE trial, which is testing a novel immunotherapeutic candidate, VTP-600, in patients with non-small cell lung cancer (NSCLC), the most common type of lung cancer. The Phase 1/2a trial is expected to enroll approximately 86 people who have been newly diagnosed with NSCLC and will be testing the safety and initial efficacy of VTP-600 in these patients.

- In April 2022, we received scientific advice from the European Medical Agency (EMA) defining a licensure pathway for our Middle East Respiratory Syndrome (MERS) vaccine product candidate, VTP-500, which has enabled the Company to both plan the development pathway and estimate expenses more accurately and completely.
- In May 2022, we completed enrollment for a Phase 1b/2a clinical trial, HBV002, to evaluate the safety and immunogenicity of VTP-300, both as monotherapy and in combination with an anti-PD-1 agent, in patients with chronic Hepatitis B whose HBV infection has been suppressed with oral antiviral medication.
- In June 2022, the first patient was dosed in a randomized, multi-center, blinded, Phase 2a Arbutus Biopharma Corporation (Arbutus) clinical trial to evaluate the safety, antiviral activity and immunogenicity of the combination of Arbutus' RNAi therapeutic candidate, AB-729, with Vaccitech's T-cell stimulating immunotherapeutic, VTP-300, and standard-of-care nucleos(t)ide reverse transcriptase inhibitor therapy for the treatment of patients with virology-suppressed chronic HBV infection.
- In June 2022, at the 2022 European Association for the Study of the Liver (EASL) International Liver Congress™, the Company presented HBV002 data showing that VTP-300, both as monotherapy and in combination with a single low dose of Nivolumab (anti-PD-1 agent) at the time of the booster dose, induced sustained reductions of HBV surface antigen (HBsAg) in some patients, and a robust T cell response, of which CD8+ T cells were predominant, against all encoded antigens in patients with chronic HBV infection.
- In July 2022, the Company completed enrollment, with the 60th patient enrolled, of the Company's Phase 1b/2 clinical trial of VTP-200, HPV001, to evaluate a potential treatment for persistent high-risk HPV infection.
- In October 2022, we announced the dosing of the first patient in HBV003, a Phase 2b clinical trial of VTP-300 designed to evaluate different timings of low dose Nivolumab and the impact of additional doses of the MVA boost, with the aim of maximizing a sustained decline in HBsAg.
- In November 2022, Dr. Young-Suk Lim, Professor of Gastroenterology in the Liver Center at University of Ulsan College of Medicine, presented a poster reporting interim HBV002 Phase 1b/2a clinical trial data on VTP-300 at the American Association for the Study of Liver Diseases conference. The presentation showed that VTP-300 immunotherapy, as monotherapy and when combined with low dose nivolumab at the boosting time point, was immunogenic and showed a sustained reduction in HBsAg in well-controlled CHB patients, and was administered with no treatment related Serious Adverse Events and infrequent transient transaminitis. Two of the five patients that responded in the combination cohort 3, with starting HBsAg levels below 100 IU/mL, achieved non-detectable levels of surface antigen at the data cutoff.
- In December 2022, the U.S. Food and Drug Administration cleared the Company's Investigational New Drug (IND) application for PCA001, a Phase 1/2 open-label clinical trial of VTP-850 in patients with rising prostate-specific antigen (PSA) after definitive local therapy for prostate cancer.

- In December 2022, the Company completed enrollment of the Phase 1b/2 clinical trial of VTP-200, HPV001, to evaluate a potential treatment for persistent high-risk HPV infection.

Pre-clinical developments:

- In April 2022, the Company launched two programs utilizing our proprietary SNAPvax platform: an immunostimulatory program to target HPV-associated cancer and a program in immunotolerance designed to induce regulatory T cells in patients with celiac disease.
- In October 2022, we announced the publication of research from VTP-1100 in *Cell* that demonstrated anti-tumor activity achieved with intravenous (IV) administration of a SNAPvax construct in an animal model. The study demonstrated that IV administration of SNAPvax expanded antigen-specific T cells and reversed suppression in the tumor microenvironment, which promoted T cell infiltration and tumor cell killing.

Key operational updates:

- In June 2022, the Company entered into a lease agreement for approximately 19,700 square feet in Germantown, Maryland. The site will house the Company's state-of-the-art wet laboratory and office space in the United States.
- In July 2022, we completed the relocation of our headquarters to the Harwell Science and Innovation Campus, Oxfordshire, United Kingdom.
- In August 2022, we filed a Registration Statement on Form S-3 for up to an aggregate of $200 million of our securities, including "at-the-market" offerings up to an aggregate of $75 million. As of December 31, 2022, we raised gross proceeds through "at-the-market" offerings of $0.7 million.
- In September 2022, we announced the promotion of Gemma Brown to Chief Financial Officer.

Recent Developments

- In January 2023, we announced the appointment of Dr. Nadège Pelletier as Chief Scientific Officer.
- In March 2023, we announced topline interim data from HPV001, a Phase 1b/2 clinical trial of VTP-200, a potential treatment for low grade HPV-related cervical lesions, which demonstrated favorable safety and immunogenicity data at interim analysis in patients with low-grade cervical HPV lesions. The HPV001 clinical trial will continue as planned to the 12-month primary endpoint.

Upcoming Milestones

- By the end of the first quarter of 2023, the Company expects to:
    - Announce final, topline data from HBV002, a Phase 1b/2a clinical trial of VTP-300, a potential component of a functional cure for chronic Hepatitis B.
- In 2023, the Company expects to:
    - Announce the dosing of the first patient in PCA001, a Phase 1/2 clinical trial of VTP-850 designed to evaluate the safety, PSA response, and immunogenicity of the VTP-850 heterologous immunotherapeutic as monotherapy in men with rising PSA after definitive local therapy for their disease (*i.e.*, biochemical recurrence).

- Move the U.S. team into a new, state-of-the-art facility in Germantown, Maryland, consisting of laboratories and office space.
- Submit IND applications for its two lead SNAPvax candidates, VTP-1000 for the treatment of celiac disease and VTP-1100 for the treatment of HPV-associated cancers.
- Present data from our HPV infectious disease program at the International Papillomavirus Conference (IPVC).
- Present data from our VTP-300 Hepatitis B programs at the EASL and the AASLD.
- Announce interim data from HBV003, a Phase 2b clinical trial of VTP-300, a potential component of a functional cure for chronic Hepatitis B.
- Announce interim efficacy data from the Phase 2a clinical trial collaboration with Arbutus of VTP-300 in combination with Arbutus' RNAi therapeutic candidate, AB-729.

2022 Financial Highlights

- **Cash position:** As of December 31, 2022, cash was $194.4 million, compared to $214.1 million as of December 31, 2021. The cash used in operating activities was $14.4 million, primarily due to the net of R&D and G&A spend offset by cash received from revenue recognized in respect of commercial sales of Vaxzevria®, interest earned on cash deposits and favorable foreign exchange movements. $5.8 million of net cash was used in investing activities, which primarily resulted from capital expenditures related to our new headquarters in Harwell, United Kingdom.
- **Revenues:** Revenue was $44.7 million in 2022 compared to $0.3 million in 2021 and was comprised primarily of the Company's share of milestone and royalties received by OUI as a result of commercial sales of Vaxzevria® by AstraZeneca, the revenue from which commenced in the first quarter of 2022.
- **Research and development expenses:** Research and development expenses were $42.4 million in 2022 compared to $20.4 million in 2021, demonstrating the growth of our team and advancement of our pipeline, particularly with VTP-300, and the SNAPvax programs on VTP-1000 and VTP-1100. The year-on-year R&D expense per program is outlined in the following table.

	Year ended December 31, 2022	**Year ended December 31, 2021**	**Change**
	$ 000	**$ 000**	**$ 000**
Direct research and development expenses by program:			
VTP-200 HPV	4,050	3,061	989
VTP-300 HBV	13,700	6,431	7,269
VTP-600 NSCLC[1]	532	687	(155)
VTP-800/850 Prostate cancer	5,011	2,433	2,578
VTP-1000/VTP-1100 (SNAPvax candidates)	5118	-	5,118
Other and earlier stage programs	1,916	1,382	534
Total direct research and development expenses	**30,327**	**13,994**	**16,333**
Internal research and development expenses:			
Personnel-related (including share-based compensation)	10,424	5,787	4,637
Facility-related	1,308	410	898
Other internal costs	291	180	111
Total research and development expense	**42,350**	**20,371**	**21,979**

[1] The VTP-600 NSCLC Phase 1/2a trial is sponsored by Cancer Research UK

- **General and administrative expenses:** General and administrative expenses were $6.4 million in 2022, compared to $25.1 million in 2021. The decrease is attributable to a $26.4 million gain on foreign exchange that offset against personnel costs of $16.8 million, insurance cost of $6.2 million, legal and professional fees of $4.3 million, and other general and administrative expenses. The general and administrative expenses reflect an increase in the Company's headcount, increased operational costs with a full year of the US operations, and the relocation of the UK headquarters in July 2022.
- **Net income:** For the financial year 2022, the Company generated a net income attributable to its shareholders of $5.3 million, or $0.14 both per fully diluted share and per basic share, compared to a net loss attributable to shareholders of $(50.9) million, or $(1.96) per fully diluted share and per basic share, for 2021.

About Vaccitech

Vaccitech is a clinical-stage biopharmaceutical company focused on the development of novel T cell immunotherapeutics designed to utilize the power of the immune system to potentially treat and cure chronic infectious diseases, autoimmune diseases, and cancer. The Company believes that its proprietary, multi-platform approach has the ability to induce higher magnitudes of T cells compared with other technologies. The Company believes that it is well positioned to address the needs of large, underserved patient populations through a diverse clinical-stage pipeline of investigational therapies targeting life-threatening diseases that pose significant public health risk and have limited treatment options. The Company's lead product candidates include VTP-300, an immunotherapy candidate designed as a component of a potential component of a functional cure for chronic hepatitis B viral (HBV) infection; VTP-200, a non-invasive, early-stage investigational treatment for persistent, high-risk human papillomavirus (HPV); VTP-850, a novel T cell investigational therapy for prostate cancer; and VTP-1000, a preclinical T cell therapeutic product candidate for immune tolerance in celiac disease. Vaccitech has proven drug development and scientific expertise in the field of immunization, co-inventing a COVID-19 vaccine with the University of Oxford, which is now approved and exclusively licensed worldwide to AstraZeneca. For more information, visit www.vaccitech.co.uk.

Forward Looking Statements

This press release contains forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, which can generally be identified as such by use of the words "would," "aim," "forward," "expect," "plan," "intend," "believe," "potential," "continue," and similar expressions, although not all forward-looking statements contain these identifying words. These forward looking statements include express or implied statements regarding the Company's future expectations, plans and prospects, and include, without limitation, statements regarding the timing and advancement of the Company's programs, including the clinical trials of VTP-200, VTP-300, and VTP-850, statements regarding the timing for the initiation of dosing of VTP-300, VTP-850, and the Company's two lead SNAPvax candidates, VTP-1000 and VTP-1100, statements regarding the timing for the potential IND applications for VTP-1000 and VTP-1100, statements regarding the presentation of data at future conferences, and statements regarding the Company's capital. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to numerous risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, risks and uncertainties related to: the success, cost and timing of the Company's product development activities and planned and ongoing clinical trials, the Company's ability to execute on its strategy, regulatory developments, approval of the Company's product candidates, the Company's ability to fund its operations, global economic uncertainty, including disruptions in the banking industry, and the impact that the COVID-19 pandemic may have on the Company's clinical trials, preclinical studies and access to capital and other risks identified in the Company's filings with the Securities and Exchange Commission (the "SEC"), including its Annual Report on Form 10-K for the year ended December 31, 2022, its Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. The Company cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. The Company expressly disclaims any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

VACCITECH PLC
CONSOLIDATED BALANCE SHEETS
(IN THOUSANDS, EXCEPT NUMBER OF SHARES AND PER SHARE AMOUNTS)

	As of December 31, 2022	As of December 31, 2021
Assets		
Cash and cash equivalents	$ 194,385	$ 214,054
Accounts receivable	323	20
Accounts receivable – related parties	5,524	-
Research and development incentives receivable	4,541	6,229
Prepaid expenses and other current assets	8,268	6,462
Total current assets	213,041	226,765
Goodwill	12,209	12,630
Property and equipment, net	7,957	1,829
Intangible assets, net	28,269	31,430
Right of use assets, net	7,753	7,257
Other assets	976	804
Total assets	$ 270,205	$ 280,715
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,748	$ 2,419
Accrued expenses and other current liabilities	8,061	7,875
Deferred revenue	-	182
Operating lease liability - current	433	523
Debt	-	159
Total current liabilities	12,242	11,158
Non-Current liabilities:		
Operating lease liability	8,340	6,540
Contingent consideration	1,711	2,371
Other non-current liabilities	965	-
Deferred tax liability, net	3,746	8,084
Total liabilities	$ 27,004	$ 28,153
Commitments and contingencies (Note 17)		
Shareholders' equity:		
Ordinary shares, £0.000025 nominal value; 37,683,531 shares authorized, issued and outstanding (December 31, 2021: authorized, issued and outstanding: 37,188,730)	1	1
Deferred A shares, £1 nominal value; 63,443 shares authorized, issued and outstanding (December 31, 2021: authorized, issued and outstanding: 63,443)	86	86
Deferred B shares, £0.01 nominal value; 570,987 shares authorized, issued and outstanding (December 31, 2021: authorized, issued and outstanding: 570,987)	8	8
Deferred C shares, £0.000007 nominal value, 27,828,231 shares authorized, issued and outstanding (December 31, 2021: authorized, issued and outstanding: 27,828,231)	0[1]	0[1]
Additional paid-in capital	379,504	369,103
Accumulated deficit	(103,243)	(108,585)
Accumulated other comprehensive loss – foreign currency translation adjustments	(33,460)	(8,488)
Total shareholders' equity attributable to Vaccitech plc shareholders'	242,896	252,125
Noncontrolling interest	305	437
Total shareholders' equity	$ 243,201	$ 252,562
Total liabilities and shareholders' equity	$ 270,205	$ 280,715

[1] Indicates amount less than one thousand.

VACCITECH PLC
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(IN THOUSANDS, EXCEPT NUMBER OF SHARES AND PER SHARE AMOUNTS)

	As of December 31, 2022	As of December 31, 2021
License revenue [1]	$ 44,694	$ 63
Service revenue	-	21
Research grants and contracts	9	184
Total revenue	44,703	268
Operating expenses		
Research and development	42,350	20,371
General and administrative	6,394	25,118
Total operating expenses	48,744	45,489
Loss from operations	(4,041)	(45,221)
Other income (expense):		
Change in fair value of derivatives embedded in convertible loan notes	-	5,994
Unrealized foreign exchange gain on convertible loan notes	-	209
Loss on extinguishment of convertible loan notes	-	(13,789)
Interest income	3,103	2
Interest expense	(19)	(2,668)
Research and development incentives	1,240	4,001
Other income, net	567	332
Total other income/(expense)	4,891	(5,919)
Profit/(loss) before income tax	850	(51,140)
Tax benefit	4,471	28
Net income/(loss)	5,321	(51,112)
Net loss attributable to noncontrolling interest	21	247
Net income/(loss) attributable to Vaccitech plc shareholders	$ 5,342	$ (50,865)
Weighted-average ordinary shares outstanding, basic	37,248,126	25,894,375
Weighted-average ordinary shares outstanding, diluted	38,169,307	25,894,375
Net income/(loss) per share attributable to ordinary shareholders, basic	$ 0.14	$ (1.96)
Net income/(loss) per share attributable to ordinary shareholders, diluted	$ 0.14	$ (1.96)
Net income/(loss)	$ 5,321	$ (51,112)
Other comprehensive loss – foreign currency translation adjustments	(25,083)	(7,248)
Comprehensive loss	(19,762)	(58,360)
Comprehensive loss attributable to noncontrolling interest	132	250
Comprehensive loss attributable to Vaccitech plc shareholders	$ (19,630)	$ (58,110)

[1] Includes license revenue from related parties for the year ended December 31, 2022, totaling $43.7 million (December 31, 2021: $nil).

IR contacts:
Christopher M. Calabrese
Managing Director
LifeSci Advisors
917-680-5608
ccalabrese@lifesciadvisors.com

Kevin Gardner
Managing Director
LifeSci Advisors
617-283-2856
kgardner@lifesciadvisors.com

Media contact:

Mike Beyer
Sam Brown, Inc.
312-961-2502
mikebeyer@sambrown.com

Company contact:
Jonothan Blackbourn
IR & PR Manager
Vaccitech
IR@vaccitech.co.uk