

**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): August 10, 2023

VACCITECH PLC

(Exact name of registrant as specified in its charter)

**England and Wales
(State or other jurisdiction
of incorporation)**

**001-40367
(Commission
File Number)**

**Not Applicable
(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:

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

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 August 10, 2023, Vaccitech plc (the “Company”) provided an update on its financial information and recent corporate developments in the quarter ended June 30, 2023. The full text of the press release issued in connection with the update 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 August 10, 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: August 10, 2023

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



Vaccitech Reports Second Quarter 2023 Financial Results and Recent Corporate Developments

OXFORD, United Kingdom, August 10, 2023 (GLOBE NEWSWIRE) -- Vaccitech plc (NASDAQ: VACC), a clinical-stage biopharmaceutical company engaged in the discovery and development of novel T cell immunotherapeutics designed to harness the power of the immune system to treat chronic infectious diseases, cancer and autoimmunity, today announced its financial results for the second quarter of 2023 and provided an overview of the Company's progress.

"In the second quarter of 2023, Vaccitech achieved important clinical milestones for two of our lead programs in HPV and HBV, which included the final analysis for the Phase 1b/2a trial of VTP-300 presented at EASL," said Bill Enright, Vaccitech's Chief Executive Officer. "Looking ahead, we remain steadfast in our focus on HBV and are eagerly anticipating interim data from our ongoing Phase 2 trials which we expect to announce by the end of the year. We have been able to extend our cash runway into the second quarter of 2025, demonstrating Vaccitech's ethos of agility and efficiency across our broad portfolio of programs."

Second Quarter 2023 and Recent Corporate Developments

Clinical developments

- In April 2023, at the 35th Annual International Papillomavirus Conference, the Company presented topline data from the HPV001 (NCT04607850) Phase 1b/2 clinical trial evaluating VTP-200 in women infected with human papillomavirus (HPV). Data included results for 42 women at Day 35, 7 days after the last dose of VTP-200. VTP-200 was generally well-tolerated and was administered with no product-related grade 3 unsolicited adverse events and no product-related severe adverse events. While the placebo group showed no antigen-specific T cell responses as measured by IFN γ ELISpot, 26 of 29 women receiving varying doses of VTP-200 showed a response. The final dataset, including data on clearance of infection and cervical lesions at 12 months post-treatment, is expected in the second quarter of 2024.
- In June 2023, at the 2023 European Association for the Study of the Liver (EASL) International Liver Congress™, the Company presented final Phase 2 HBV002 (NCT04778904) 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 second dose, induced meaningful, durable reductions of hepatitis B surface antigen (HBsAg) and that reductions were most prominent in patients with lower baseline HBsAg. VTP-300 led to a decline in HBsAg in the majority of people infected with genotypes B and C viruses. In addition, VTP-300-induced T cells showed cross-reactivity to the core antigen from genotypes A to E in ELISpot assays using peripheral blood mononuclear cells from VTP-300-treated healthy subjects and genotype-specific peptides A-E.
- Also in June 2023, the Company announced dosing of the first patient in the PCA001 clinical trial evaluating its next generation product candidate, VTP-850, in prostate cancer (NCT05617040). PCA001 is a multi-center, Phase 1/2 trial designed to determine the recommended Phase 2 regimen and evaluate the safety, efficacy, as measured by prostate-specific antigen response (PSA), and T cell response of VTP-850 monotherapy in men with prostate cancer with rising PSA after definitive local therapy for their disease (i.e. biochemical recurrence).

Key operational updates

- In June 2023, the Company completed relocation of its U.S. team to a new, state-of-the-art laboratory and office facility in Germantown, Maryland.
- In July 2023, the Company announced the retirement of Dr. Margaret Marshall, Chief Medical Officer, effective immediately. In connection with her retirement, Dr. Marshall and the Company will enter into a consulting agreement.

Upcoming Milestones

- In the second half of 2023, the Company expects to:
 - o Announce interim efficacy data from HBV003 (NCT05343481), a Phase 2b clinical trial of VTP-300, that further evaluates its potential as a component of a functional cure for chronic Hepatitis B.
 - o Announce interim efficacy data from the Phase 2a clinical trial (ACTRN12622000317796) collaboration with Arbutus of VTP-300 in combination with Arbutus' siRNA therapeutic candidate, AB-729 for chronic hepatitis B.
 - o Submit an Investigational New Drug (IND) application for VTP-1000, the Company's lead SNAPvax technology candidate, for the treatment of celiac disease.

Q2 2023 Financial Highlights

- **Cash position:** As of June 30, 2023, the Company had cash and cash equivalents of \$173.0 million, compared to \$191.3 million as of March 31, 2023. The net cash used in operating activities was \$17.0 million, primarily resulting from our net loss of \$23.8 million adjusted by share based compensation of \$2.0 million, depreciation and amortization of \$1.3 million, and changes in our operating assets and liabilities. \$3.0 million was used for investing activities, primarily from capital expenditures related to leasehold improvements on our new facility in Germantown, Maryland, consisting of laboratories and office space. \$0.1 million was provided by financing activities being the proceeds received from the issuance of ordinary shares represented by American Depositary Shares through the Company's "at-the-market" sales agreement, net of issuance costs. Based on current research and development plans, we expect our cash runway to fund our operating expenses and capital expenditure requirements into the second quarter of 2025.

- **Revenue:** Revenue consisted of \$0.3 million in the second quarter of 2023 compared to \$0.5 million in the first quarter of 2023. Revenue was comprised of the Company's share of royalties received by Oxford University Innovation (OUI) as a result of commercial sales of Vaxzevria® by AstraZeneca.
- **Research and development expenses:** Research and development expenses were \$13.5 million in the second quarter of 2023 compared to \$9.8 million in the first quarter of 2023, showing increased spend due to phasing of clinical and pre-clinical trials. VTP-300 HBV research and development expenses increased as a result of the Phase 2 HBV002 final data and the two ongoing phase 2b clinical trials. The research and development expenses related to SNAPvax candidates, VTP-1000/VTP-1100 Celiac/ HPV Cancer, increased due to IND-enabling studies. The quarter-on-quarter R&D expense per program is outlined in the following table.

	Three months ended June 30, 2023 \$000	Three months ended March 30, 2023 \$000	Change \$000
Direct research and development expenses by program:			
VTP-200 HPV	1,837	1,338	499
VTP-300 HBV	3,757	2,118	1,639
VTP-600 NSCLC ¹	79	275	(196)
VTP-850 Prostate cancer	242	215	27
VTP-1000/VTP-1100 Celiac/HPV Cancer	3,018	1,572	1,446
Other and earlier stage programs	701	280	421
Total direct research and development expenses	9,634	5,798	3,836
Internal research and development expenses:			
Personnel-related (including share-based compensation)	3,388	3,601	(213)
Facility-related	202	371	(169)
Other internal costs	319	44	275
Total internal research and development expenses	3,909	4,016	(107)
Total research and development expense	13,543	9,814	3,729

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

- **General and administrative expenses:** General and administrative expenses were \$13.1 million in the second quarter of 2023, compared to \$12.1 million in the first quarter of 2023. The increase was mainly attributable to the unrealized foreign exchange loss of \$4.2 million in the second quarter of 2023, compared to \$3.5 million in the first quarter of 2023.
- **Net loss:** For the second quarter of 2023, the Company generated a net loss attributable to its shareholders of \$23.8 million, or \$0.62 per share on both basic and fully diluted bases, compared to a net loss attributable to shareholders of \$18.2 million, or \$0.48 per share on both basic and fully diluted bases in the first quarter of 2023.

About Vaccitech

Vaccitech is a clinical-stage biopharmaceutical company engaged in the discovery and development of novel T cell immunotherapeutics designed to harness the power of the immune system to treat chronic infectious diseases, cancer and autoimmunity. The Company stands apart through a proprietary, multi-platform approach that has shown the ability to induce higher magnitudes of T cells compared with other technologies. Vaccitech is uniquely 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 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 candidate designed to restore 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 statement

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 potential IND application for VTP-1000, statements regarding the presentation of interim data, including with respect to VTP-300, and statements regarding the Company's capital, including its cash runway. 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
CONDENSED CONSOLIDATED BALANCE SHEETS
(IN THOUSANDS, EXCEPT NUMBER OF SHARES AND PER SHARE AMOUNTS)
(UNAUDITED)

	June 30, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 173,030	\$ 194,385
Accounts receivable	—	323
Accounts receivable - related parties	349	5,524
Research and development incentives receivable	3,137	4,541
Prepaid expenses and other current assets	8,261	8,268
Total current assets	184,777	213,041
Goodwill	12,209	12,209
Property and equipment, net	13,741	7,957
Intangible assets, net	26,688	28,269
Right of use assets, net	7,707	7,753
Other assets	1,006	976
Total assets	\$ 246,128	\$ 270,205
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 2,429	\$ 3,748
Accrued expenses and other current liabilities	8,547	8,061
Operating lease liability - current	1,135	433
Total current liabilities	12,111	12,242
Non-Current liabilities:		
Operating lease liability	11,044	8,340
Contingent consideration	2,117	1,711
Deferred tax liability, net	2,094	3,746
Other non-current liabilities	1,300	965
Total liabilities	\$ 28,666	\$ 27,004
Commitments and contingencies (Note 14)		
Shareholders' equity:		
Ordinary shares, £0.000025 nominal value; 38,524,059 shares authorized, issued and outstanding (December 31, 2022: authorized, issued and outstanding: 37,683,531)	1	1
Deferred A shares, £1 nominal value; 63,443 shares authorized, issued and outstanding (December 31, 2022: authorized, issued and outstanding: 63,443)	86	86
Deferred B shares, £0.01 nominal value; nil shares authorized, issued and outstanding (December 31, 2022: authorized, issued and outstanding: 570,987)	—	8
Deferred C shares, £0.000007 nominal value, nil shares authorized, issued and outstanding (December 31, 2022: authorized, issued and outstanding: 27,828,231)	—	0 ¹
Additional paid-in capital	385,636	379,504
Accumulated deficit	(145,225)	(103,243)
Accumulated other comprehensive loss – foreign currency translation adjustments	(23,289)	(33,460)
Total shareholders' equity attributable to Vaccitech plc shareholders'	217,209	242,896
Noncontrolling interest	253	305
Total shareholders' equity	\$ 217,462	\$ 243,201
Total liabilities and shareholders' equity	\$ 246,128	\$ 270,205

¹indicates amount less than thousand

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

	Three months ended		Six months ended	
	June 30, 2023	June 30, 2022	June 30, 2023	June 30, 2022
License revenue ⁽¹⁾	\$ 334	\$ 17,063	\$ 802	\$ 32,072
Research grants and contracts	—	—	—	9
Total revenue	<u>334</u>	<u>17,063</u>	<u>802</u>	<u>32,081</u>
Operating expenses				
Research and development	13,543	9,720	23,357	20,421
General and administrative	13,128	(5,892)	25,266	(2,156)
Total operating expenses	<u>26,671</u>	<u>3,828</u>	<u>48,623</u>	<u>18,265</u>
(Loss)/income from operations	<u>(26,337)</u>	<u>13,235</u>	<u>(47,821)</u>	<u>13,816</u>
Other income (expense):				
Interest income	522	669	2,110	752
Interest expense	(14)	(7)	(14)	(8)
Research and development incentives	559	826	1,716	1,874
Other income	310	51	310	51
Total other (expense) income	<u>1,377</u>	<u>1,539</u>	<u>4,122</u>	<u>2,669</u>
(Loss)/profit before income tax	<u>(24,960)</u>	<u>14,774</u>	<u>(43,699)</u>	<u>16,485</u>
Tax benefit	1,136	915	1,652	1,778
Net (loss)/income	<u>(23,824)</u>	<u>15,689</u>	<u>(42,047)</u>	<u>18,263</u>
Net loss attributable to noncontrolling interest	22	4	65	26
Net (loss)/income attributable to Vaccitech plc shareholders	<u>(23,802)</u>	<u>15,693</u>	<u>(41,982)</u>	<u>18,289</u>
Weighted-average ordinary shares outstanding, basic	38,407,672	37,202,600	38,211,625	37,196,843
Weighted-average ordinary shares outstanding, diluted	38,407,672	38,174,426	38,211,625	38,260,579
Net (loss)/income per share attributable to ordinary shareholders, basic	<u>\$ (0.62)</u>	<u>\$ 0.42</u>	<u>\$ (1.10)</u>	<u>\$ 0.49</u>
Net (loss)/income per share attributable to ordinary shareholders, diluted	<u>\$ (0.62)</u>	<u>\$ 0.41</u>	<u>\$ (1.10)</u>	<u>\$ 0.48</u>
Net (loss)/income	\$ (23,824)	\$ 15,689	\$ (42,047)	\$ 18,263
Other comprehensive gain/(loss) – foreign currency translation adjustments	5,604	(16,807)	10,184	(22,790)
Comprehensive loss	<u>(18,220)</u>	<u>(1,118)</u>	<u>(31,863)</u>	<u>(4,527)</u>
Comprehensive loss attributable to noncontrolling interest	15	34	52	71
Comprehensive loss attributable to Vaccitech plc shareholders	<u>\$ (18,205)</u>	<u>\$ (1,084)</u>	<u>\$ (31,811)</u>	<u>\$ (4,456)</u>

⁽¹⁾Includes license revenue from related parties for the three and six month periods ended June 30, 2023 of \$0.3 million and \$0.8 million, respectively and for the three and six month periods ended June 30, 2022 of \$17.1 million and \$32.1 million, respectively.

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