Vaccitech Reports First Quarter 2023 Financial Results and Recent Corporate Developments

May 12, 2023

OXFORD, United Kingdom, May 12, 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 the first quarter of 2023 and an overview of the Company's progress.

"2023 has kicked off strongly for Vaccitech. In the first quarter, we strengthened our leadership team with the addition of Dr. Nadège Pelletier as our new Chief Scientific Officer, we generated positive final proof of concept data from one of our hepatitis B (HBV) trials, and very promising interim data from our human papillomavirus (HPV) program – both disease areas of high unmet medical need," said Bill Enright, Vaccitech's Chief Executive Officer. "Overall, this has been an incredibly active quarter and we expect to sustain this momentum as we push towards additional data from our wider hepatitis B program as the year progresses."

Dr. Meg Marshall, Vaccitech's Chief Medical Officer, commented, "This quarter has seen the achievement of important milestones for both of our lead product candidates in HBV and HPV. Our HBV002 trial for VTP-300 met its primary and secondary endpoints. The topline final data support proof of concept and have shown a generally favorable tolerability profile and meaningful sustained reductions in hepatitis B surface antigen (HBsAg), supporting our belief that VTP-300 has potential to be a critical component of a functional cure for patients that are chronically infected with hepatitis B. Additionally, the interim data from APOLLO, our HPV clinical trial, showed a favorable tolerability and promising immunogenicity profile, highlighting VTP-200's potential for women with persistent high-risk HPV infections, who currently have no treatment options until they develop high grade lesions."

First Quarter 2023 and Recent Corporate Developments

Clinical developments

- HBV Therapeutic (VTP-300): In March 2023, we announced positive topline final data from the HBV002 Phase 2 clinical trial of VTP-300. The completed trial, which included 55 patients with chronic hepatitis B (CHB), supported proof of concept for VTP-300 as well as the generally favorable tolerability profile previously reported with VTP-300, with no incidents of VTP-300-related Grade 3 adverse events or product-related serious adverse events (SAEs) following study dosing. VTP-300 was observed to induce meaningful, sustained reductions of HBsAg in patients with CHB. Declines were most prominent in patients with lower baseline HBsAg. The final results of the immunology assays are currently being analyzed and the full data, including tolerability results and immunology pharmacodynamic biomarker readouts, will be presented at the upcoming European Association for the Study of the Liver (EASL) Congress, June 21-24, 2023.

- In March 2023, we announced topline interim safety and immunogenicity data from the APOLLO Phase 1b/2 clinical trial in women with low-grade cervical HPV lesions. These data, from the first 58 women enrolled who reached their 6-month timepoint in APOLLO placebo-controlled study, were presented as a poster at the International Papillomavirus Conference (IPVC).

- In April 2023, our Chief Medical Officer, Dr. Meg Marshall, presented interim data from APOLLO at the 35th Annual IPVC. The poster included immunogenicity data on 45 out of the 58 women, who were enrolled in the immunogenicity sub-study, at Day 35, 7 days after the last dose of VTP-200, split by active treatment versus placebo. While the placebo group showed no antigen-specific T cell responses as measured by IFN-gamma, 26 of 29 women receiving varying doses of VTP-200 showed a response. The pooled active groups showed meaningful responses, with the average being greater than 1,000 spot-forming units per million peripheral blood mononuclear cells. Of the seven antigens (*i.e.:* E1, E2, E4, E5, E6, E7), responses were strongest to the E1, E2 and E6 antigens. In addition, intracellular cytokine staining data from the active groups showed both a CD4 response and a larger CD8 response, as expected. VTP-200 was generally well-tolerated and was administered with no product-related Grade 3 unsolicited adverse events and no product-related significant adverse events. 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.

Management Team

- In January 2023, we announced the appointment of Nadège Pelletier, Ph.D., as Chief Scientific Officer.

- In April 2023, we announced the planned retirement of Chris Ellis, Chief Operating Officer, effective October 31, 2023.

Upcoming Milestones

- In 2023, the Company expects to:
  - Present data from our VTP-300 Hepatitis B programs at the EASL and the AASLD meetings.
  - Complete the move of the U.S. team into a new, state-of-the-art facility in Germantown, Maryland, consisting of laboratories and office space.
  - Dose the first patient in PCA001, a Phase 1/2 clinical trial of VTP-850 designed to evaluate the safety, prostate-specific antigen (PSA) response, and immunogenicity of the immunotherapeutic candidate VTP-850 in men with rising PSA after definitive local therapy for their disease (*i.e.*, biochemical recurrence).
  - Submit an IND application for our lead SNAPvax candidate, VTP-1000, for the treatment of celiac disease.
  - 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.

Q1 2023 Financial Highlights

- **Cash position:** As of March 31, 2023, cash was $191.3 million, compared to $194.4 million as of December 31, 2022. The cash used in operating activities was $3.2 million, primarily resulting from our net loss of $18.2 million adjusted by share based compensation of $2.2 million, depreciation and amortization of $1.2 million, foreign exchange loss of $3.5 million, and changes in our operating assets and liabilities, net of $8.3 million. $2.5 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. $1.7 million was provided by financing activities, primarily being the net proceeds received from the issuance of ordinary shares through the "at-the-market" sales agreement. Based on current research and development plans, we expect our cash runway to fund our operating expenses and capital expenditure requirements into the first quarter of 2025.
- **Revenues:** Revenue were $0.5 million in the first quarter of 2023 compared to $15.0 million in the comparable period of the previous year. 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 $9.8 million in the first quarter of 2023 compared to $10.7 million in the comparable period of the previous year, showing slightly reduced spend due to timepoints and phasing of clinical trials, particularly with the completion of HBV002 clinical trial. The quarter-on-quarter R&D expense per program is outlined in the following table.

	Three months ended March 31, 2023		**Three months ended March 31, 2022**		**Change**
	$000		**$000**		**$000**
Direct research and development expenses by program:					
VTP-200 HPV	1,338		1,156		182
VTP-300 HBV	2,118		4,185		(2,067)
VTP-600 NSCLC[1]	275		162		113
VTP-850 Prostate cancer	215		1,339		(1,124)
VTP-1000/VTP-1100 (SNAPvax candidates)	1,572		-		1,572
Other and earlier stage programs	280		739		(459)
Total direct research and development expenses	**5,798**		**7,581**		**(1,783)**
Internal research and development expenses:					
Personnel-related (including share-based compensation)	3,601		2,726		875
Facility-related	371		340		31
Other internal costs	44		54		(10)
Total internal research and development expenses	**4,016**		**3,120**		**896**
Total research and development expense	**9,814**		**10,701**		**(887)**

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

- **General and administrative expenses:** General and administrative expenses were $12.1 million in the first quarter of

2023, compared to $3.7 million in the comparable period of the previous year. The increase was mainly attributable to the unrealized foreign exchange loss in the first quarter of 2023 of $3.5 million, compared to an unrealized foreign exchange gain in the first quarter of 2022 of $5.3 million.

- **Net loss/income:** For the first quarter of 2023, the Company generated a net loss attributable to its shareholders of $18.2 million, or $0.48 per share on both basic and fully diluted bases, compared to a net income attributable to shareholders of $2.6 million, or $0.07 per share on both basic and fully diluted bases for the first quarter of 2022.

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 treat and cure chronic infectious diseases, autoimmune diseases, and cancer. 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 initiation of dosing of VTP-300, VTP-850, statements regarding the timing for the potential IND application for VTP-1000, statements regarding the presentation of data at future conferences, 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)

	March 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 191,328	$ 194,385
Accounts receivable	172	323
Accounts receivable - related parties	768	5,524
Research and development incentives receivable	2,501	4,541
Prepaid expenses and other current assets	5,896	8,268
Total current assets	200,665	213,041
Goodwill	12,209	12,209
Property and equipment, net	12,712	7,957
Intangible assets, net	27,479	28,269
Right of use assets, net	7,723	7,753
Other assets	1,028	976
Total assets	$ 261,816	$ 270,205

LIABILITIES AND SHAREHOLDERS' EQUITY

Current liabilities:		
Accounts payable	$ 4,327	$ 3,748
Accrued expenses and other current liabilities	7,012	8,061
Operating lease liability - current	649	433
Total current liabilities	11,988	12,242
Non-Current liabilities:		
Operating lease liability	10,005	8,340
Contingent consideration	1,710	1,711
Deferred tax liability, net	3,230	3,746
Other non-current liabilities	1,314	965
Total liabilities	$ 28,247	$ 27,004
Commitments and contingencies (Note 14)		
Shareholders' equity:		
Ordinary shares, £0.000025 nominal value; 38,357,025 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	383,523	379,504
Accumulated deficit	(121,423)	(103,243)
Accumulated other comprehensive loss – foreign currency translation adjustments	(28,886)	(33,460)
Total shareholders' equity attributable to Vaccitech plc shareholders'	233,301	242,896
Noncontrolling interest	268	305
Total shareholders' equity	$ 233,569	$ 243,201
Total liabilities and shareholders' equity	$ 261,816	$ 270,205

[1] indicates 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	
	March 31, 2023	**March 31, 2022**
License revenue [1]	$ 468	$ 15,009
Research grants and contracts	—	9
Total revenue	468	15,018
Operating expenses		
Research and development	9,814	10,701
General and administrative	12,138	3,663
Total operating expenses	21,952	14,364
(Loss)/income from operations	(21,484)	654
Other income/(expense):		
Interest income	1,588	83
Interest expense	—	(74)
Research and development incentives	1,157	1,048
Total other income/(expense)	2,745	1,057
(Loss)/profit before income tax	(18,739)	1,711
Tax benefit	516	863
Net (loss)/income	(18,223)	2,574
Net loss attributable to noncontrolling interest	43	22
Net (loss)/income attributable to Vaccitech plc shareholders	(18,180)	2,596
Weighted-average ordinary shares outstanding, basic	38,013,399	37,191,022
Weighted-average ordinary shares outstanding, diluted	38,013,399	38,346,668

Net (loss)/income per share attributable to ordinary shareholders, basic	$ (0.48)	$ 0.070
Net (loss)/income per share attributable to ordinary shareholders, diluted	$ (0.48)	$ 0.068
Net (loss)/income	$ (18,223)	$ 2,574
Other comprehensive gain/(loss) – foreign currency translation adjustments	4,580	(5,983)
Comprehensive loss	(13,643)	(3,409)
Comprehensive loss attributable to noncontrolling interest	37	37
Comprehensive loss attributable to Vaccitech plc shareholders	$ (13,606)	$ (3,372)

[1] Includes license revenue from related parties for the three month periods ended March 31, 2023 and 2022, of $0.5 million and $15.0 million, respectively.

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