VBL Therapeutics Reports First Quarter 2022 Financial Results and Provides Corporate Update

May 17, 2022

OVAL Phase 3 top-line data expected in 2H 2022; with positive results, VBL anticipates submitting a BLA to the FDA in 1H 2023

Conference Call and Webcast at 8:30 a.m. ET Today

TEL AVIV, Israel and NEW YORK, May 17, 2022 (GLOBE NEWSWIRE) -- VBL Therapeutics (Nasdaq: VBLT) (VBL), a late-clinical stage biotechnology company developing first-in-class therapeutics for difficult-to-treat malignant solid tumors and immune or inflammatory indications, today announced financial results for the first quarter ended March 31, 2022, and provided a corporate update.

"We continue to execute on our development and strategic objectives, which we believe have positioned us for a potentially transformational year," said Dror Harats, M.D., Chief Executive Officer of VBL. "Completion of enrollment in the Phase 3 OVAL trial in recurrent platinum-resistant ovarian cancer in the first quarter of 2022 was a major milestone, and we look forward to the progression free survival primary endpoint top-line data readout expected in the second half of 2022. We are also expecting preliminary clinical data from the ofra-vec Phase 2 trials in metastatic colorectal cancer and recurrent glioblastoma multiforme in 2022. In parallel with these oncology programs, we are advancing our pipeline and plan to enter the clinic in the second half of the year with VB-601, the first product candidate from our novel anti-inflammatory program targeting monocytes."

First Quarter of 2022 and Recent Corporate Highlights

Ofra-vec Oncology Program

- Completed enrollment in the Phase 3 OVAL registration-enabling trial evaluating ofra-vec (ofranergene obadenovec; `VB-111`) in recurrent platinum-resistant ovarian cancer, with a total of 409 patients enrolled globally.
- The U.S. Food and Drug Administration (FDA) granted fast track designation for ofra-vec in combination with paclitaxel for the treatment of platinum-resistant ovarian cancer.
- The Independent Data Safety Monitoring Committee (iDSMC) conducted a pre-planned safety review of the 370 patients randomized in the OVAL trial by December 31, 2021, and unanimously recommended that the trial continue as planned.
- VBL hosted a key opinion leader (KOL) event on ovarian cancer in New York City, NY on April 11 featuring KOLs Bradley J. Monk, M.D., FACS, FACOG (University of Arizona College of Medicine; Creighton University School of Medicine), Richard Penson, M.D., MRCP (Massachusetts General Hospital) and Kathleen Moore, M.D. (University of Oklahoma College of Medicine). A replay of the event is archived here.
- Ofra-vec Phase 2 clinical trials in recurrent glioblastoma multiforme (rGBM) and metastatic colorectal cancer (mCRC) continue as planned, with preliminary data from both trials expected in 2022.

VB-601 Inflammation Program

- Presented for the first time molecular mechanistic data on the Monocyte Targeting Technology (MTT) and lead candidate VB-601 at the IMMUNOLOGY 2022 conference in Portland, OR on May 8, 2022. Data explained how VB-601 inhibited the migration of monocytes into inflamed tissues, providing a novel and differentiated approach with potential applications in various chronic inflammatory indications.
- Prof. Dror Harats delivered a presentation on VB-601 at the LifeSci Partners Immunology & Inflammation Symposium on May 12, 2022. The presentation is archived here.
- IND-enabling toxicology studies have been successfully completed for VB-601 and VBL expects to initiate a first-in-human clinical trial for the program in the second half of 2022.

Presentations at 2022 ASCO Annual Meeting

- Two abstracts highlighting ofra-vec clinical research have been selected for presentation at the upcoming American Society of Clinical Oncology (ASCO) 2022 Annual Meeting taking place June 3-7, 2022. These Trial in Progress posters will highlight the Phase 3 OVAL trial of ofra-vec in platinum-resistant ovarian cancer and the Phase 2 trial in surgically accessible rGBM.

Corporate

- Strengthened the management team with the appointment of Matthew Trudeau to the newly created position of Chief Commercial Officer and initiated the build out of U.S. operations to further advance VBL's strategic plan to become a commercial organization.

Financial Results for the First Quarter of 2022

- At March 31, 2022, VBL had cash, cash equivalents, short-term bank deposits and restricted bank deposits of $44.8 million. VBL expects that its cash, cash equivalents, short-term bank deposits, and restricted bank deposits will be sufficient to fund currently planned operating expenses and capital expenditures for at least a year beyond the Phase 3 OVAL trial top-line progression free survival (PFS) results.
- For the quarter ended March 31, 2022, VBL reported a net loss of $10.4 million, or ($0.13) per basic share, compared to a net loss of 6.3 million, or ($0.12) per basic share, in the comparable period in 2021.
- For the quarter ended March 31, 2022, total operating expenses were approximately $10.7 million, consisting of $7.5 million in research and development expenses, net, and $3.2 million in general and administrative expenses. This compares with total operating expenses of $6.5 million in the first quarter ended March 31, 2021, which was comprised of $4.8 million in research and development expenses, net, and $1.7 million in general and administrative expenses.

Conference Call and Webcast:
Tuesday, May 17 at 8:30 a.m. ET
Conference ID: 13729281
United States: 1-877-407-9208
Israel Local: 1 809 406 247
International: 1-201-493-6784
Webcast: https://edge.media-server.com/mmc/p/8pjhkd83

About the OVAL Phase 3 Clinical Trial

OVAL (VB-111-701/GOG-3018) is an international Phase 3 randomized, pivotal registration-enabling clinical trial comparing a combination of ofra-vec (ofranergene obadenovec; `VB-111`) and paclitaxel to placebo plus paclitaxel, in adult patients with recurrent platinum-resistant ovarian cancer. The OVAL trial has two primary endpoints: progression free survival (PFS) and overall survival (OS). Successfully meeting either primary endpoint has the potential to support a Biologics License Application (BLA). Meeting the PFS endpoint, with a top-line readout anticipated in the second half of 2022, could accelerate BLA submission by approximately one year, subject to discussions with the U.S. Food and Drug Administration. A top-line readout of the OS primary endpoint is anticipated in 2023. OVAL is being conducted in collaboration with the GOG Foundation, Inc., an independent international non-profit organization with the purpose of promoting excellence in the field of gynecologic malignancies. For more information, refer to Clinicaltrials.gov NCT03398655.

About VBL Therapeutics

Vascular Biogenics Ltd., operating as VBL Therapeutics (VBL), is a late clinical-stage biopharmaceutical company committed to developing next-generation, targeted medicines for difficult-to-treat medical conditions. Using our novel platform technologies, we have created a pipeline of therapeutics to uniquely address cancer and immune-inflammatory diseases with the goal of significantly improving patient outcomes and overcoming the limitations of currently approved treatments. Our product candidates are built off of our two platform technologies: Vascular Targeting System (VTS™), a gene-based technology targeting newly formed blood vessels, and Monocyte Targeting Technology (MTT), an antibody-based technology able to specifically inhibit monocyte migration for immune-inflammatory applications. Our lead oncology product candidate, ofra-vec (ofranergene obadenovec; `VB-111`), is an investigational targeted anti-cancer gene-based agent in development to treat a wide range of solid tumors. Ofra-vec is currently being studied in a Phase 3 registration-enabling clinical trial (NCT03398655) for platinum-resistant ovarian cancer. To learn more about VBL, please visit vblrx.com or follow VBL on LinkedIn, Twitter, YouTube or Facebook.

Forward Looking Statements

This press release contains forward-looking statements. All statements other than statements of historical fact are forward-looking statements, which are often indicated by terms such as “anticipate,” “believe,” “could,” “estimate,” “expect,” “goal,” “intend,” “look forward to,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “will,” “would” and similar expressions. These forward-looking statements may include, but are not limited to, statements regarding the timing of data readouts for multiple ofra-vec clinical trials, including in recurrent platinum-resistant ovarian cancer, rGBM and mCRC; timing of submission of a BLA for ofra-vec to the FDA; timing of the initiation of a first-in-human trial for VB-601; statements regarding 2022 being a transformational year; buildout of a presence in the United States; and other statements regarding VBL’s plans and beliefs regarding its programs, including their clinical development, therapeutic potential and clinical results. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. Among the factors that could cause actual results to differ materially from those described or projected herein include uncertainties associated generally with the development of pharmaceutical product candidates, and include risks associated with research and development, clinical trials and related regulatory reviews and approvals, the risk that historical clinical trial results may not be predictive of future trial results, that VBL’s financial resources do not last for as long as anticipated, and that VBL may not realize the expected benefits of its intellectual property protection. In particular, the DSMC recommendation that the OVAL study proceed is not assurance that the study will meet its co-primary endpoints of PFS and OS once completed, or that VBL will obtain positive results to support further development of this candidate. A further list and description of these risks, uncertainties and other risks can be found in VBL’s regulatory filings with the U.S. Securities and Exchange Commission (SEC), including in its annual report on Form 20-F for the year ended December 31, 2021, and subsequent filings with the SEC. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. VBL undertakes no obligation to update or revise the information contained in this press release, whether as a result of new information, future events or circumstances or otherwise.

CONTACT:
Daniel Ferry
LifeSci Advisors
+1 (617) 430-7576
daniel@lifesciadvisors.com

VASCULAR BIOGENICS LTD.
STATEMENTS OF FINANCIAL POSITION
(UNAUDITED)

	March 31, 2022	December 31, 2021
	U.S. dollars in thousands	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 13,252	$ 21,986
Short-term bank deposits	31,221	31,164
Other current assets	2,044	1,697
Total current assets	46,517	54,847
Non-current assets:		
Restricted bank deposits	360	362
Long-term prepaid expenses	164	182
Funds in respect of employee rights upon retirement	407	415
Property, plant and equipment, net	6,949	6,847
Operating lease right-of-use assets	1,892	2,008
Total non-current assets	9,772	9,814
Total assets	$ 56,289	$ 64,661
LIABILITIES, ORDINARY SHARES SUBJECT TO POSSIBLE REDEMPTION AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accruals:		
Trade	$ 6,188	$ 4,331
Other	3,799	4,408
Deferred revenue	546	658
Current maturity of operating leases liability	516	529
Total current liabilities	$ 11,049	$ 9,926
Non-current liabilities:		
Liability for employee rights upon retirement	580	546
Operating lease liability	1,657	1,823
Other non-current liability	205	188
Total non-current liabilities	2,442	2,557
Total liabilities	**$ 13,491**	**$ 12,483**
Ordinary shares subject to possible redemption, 615,366 shares at redemption value (see note 4)	-	1,598
Shareholders' equity:		
Ordinary shares, NIS 0.01 par value; Authorized as of March 31, 2022 and December 31, 2021, 150,000,000 shares; issued and outstanding as of March 31, 2022 and December 31, 2021 69,337,312 and 68,711,584 shares, respectively (excluding -0- and 615,366 shares subject to possible redemption, as of March 31, 2022 and December 31, 2021, respectively)	173	171
Additional paid in capital	311,999	309,355
Warrants	3,127	3,127
Accumulated deficit	(272,501)	(262,073)
Total equity	42,798	50,580
Total liabilities and equity	**$ 56,289**	**$ 64,661**

VASCULAR BIOGENICS LTD.
STATEMENTS OF NET LOSS AND COMPREHENSIVE LOSS
(UNAUDITED)

	Three Months Ended March 31,	
	2022	2021
	U.S. dollars in thousands	
Revenues	$ 113	$ 185
Cost of revenues	(55)	(90)
Gross profit	58	95
Research and development expenses, net	7,460	4,769
General and administrative expenses	3,162	1,673
Operating loss	10,564	6,347
Financial income	(146)	(84)
Financial expenses	10	20
Financial income, net	(136)	(64)
Net loss and comprehensive loss	$ 10,428	$ 6,283
	U.S. dollars	
Loss per share (see note 3)		
Basic and diluted	$ 0.13	$ 0.12
	Number of shares	
Weighted average ordinary shares outstanding		
Basic and diluted	77,386,967	52,113,675