RNS Number : 4436T
NetScientific PLC
14 November 2023

RNS: For immediate release

NetScientific plc

PDS Biotech Reports Third Quarter 2023 Financial Results and Provides Business Update

- *Announced 75% of ICI-naive patients alive at 36 months in the NCI-led triple Phase 2 combination trial for advanced HPV16-positive cancer patients; published median overall survival of 7-11 months with FDA approved ICI1*
- *Announced 2-year overall survival rate of 74% in VERSATILE-002 Phase 2 trial of ICI-naïve HPV16-positive recurrent or metastatic head and neck cancer patients; published 2-year overall survival of less than 30% with FDA approved ICI1*
- *Announced interim safety and immune response data for Phase 1/2 clinical trial evaluating docetaxel and PDS01ADC in metastatic prostate cancer patients; PSA decline was seen in all 18 patients and 61% of patients had at least a 60% decrease in PSA levels*
- *Company to host conference call and webcast today at 8:00 AM EST*

NetScientific Plc (AIM: NSCI), the deep tech and life sciences VC investment group, reports that its portfolio company, PDS Biotechnology Corporation (Nasdaq: PDSB), a clinical-stage immunotherapy company developing a growing pipeline of targeted cancer immunotherapies and infectious disease vaccines based on the company's proprietary T cell activating platforms, has announced its financial results for the quarter ended September 30, 2023.

Frank Bedu-Addo, PhD, Chief Executive Officer of PDS Biotech said:

"We are pleased with the outcome of the National Cancer Institute (NCI)-led Phase 2 triple combination trial of PDS0101, PDS01ADC (formerly known as PDS0301) and an investigational immune checkpoint inhibitor (ICI). The data show that 75% of immune checkpoint inhibitor (ICI)-naïve patients remain alive at three years, and the 12-month overall survival (OS) rate in the ICI-resistant patients is 72. Furthermore, the triple combination continues to be well tolerated, with only 4% of patients reported to have Grade 4 treatment-related adverse events."

He continued:

"As the development of our IL12 fused antibody-drug conjugate or ADC, PDS01ADC, continues to progress, its potential to overcome key safety and efficacy limitations associated with existing cytokine therapy is reinforced. Data presented at Cytokines 2023 marked the first-in-human clinical trial evaluating the combination of docetaxel chemotherapy and PDS01ADC to treat advanced metastatic castration sensitive (mCSPC) and castration resistant prostate cancer (mCRPC). Decreases in prostate-specific antigen (PSA) levels were reported in all patients. In addition, with our lead candidate PDS0101, the interim Phase 2 VERSATILE-002 data presented during our Key Opinion Leader (KOL) roundtable showed a 2-year overall survival rate of 74% in ICI-naïve human papillomavirus (HPV)16- recurrent/metastatic head and neck cancer patients. We are excited about the strides we are making across our pipeline, fuelled by our commitment to developing groundbreaking therapies that revolutionize cancer treatments."

Recent Business Highlights:
PDS0101 Lead Drug Candidate

- **VERSATILE-003:** Received feedback from the U.S. Food and Drug Administration (FDA) regarding the Phase 3 clinical protocol for a randomized, controlled multicentre trial of PDS0101 in combination with Merck's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab) in patients with HPV16-positive recurrent and/or metastatic head and neck cancer. PDS Biotech anticipates initiation of VERSATILE-003 in Q1 2024.
- **VERSATILE-002**: Phase 2 open-label, multicentre clinical trial of PDS0101 in combination with KEYTRUDA® in patients with HPV16-positive recurrent and/or metastatic head and neck cancer.
    - Hosted KOL roundtable on interim VERSATILE-002 data and current and future treatments. Highlights from ICI-naïve patients:
        - 24-month OS rate of 74%; published 24-month OS less than 30% data with approved ICIs for head and neck cancer.[2]
        - Well tolerated with no patients having Grade 4 or 5 combination treatment-related adverse events. Thirteen percent with Grade 3 combination treatment-related adverse events.
    - Presented biomarker data at European Society for Medical Oncology Congress 2023, highlighting that the combination of PDS0101 and KEYTRUDA® has the potential to promote a TH1 immune response which is known to promote a strong CD8 T cell response. Biomarker data demonstrated that the combination promotes the induction of HPV16-specific multifunctional CD8 T cells.
- **IMMUNOCERV:** Phase 2 clinical trial investigating PDS0101 in combination with standard-of-care (SOC) chemoradiotherapy (CRT) in the treatment of locally advanced cervical cancer patients with large tumours over 5 cm in size and/or cancer that has spread to the lymph nodes.
    - Data presented at American Society for Radiation Oncology 2023 Annual Meeting demonstrated PDS0101, in combination with SOC CRT, was associated with a rapid decline in HPV circulating cell-free DNA, a potential predictive biomarker of treatment response. Ninety-two percent reduction in ctDNA

DNA, a potential predictive biomarker of treatment response. Ninety-two percent reduction in ctDNA with PDS0101 and SOC and 53% reduction was seen with SOC at 5 weeks.

PDS01ADC (formerly known as PDS0301): IL12 Fused Antibody Drug Conjugate

- **NCI-led Triple Combination:** Phase 2 clinical trial for combination therapy of PDS0101, PDS01ADC and an investigational ICI for the treatment of recurrent/metastatic HPV-positive, ICI-naïve and ICI-resistant HPV16-positive cancers including anal, cervical, head and neck, vaginal and vulvar cancers.
  - ICI-naïve group:
    - 75% of patients remain alive at 36 months; published median OS data in similar patients is 7-11 months.[1] The median OS has not yet been reached.
  - ICI-resistant group:
    - 12-month OS rate of 72%.
    - Median OS approximately 20 months; published median OS in HPV-positive ICI-resistant cancer is 3.4 months[3].
  - Responses were seen in all HPV-positive tumour types.
- **NCI-led PDS01ADC + Docetaxel:** Phase 1/2, open-label, single-arm trial of PDS01ADC in combination with docetaxel in advanced mCSPC and mCRPC.
  - Presented interim safety and immune response data of the combination in the first clinical trial of an immunocytokine with docetaxel in prostate cancer patients at Cytokines 2023.
  - Decrease in PSA levels was seen in all patients at all three tested doses of PDS01ADC and 61% of patients had at least a 60% decrease in PSA levels.
    - All doses of the combination were well tolerated with one patient experiencing Grade 4 neutropenia.
- Presented data from the NCI-led preclinical study evaluating PDS0101, PDS01ADC and an HDAC inhibitor at the Society for Immunotherapy of Cancer's 38th Annual Meeting, demonstrating anti-tumour activity against ICI-resistant cancers.

PDS0202 Universal Flu Candidate

- Presented data from the preclinical universal flu vaccine program at 9th European Scientific Working Group on Influenza, demonstrating the potential ability of PDS0202 to neutralize multiple influenza viruses. PDS0202 also demonstrated the ability to prevent viral replication in the lungs of ferrets and provide complete protection after challenge with lethal doses of the H1N1 influenza virus.

Third Quarter 2023 Financial Results

Net loss for the three months ended September 30, 2023 was approximately $10.8 million, or $0.35 per basic share and diluted share, compared to a net loss of approximately $7.4 million, or $0.26 per basic and diluted share, for the three months ended September 30, 2022. The higher net loss reported for the three months ended September 30, 2023 is primarily due to the increase in research and development expenses and general and administrative expenses.

Research and development expenses increased to $6.4 million for the three months ended September 30, 2023 from $4.4 million for the three months ended September 30, 2022. The increase of $2.0 million is primarily attributable to an increase of $1.3 million in clinical trials, and $0.7 million in personnel costs, including $0.3 million in non-cash stock-based compensation.

General and administrative expenses increased to $4.1 million for the three months ended September 30, 2023 from $2.9 million for the three months ended September 30, 2022. The increase of $1.2 million is primarily attributable to an increase of $0.7 million in personnel costs, including $0.5 million in non-cash stock-based compensation, and $0.5 million in investor relations costs.

PDS Biotech's cash balance as of September 30, 2023 was approximately $54.3 million. PDS Biotech believes that, with initiating the VERSATILE-003 Phase 3 clinical trial in the first quarter of 2024, its available cash resources will sustain operational and research and development endeavours into the third quarter of 2024. PDS Biotech expects to execute its current operational and research and development endeavours by obtaining additional capital, principally through entering into collaborations, strategic alliances or license agreements with third parties and/or additional public or private debt and/or equity financings. The Company has had and continues to provide, what the Company believes to be favourable development milestones to the market and has upcoming development milestones.

References:

[1] Baumi J, et al. J Clin Oncol 2017:1542-49 and Morris VK, et al. Lancet Oncol 2017;18:446-53.

[2] Ferris R.L., Nivolumab for Recurrent Squamous-Cell Carcinoma of the Head and Neck; N Engl J Med 2016; 375:1856-1867; Burtness B et al., Pembrolizumab alone or with chemotherapy versus cetuximab with chemotherapy for recurrent or metastatic squamous cell carcinoma of the head and neck (KEYNOTE- 048): a randomized, open-label phase 3 study; Lancet 2019; 394(10212):1915-1928. *No control or comparative studies have been conducted between immune checkpoint inhibitors and PDS0101.
https://www.opdivo.com/head-and-neck-cancer
https://www.keytruda.com/head-and-neck-cancer/keytruda-clinical-trials/

[3] Strauss J et al. Journal for ImmunoTherapyof Cancer 2020;8:e001395

About PDS0101

PDS0101, PDS Biotech's lead candidate, is a novel investigational human papillomavirus (HPV)-targeted immunotherapy that stimulates a potent targeted T cell attack against HPV-positive cancers. PDS0101 is given by subcutaneous injection alone or in combination with other immunotherapies and cancer treatments. In a Phase 1 study of PDS0101 in monotherapy, the treatment demonstrated the ability to generate multifunctional HPV16-targeted CD8 and CD4 T cells with minimal toxicity. Interim data suggests PDS0101 generates clinically active immune responses, and the combination of PDS0101 with other treatments can demonstrate significant disease control by reducing or shrinking tumours, delaying disease progression and/or prolonging survival. The combination of PDS0101 with other treatments does not appear to compound the toxicity of other agents.

About PDS01ADC

PDS01ADC, formerly PDS0301, is a novel investigational tumour-targeting antibody drug conjugate of Interleukin 12 (IL-12) that enhances the proliferation, potency and longevity of T cells and natural killer cells in the tumour microenvironment. PDS01ADC is given by subcutaneous injection and is designed to improve the safety profile of IL-12 and to enhance the anti-tumour response.

The Condensed Consolidated Balance Sheets; The Condensed Consolidated Statements of Operations and Comprehensive Loss (Unaudited) and the Condensed Consolidated Statements of Cash Flows (Unaudited) are available on the full version of PDS Biotech's announcement.

A full version of PDS Biotech's announcement can be accessed here:
https://pdsbiotech.com/index.php/investors/news-center/press-releases/press-releases1/125-2023-news/886-iotecheportshirduarter2023inancialesultsan20231114

-Ends-

For more information, please contact:

NetScientific	
Ilian Iliev, CEO	Via Belvedere Communications
Panmure Gordon (UK) Limited (NOMAD and Broker)	
Emma Earl / Freddy Crossley / Mark Rogers (Corporate Finance)	+44 (0)20 7886 2500
Rupert Dearden (Corporate Broking)	
Belvedere Communications	
John West / Llew Angus / Lily Pearce	+44 (0)20 7653 8702

About NetScientific

NetScientific plc (AIM: NSCI) is a deep tech and life sciences VC investment group with an international portfolio of innovative companies.

NetScientific identifies, invests in, and builds high growth companies in the UK and internationally. The company adds value through the proactive management of its portfolio, progressing to key value inflection points, and delivering investment returns through partial or full liquidity events.

NetScientific differentiates itself by employing a capital-light investment approach, making judicial use of its balance sheet and syndicating investments through its wholly owned VC subsidiary, EMV Capital. The group secures a mixture of direct equity stakes and carried interest stakes in its portfolio of companies, creating a lean structure that can support a large portfolio.

NetScientific is headquartered in London, United Kingdom, and is admitted to trading on AIM, a market operated by the London Stock Exchange.

www.netscientific.net

About PDS Biotechnology

PDS Biotech is a clinical-stage immunotherapy company developing a growing pipeline of targeted cancer and infectious disease immunotherapies based on our proprietary Versamune®, Versamune® plus PDS01ADC, and Infectimune® T cell-activating platforms. We believe our targeted immunotherapies have the potential to overcome the limitations of current immunotherapy approaches through the activation of the right type, quantity and potency of T cells. To date, our lead Versamune® clinical candidate, PDS0101, has demonstrated the ability to reduce and shrink tumours and stabilize disease in combination with approved and investigational therapeutics in patients with a broad range of HPV16-associated cancers in multiple Phase 2 clinical trials and plan to advance into a Phase 3 clinical trial in combination with KEYTRUDA® for the treatment of recurrent/metastatic HPV16-positive head and neck cancer in the first quarter 2024. Our Infectimune® based vaccines have also demonstrated the potential to induce not only robust and durable neutralizing antibody responses, but also powerful T cell responses, including long-lasting memory T cell responses in pre-clinical studies to date.

www.pdsbiotech.com

This information is provided by RNS, the news service of the London Stock Exchange. RNS is approved by the Financial Conduct Authority to act as a Primary Information Provider in the United Kingdom. Terms and conditions relating to the use and distribution of this information may apply. For further information, please contact rns@lseg.com or visit www.rns.com.

RNS may use your IP address to confirm compliance with the terms and conditions, to analyse how you engage with the information contained in this communication, and to share such analysis on an anonymised basis with others as part of our commercial services. For further information about how RNS and the London Stock Exchange use the personal data you provide us, please see our Privacy Policy.

END

MSCFZMMMVDNGFZM