Portage Biotech Announces Results for Fiscal Quarter Ended September 30, 2022

November 29, 2022

--Updated Data on Phase 1/2 Trial Evaluating PORT-2 Presented at the Society for Immunotherapy of Cancer's (SITC) Annual Meeting--

--Clinical Collaboration Agreement Entered into with Merck for Evaluation of PORT-2 in combination with KEYTRUDA® (pembrolizumab) for the treatment of patients with first-line and refractory non-small cell lung cancer (NSCLC)--

--Focused Clinical Development Goals on Producing Nine Phase 1b/Phase 2 Data Readouts in Multiple Tumor Types Over the Next Two Years--

WESTPORT, Conn., Nov. 29, 2022 (GLOBE NEWSWIRE) -- Portage Biotech Inc., (NASDAQ: PRTG) ("Portage" or the "Company"), a clinical-stage immuno-oncology company developing therapies to improve patient lives and increase survival by avoiding and overcoming cancer treatment resistance, today announced financial results for the fiscal quarter ended September 30, 2022.

"During the quarter and in recent weeks we have continued to demonstrate progress of our invariant natural killer T cell (iNKT) agonist, PORT-2, as well as our broader portfolio of immuno-oncology assets," said Dr. Ian Waters, Chief Executive Officer and Chairman of Portage Biotech. "Updates on PORT-2 include the data presented from our IMPORT-201 Phase 1/2 clinical trial of PORT-2 (IMM60) at the SITC annual conference, which continue to show PORT-2 has a favorable safety and tolerability profile as a monotherapy at all doses tested to date. We also announced a new clinical collaboration agreement with Merck to evaluate PORT-2 in combination with KEYTRUDA® (pembrolizumab), and look forward to exploring how this therapeutic combination may further enhance long-term clinical benefit for a wide range of patients with cancer. We are also preparing to launch our company-sponsored ADPORT-601 adenosine trial for PORT-6 and PORT-7 in the U.S. We look forward to building on this progress and advancing our broader strategy of de-risked clinical development, and are well positioned to deliver on multiple catalysts in the coming months."

Pipeline & Clinical Program Highlights from the Quarter Ended September 30, 2022 and Recent Weeks

- Entered into a clinical collaboration agreement with Merck (known as MSD outside the US and Canada) for the evaluation of Portage's lead iNKT agonist, PORT-2, in combination with KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 (programmed death receptor-1) therapy, for patients with first-line as well as PD-1 refractory NSCLC.
  - Under the terms of the collaboration, Merck will be providing KEYTRUDA for Portage Biotech's IMPORT-201 trial, a Phase 1/2 clinical trial of PORT-2 for patients with NSCLC and advanced melanoma (also known as KEYNOTE E69). The two companies will establish a Joint Development Committee to optimally evaluate the trial's combination arms.
- Presented updates from ongoing Phase 1/2 clinical trial of PORT-2 (IMM60) iNKT agonist for patients with NSCLC and advanced melanoma at the Society for Immunotherapy of Cancer's 37 th Annual Meeting.
  - The poster presentation included updated data from the IMPORT-201 clinical trial, a multi-arm Phase 1/2 trial evaluating PORT-2 in multiple settings including first-line and refractory NSCLC and refractory melanoma, both as a monotherapy and in combination with Merck's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab). The presented data builds on previous results shared at the 2022 American Society of Clinical Oncology (ASCO) meeting in June 2022.
  - The presented data are available here.

Financial & Business Highlights from Quarter Ended September 30, 2022

- Acquired four best-in-class assets targeting the adenosine pathway as a result of the Tarus Therapeutics transaction in July 2022.
- Acquired outstanding minority interest of iNKT agonist platform from iOx Therapeutics in July 2022.
- Executed committed share purchase agreement for up to $30 million in value of ordinary shares with Lincoln Park Capital Fund, LLC, potentially extending Portage's total cash runway into 2024.

Financial Results from Quarter Ended September 30, 2022

The Company generated a net loss and other comprehensive loss of approximately $1.1 million during the three months ended September 30, 2022 (the "Fiscal 2023 Quarter"), compared to a net loss and other comprehensive loss of approximately $2.9 million during the three months ended September 30, 2021 (the "Fiscal 2022 Quarter"), a decrease in loss of $1.8 million year over year. The principal reason for the decrease in net loss and other comprehensive loss was the net deferred income tax benefit of $2.5 million recognized in the Fiscal 2023 Quarter, compared to $0.5 million in the Fiscal 2022 Quarter. The principal components of the current year benefit were $2.2 million recognized with respect to the foreign currency effect on the deferred income tax liability settleable in foreign currency and the recognition of $0.3 million of current period losses generated during the Fiscal 2023 Quarter.

Operating expenses, which include research and development and general and administrative expenses, were $3.6 million in the Fiscal 2023 Quarter, compared to $3.3 million in the Fiscal 2022 Quarter, an increase of $0.3 million, which is discussed more fully below.

Research & development costs increased by approximately $0.2 million, or approximately 15%, from approximately $1.3 million in the Fiscal 2022 Quarter, to approximately $1.5 million in the Fiscal 2023 Quarter. The increase was attributable to clinical trial costs largely associated with the iNKT clinical trials in the Fiscal 2023 Quarter of $0.2 million. There were no such costs incurred in the Fiscal 2022 Quarter. Additionally, the Company incurred payroll-related expenses of $0.5 million in Fiscal 2023 Quarter, compared to $0.2 million in the Fiscal 2022 Quarter. The increase was attributable to increases in staff, as well as the formalization of a compensation program designed to be competitive in the market and attract and retain a strong management group. Additionally, the Company incurred costs of $0.03 million associated with the National Cancer Institute Collaboration Research and Development Agreement (CRADA program) in the Fiscal 2023 Quarter. These increases were partially offset by a reduction in non-cash share-based compensation expense with respect to stock options to purchase ordinary shares granted to employees, which was attributable to (a) the vesting over time of a portion of prior year grants; and (b) the decrease in the fair value of grants made in fiscal 2022.

General and administrative expenses increased by approximately $0.1 million, or approximately 5%, from approximately $2.0 million in the Fiscal 2022 Quarter, to approximately $2.1 million in the Fiscal 2023 Quarter. The principal reason for the increase was the $0.4 million increase in professional fees, of which approximately $0.1 million was attributable to legal fees associated with the acquisition of four pipeline candidates from the Tarus merger targeting the adenosine pathway and $0.2 million was attributable to stamp fees in the U.K. related to acquiring the outstanding minority interest of our iNKT agonist platform. Additionally, payroll-related expenses increased by $0.2 million due to the formalization of a compensation program adopted in the Fiscal 2023 Quarter. These increases were partially offset by a decrease in non-cash share-based compensation expense of $0.5 million attributable to the vesting of certain stock options granted in prior years and lower fair value associated with more recent grants, the decrease of $0.1 million associated with directors and officers insurance attributable to lower premiums under the policy.

As of September 30, 2022, the Company had approximately $15.0 million of cash and cash equivalents, reflecting settlement of the $3.0 million liabilities assumed with our acquisition of the adenosine pipeline during the Fiscal 2023 Quarter.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co. LLC., Rahway, N.J., USA.

About Portage Biotech Inc.
Portage is a clinical-stage immuno-oncology company advancing first-in-class therapies to improve long-term treatment response and quality of life in patients with evasive cancers. Portage's access to next-generation technologies coupled with a deep understanding of biological mechanisms enables the identification of the most promising clinical therapies and product development strategies that accelerate these medicines through the translational pipeline. Portage's portfolio consists of six diverse platforms, with lead programs including invariant natural killer T cell (iNKT) agonists and a suite of therapeutics targeting the adenosine pathway. Portage expects to report multiple clinical readouts through the end of 2024. For more information, please visit www.portagebiotech.com, follow us on Twitter at @PortageBiotech or find us on LinkedIn at Portage Biotech Inc.

Forward-Looking Statements
All statements in this news release, other than statements of historical facts, including without limitation, statements regarding about the Company's information that are forward-looking in nature and, business strategy, plans and objectives of management for future operations and those statements preceded by, followed by or that otherwise include the words "believe," "expects," "anticipates," "intends," "estimates," "will," "may," "plan," "potential," "continue," or similar expressions or variations on such expressions are forward-looking statements. For example, statements regarding the Company's plans to advance first-in-class therapies to improve long-term treatment response and quality of life in patients with evasive cancers; the Company's plans to identify the most promising clinical therapies and product development strategies that accelerate these medicines through the translational pipeline; the Company's plans to report multiple clinical readouts through the end of 2024; the safety and tolerability profile of PORT-2; the Company's collaboration agreement with Merck to evaluate PORT-2 in combination with KEYTRUDA® (pembrolizumab) for the treatment of patients with first-line and refractory NSCLC; the Company's preparations to launch of ADPORT-601 adenosine trial for PORT-6 and PORT-7 in the U.S.; advancing the Company's broader strategy of de-risked clinical development; and the Company's ability to deliver on multiple catalysts in the coming months and forward-looking statements. as a result, Forward-looking statements are subject to certain risks and uncertainties, including , but are not limited to: the Company's plans and ability to develop and commercialize product candidates and the timing of these development programs; the Company's clinical development of its product candidates, including the results of current and future clinical trials; the benefits and risks of the Company's product candidates as compared to others; the Company's maintenance and establishment of intellectual property rights in its product candidates; the Company's need for financing and its estimates regarding its capital requirements and future revenues and profitability; the Company's estimates of the size of the potential markets for its product candidates; its selection and licensing of product candidates; and other factors set forth in "Item 3 - Key Information-Risk Factors" in the Company's Annual Report on Form 20-F for the year ended March 31, 2022. Although the Company believes that the expectations reflected in these forward-looking statements are reasonable, undue reliance should not be placed on them as actual results may differ materially from these forward-looking statements. The forward-looking statements contained in this news release are made as of the date hereof, and the Company undertakes no obligation to update publicly or revise any forward-looking statements or information, except as required by law.

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Portage Biotech Inc.
Condensed Consolidated Interim Statements of Operations and Other Comprehensive Income (Loss)
(U.S. Dollars in thousands, except per share amounts)
(Unaudited – see Notice to Reader dated November 29, 2022)

	Three months ended September 30,		Six months ended September 30,	
	2022	2021	**2022**	**2021**
	In 000'$	In 000'$	**In 000'$**	In 000'$
Expenses				
Research and development	**$ 1,565**	$ 1,330	**$ 3,441**	$ 2,876
General and administrative expenses	**2,088**	2,000	**4,299**	4,047
Loss from operations	**(3,653)**	(3,330)	**(7,740)**	(6,923)
Change in fair value of deferred purchase price payable - Tarus and deferred obligation - iOx milestone	**70**	–	**70**	–
Share of loss in associate accounted for using equity method	**(56)**	(58)	**(116)**	(102)
Change in fair value of warrant liability	**24**	15	**25**	384
Foreign exchange transaction loss	**(58)**	–	**(110)**	–
Interest income	**44**	–	**65**	–
Interest expense	**(9)**	(7)	**(9)**	(41)
Loss before provision for income taxes	**(3,638)**	(3,380)	**(7,815)**	(6,682)
Income tax benefit	**2,553**	503	**5,105**	582
Net loss and other comprehensive loss	**$ (1,085)**	$ (2,877)	**$ (2,710)**	$ (6,100)
Net (loss) income attributable to:				
Owners of the Company	**$ (949)**	$ (2,975)	**$ (2,678)**	$ (6,041)
Non-controlling interest	**(136)**	98	**(32)**	(59)
Net loss	**$ (1,085)**	$ (2,877)	**$ (2,710)**	$ (6,100)
Comprehensive (loss) income attributable to:				
Owners of the Company	**$ (949)**	$ (2,975)	**$ (2,678)**	$ (6,041)
Non-controlling interest	**(136)**	98	**(32)**	(59)
Total comprehensive loss for period	**$ (1,085)**	$ (2,877)	**$ (2,710)**	$ (6,100)
Loss per share				
Basic and diluted	**$ (0.06)**	$ (0.22)	**$ (0.18)**	$ (0.47)
Weighted average shares outstanding				
Basic and diluted	**16,742**	13,332	**15,056**	12,776

Portage Biotech Inc.
Condensed Consolidated Interim Statements of Financial Position
(U.S. Dollars in thousands)
(Unaudited – see Notice to Reader dated November 29, 2022)

As of,	**September 30, 2022**	**March 31, 2022**
		(Audited)
Assets		
Current assets		
Cash and cash equivalents	**$ 15,038**	$ 23,352
Prepaid expenses and other receivables	**1,542**	1,480
Convertible note receivable, including accrued interest	**590**	–
	17,170	24,832
Long-term assets		
Investments in associates	**1,557**	1,673
Investments in private companies	**7,409**	7,409
Goodwill	**43,464**	43,324
In-process research and development	**145,986**	117,388
Deferred commitment fee	**900**	–
Other assets, including equipment, net	**39**	36
Total assets	**$ 216,525**	$ 194,662
Liabilities and Equity		
Current liabilities		

Accounts payable and accrued liabilities	**$ 1,425**	$ 750
Warrant liability	**8**	33
	1,433	783
Non-current liabilities		
Deferred tax liability	**23,339**	28,445
Deferred purchase price payable - Tarus	**8,522**	–
Deferred obligation - iOx milestone	**5,424**	–
	37,285	28,445
Total liabilities	**38,718**	29,228
Shareholders' Equity		
Capital stock	**215,830**	158,324
Stock option reserve	**19,329**	16,928
Accumulated other comprehensive income	**958**	958
Accumulated deficit	**(57,683)**	(55,005)
Total equity attributable to owners of the Company	**178,434**	121,205
Non-controlling interest	**(627)**	44,229
Total equity	**177,807**	165,434
Total liabilities and equity	**$ 216,525**	$ 194,662

Source: Portage Biotech, Inc.