

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 6-K

**REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE SECURITIES
EXCHANGE ACT OF 1934**

For the month of August 2021

Commission File Number: **0-30314**

Portage Biotech Inc.

(Exact name of Registrant as specified in its charter)

N/A

(Translation of Registrant's name into English)

British Virgin Islands

(Jurisdiction of incorporation or organization)

Craigmuir Chambers, Road Town, Tortola, British Virgin Islands, VG1110.

(Address of principal executive offices)

c/o Portage Services Ltd, Ian Walters, 203.221.7376

6 Adelaide Street East, Suite 300, Toronto, Ontario, Canada M5C 1H6

(Name, telephone, e-mail and/or facsimile number and Address of Company Contact Person)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F [X] Form 40-F []

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ____

Note: Regulation S-T Rule 101(b)(1) only permits the submission in paper of a Form 6-K if submitted solely to provide an attached annual report to security holders.

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ____

Note: Regulation S-T Rule 101(b)(7) only permits the submission in paper of a Form 6-K if submitted to furnish a report or other document that the registrant foreign private issuer must furnish and make public under the laws of the jurisdiction in which the registrant is incorporated, domiciled or legally organized (the registrant's "home country"), or under the rules of the home country exchange on which the registrant's securities are traded, as long as the report or other document is not a press release, is not required to be and has not been distributed to the registrant's security holders, and, if discussing a material event, has already been the subject of a Form 6-K submission or other Commission filing on EDGAR.

EXHIBIT INDEX

Exhibit Number **Description**

[99.1](#) [Press Release dated August 12, 2021](#)

SIGNATURES

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, thereunto duly authorized.

Portage Biotech Inc.
(Registrant)

Date: August 12, 2021

/s/ Ian Walters
Ian Walters
Chief Executive Officer

Portage Biotech Issues Letter to Shareholders

WESTPORT, Conn., Aug. 12, 2021 (GLOBE NEWSWIRE) -- Portage Biotech Inc., (NASDAQ: PRTG) (“Portage” or the “Company”) a clinical-stage immuno-oncology company focused on the development of therapies targeting cancer treatment resistance, today issued the following letter to shareholders:

Dear Shareholders,

On behalf of the team at Portage Biotech, Inc., I am pleased to provide you with a corporate update, reflecting on the progress that we have made throughout the first half of 2021 and the foundation these accomplishments have built – both for the remainder of the year and for the future.

Over the past six months, Portage has progressed its research and development for novel immuno-oncology therapeutics while simultaneously launching an important business transformation to strongly position itself for accelerated development of its innovative cancer treatments. As such, we are pleased to note that the first three assets within our portfolio have entered the clinic, a milestone achievement driven by our vision of helping those with cancer achieve durable responses and a better quality of life.

A key initiative of this transformation has been enhanced and proactive communication with our stakeholders. We have increased the frequency of our communications, launched a redesigned investor section on our website with easy access to news, publication, filing, and stock materials, establishing a regular cadence with our financial reporting and providing our shareholders with updates as new assets have entered the clinic. We have shared our insights and approach with multiple industry outlets including the BioWorld Report, the Empowered Patient Podcast and Forbes, who have featured Portage, our innovative drug development engine and our novel assets. In addition, we plan to have a presence at key investor conferences in late 2021.

To establish Portage as a leader in novel immunotherapy development, we have proactively taken actions necessary to reach new milestones, beginning with our listing on Nadsaq. To date, we have increased financial resources and attracted new investments with over \$29 million raised since our March 31 year end, including \$2.6 million through the implementation of an At-The-Market facility (ATM) and our recent financing of \$26.5 million in late June 2021. These financings are the first with formal biotech institutional support and provide us with sufficient cash runway to advance our iNKT agonists and other assets through multiple data milestones and other value-driving catalysts over the next 18-24 months.

We believe that a tremendous opportunity exists within the immuno-oncology market for best-in-class cancer therapies, and are determined to evaluate our novel assets and asset combinations to address cancer patients’ unmet medical needs. These recent milestones, outlined below, build the core foundation of Portage’s evolution and offer us the opportunity to reduce our cost of capital while providing supplemental capital to further leverage our drug product development engine as we aim to deliver on our objectives for the second half of 2021 and 2022.

Propelling our 2 novel iNKT agonists into the clinic in several indications

Our lead asset and immediate value driver, the invariant natural killer T cell (iNKT) platform, bridges the innate and adaptive immune system, providing broad potential to reprogram the immune response and re-sensitize PD-1 resistant tumors.

To maximize the iNKT technology’s impact on the standard of care for cancer patients to achieve durable treatment responses and a better quality of life, we have established a three-pronged developmental strategy. Our clinical development plan highlights the distinctive utility of iNKTs in three different settings: 1) a liposomal formulation iNKT agonist, 2) nanoparticle coformulation of our iNKT agonist with an antigen to establish immune priming and boosting and lastly, 3) iNKT agonists can be used as a universal agent to boost responses with cell therapies.

In our last R&D update, we noted that promising preclinical data for our iNKT agonist platforms, PORT-2 and PORT-3, was propelling us to move them into the clinic as quickly as possible. We are proud to say that we have entered the clinic, achieving the following milestones:

- **Dosing the first patient in a Phase 1 study of PORT-3**

The first patient was dosed in the PRECIOUS Phase 1 study of PORT-3, our nanoparticle coformulation of our iNKT agonist (IMM60) and NY-ESO-1 in patients with NY-ESO-1 expressing tumors. The Phase 1 portion of the trial is expected to enroll 15 patients while the randomized Phase 2 portion is expected to enroll an additional 42 patients. This platform is designed to demonstrate proof of concept with NY-ESO-1 as our enrichment factor for patient accrual. Our patent position extends to other known tumor antigens and we are prepared to rapidly launch other assets into the clinic if we see strong activity of this formulation. Notably, Portage received additional grant support from the Horizon 2020 program to explore next generation targeted nanoparticles.

- **Dosing of the first patient in a Phase 1/2 study of PORT-2**

We recently dosed the first patient in the IMP-MEL randomized Phase 1/2 clinical trial of PORT-2, a liposomal formulation of our IMM60 iNKT agonist both as a monotherapy and in combination with standard of care (Keytruda) in melanoma and NSCLC. The PORT-2 study has 6 arms and is expected to enroll up to 100 patients.

Aligning with the commencement of our Phase 1/2 clinical trial of PORT-2, The recent Gilead-Kite/Appia collaboration has served as further validation of the role of iNKT cells in cancer. We have plans to assess the potential for iNKTs for use as a universal boosting agent in combination with the ever-growing pipeline of cell therapies. This combination may offer a way to further activate an adaptive response after the cells are readministered to the patient.

There is substantial opportunity for potential expansion in the PD-1 market with PORT-2 and PORT-3. 70-80% of patients do not respond or have a limited response to existing therapies, such as PD-1 checkpoint inhibitors. The market is saturated with 14 approved PD-1 antibodies, and every major pharma company competing in this space. With iNKT agonists upregulating expression of PD-L1, patient populations who are typically not good candidates for PD-1 antibodies due to their lack of or low expression of PD-L1 may be able to utilize PORT 2 or PORT-3 to sensitize tumors to PD-1 agents. Extending the use of PD-1 antibodies represents a significant upside for one of these companies competing for market share, should they choose to partner with Portage.

With the \$26.5 million gross proceeds from our recent public offering secured, we're able to accelerate development activities and provide two years of capital runway, enough to complete Phase 1 and Phase 2 clinical trials for our iNKT agonists. Our goal with our iNKT agonist platforms is to expand the number of sites and countries that can accrue to the PORT-2 and PORT-3 studies and provide additional operational support. We're on a trajectory to achieve numerous milestones across our pipeline, as well as de-risking events and valuation inflection points. This includes 10 or more different data catalysts across our entire portfolio, a select portion of which are made possible with this cash runway. Throughout 2021 and 2022, we plan to provide multiple data readouts, ranging from safety assessment and dose finding to ten or more different Phase 2 clinical efficacy assessments. We take pride in our innovative drug development engine and lean, experienced team that knows how to de-risk assets, focusing on the most promising studies and study designs to maximize value for our shareholders, enabling us to achieve operational and capital efficiency.

Amphiphilic platform development progress

In addition to our iNKT platform, we have also advanced development of PORT-1 (INT230-6 being developed by Intensity Therapeutics with assistance from Portage). PORT-1 consists of amphiphilic solutions that deliver cancer-killing agents directly to target tumors following intratumoral injection. Newly released interim safety and survival data from the Phase 1/2 IT-01 study presented at ASCO 2021 demonstrated that both INT230-6 (PORT-1) monotherapy and combination therapy with immune checkpoint drugs are well-tolerated. The proven mechanism of action includes direct tumor-killing effects, as well as responses generated in non-injected tumors (abscopal responses) resulting from antigen presentation and immune activation. PORT-1 is the first of Portage's assets that entered the clinic and has demonstrated proof-of-concept in humans.

The IT-01 study is ongoing with additional clinical data reads expected over the next 12-18 months, conducted in collaboration with and oversight by joint development teams with Bristol Myers Squibb and Merck. The team has expanded its collaboration efforts with the INVINCIBLE study, conducted by the Ottawa Hospital and the Ontario Institute for Cancer Research. The company plans on presenting updates from the INVINCIBLE and IT-01 studies at upcoming industry meetings.

Expanded investor base & support of Portage's platforms and pipeline

Added visibility and support is crucial in our ongoing efforts to secure financing capable of fueling our drug development engine and propelling our five platform technologies into and through the clinic. Through strategic evaluation and planning, we came to the executive decision that we could be best positioned for this enhanced visibility through the Nasdaq stock exchange, prompting our listing to Nasdaq in February 2021. This played a key role in securing our spot on the Russell 2000 Index, which is widely used by investment managers and institutional investors for index funds and as benchmarks for active investment strategies.

Every step we've taken has led up to the financing we completed in June 2021, which has made our investor base even stronger with the addition of fundamental biotech institutional support. Through this financing, we opened our doors and welcomed several institutional investors into our strategic vision and approach at an exciting and important time of rapid growth for the Company.

Investor demand and confidence in Portage was overwhelmingly positive and reflective of both the potential of the Company's technology and our leadership team's experience and capacity to execute on the development of the most promising immuno-oncology assets. Despite facing a challenging time to complete a financing, we were able to showcase the potential of our innovative development engine, our novel iNKT agonists, and our foundation for accelerated development in the coming months, to raise over \$29 million in gross proceeds since Portage's March 31, 2021 fiscal year end.

Backed by this support, Portage is now strongly positioned to achieve its objectives with the hopes of repeating the success we historically achieved with Biohaven. The financing, coupled with the addition to the Russell 2000, has also enhanced the liquidity profile of our stock.

In the coming year we plan to progress our preclinical and clinical pipeline significantly. We are looking to accelerate preclinical development of our PORT-4 platform, which may potentially increase the potency and improve the safety of numerous anti-cancer drugs through co-delivery of combination treatments to the tumor, and our PORT-5 STING platform, which provides distinct advantages over chemical intratumoral approaches by offering a potent immune priming and boosting pathway within a virus-like particle (VLP) to enable convenient systemic administration and traffic to the correct targets. We continue to work with our artificial intelligence partners to identify new assets to add to the portfolio. Our ambitious goal is to bringing 1-2 new

products into the clinic each year. To enable the pipeline growth and advancement, it is of the utmost importance to us to continue to build relationships with fundamental biotech investors and to engage with potential big pharma partners to discuss strategies to accelerate the entry of these products to the market.

On behalf of the Portage team and Board members, we thank you for your continued support as we build on this initial transformation to accelerate growth of our pipeline, business and programs over the coming months. To stay up to date on the latest announcements, presentations, filings and publications, please sign up for alerts on the new investor section of our website at <https://ir.portagebiotech.com>.

Regards,

Ian Walters, CEO of Portage Biotech, Inc.

About Portage Biotech Inc.

Portage is a clinical-stage immuno-oncology company advancing first-in-class therapies that target known checkpoint resistance pathways to improve long-term treatment response and quality of life in patients with evasive cancers. The Company'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 five diverse platforms, leveraging delivery by intratumorals, nanoparticles, liposomes, aptamers and virus-like particles. Within these five platforms, Portage has 10 products currently in development with multiple clinical readouts expected over the next 12-24 months. 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

This news release contains statements about the Company's information that are forward-looking in nature and, as a result, are subject to certain risks and uncertainties. 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 the 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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