
BIVICTRIX THERAPEUTICS LIMITED

*(Incorporated in England and Wales under the Companies Act 2006
with registered number 13470690)*

BUSINESS UPDATE



Forward-Looking Statements

This update contains "forward-looking statements" which includes all statements other than statements of historical fact including, without limitation, those regarding the Company's financial position, business strategy, plans and objectives of management for future operations, or any statements preceded by, followed by or that include the words "targets", "believes", "expects", "aims", "intends", "will", "may", "might", "anticipates", "would", "could", "shall", "estimate", "plans", "predicts", "continues", "assumes", "positioned", or similar expressions or negatives thereof. Such forward-looking statements involve known and unknown risks, uncertainties and other important factors beyond the Company's control that could cause the actual results, performance or achievements of the Company to be materially different from future results, performance or achievements expressed or implied by such forward-looking statements. Such forward-looking statements are based on numerous assumptions regarding the Company's present and future business strategies and the environment in which the Company will operate in the future. These forward-looking statements speak only as at the date of this update. The Company expressly disclaims any obligation or undertaking to disseminate any updates or revisions to forward-looking statements contained herein to reflect any change in the Company's expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based unless required to do so by applicable law. All subsequent oral or written forward-looking statements attributed to the Company or any persons acting on its behalf are expressly qualified in their entirety by the cautionary statement above.

Directors:

Dr Michael Glen Kauffman (*Chair*)
Tiffany Jane Thorn (*Chief Executive Officer*)
Dr Robert Edward Hawkins (*Non-Executive Director*)
Susan Day Lowther (*Non-Executive Director*)
William Drummond Paris (*Non-Executive Director*)

Registered Office:

Mereside
Alderley Park
Alderley Edge
Macclesfield
SK10 4TG

2 May 2025

Business Update

1. Business Update






We last wrote to Shareholders on 19 December 2024 which provided an update on the activities at BiVictriX following our delisting from AIM last year, as well as an update on our fundraising activities.

Since then, we have continued to make progress across the business, albeit, the large fundraising exercise is taking longer than we originally envisaged, reflecting current investment conditions for our sector.

Pipeline Update

Our current pipeline and priority of assets is illustrated below and further details on the current progress and status of our key programs is included in this update.

Figure 1: BiVictriX pipeline – April 2025.

	Program	Indications	Discovery	Preclinical	IND-Enabling	Milestones
Solid Tumors	BVX002 B7H4xTarget X Bispecific ADC	Ovarian Cancer & Other Solid Tumors				• 2H 2026 – IND submission
	BVX004 Undisclosed Bispecific ADC	Multiple Solid Tumor				
	Bispecific ADC target library	Multiple Tumor Indications				Target pair library identified across multiple solid tumor indications
Hematological Malignancies	BVX001¹ CD7xCD33 Bispecific ADC	Acute Myeloid Leukemia & Myelodysplastic Syndrome				• Partnership Candidate
	Bispecific ADC target library	Heme Malignancies				

1. Orphan drug designation granted in April 2024

BVX002

As communicated in our December 2024 shareholder update, preclinically, BVX002 has demonstrated highly promising tumour selectivity and efficacy in solid tumour models, with tumour regressions of up to 63% reported. The target market is large with 62% of patients with Ovarian Cancer not eligible to receive the market-leading ADC, AbbVie's Elahere®. This patient cohort retains co-presence of both of the BVX002 target antigens and therefore our data illustrates that they would be eligible for treatment with BVX002.

Internal data from preclinical models provide supporting evidence that BVX002 should be able to effectively treat patients with both variable levels of expression of the two target antigens; this is in contrast to competitor ADCs in Ovarian Cancer which generally depend on high levels of cancer target expression for patient eligibility and therefore only target a subset of patients. The ability to target tumour heterogeneity more effectively constitutes a key differentiation of our BVX002 ADC compared to the traditional monospecific ADC approach.

To provide further compelling data that our program is able to effectively treat patients with variable levels of expression of both of the two target antigens, in the next few weeks we will be commencing a head-to-head data trial of our BVX002 lead candidate versus 2 clinical-stage competitors in a mouse model of Ovarian cancer. We expect this data to be available towards the end of Q2 2025.

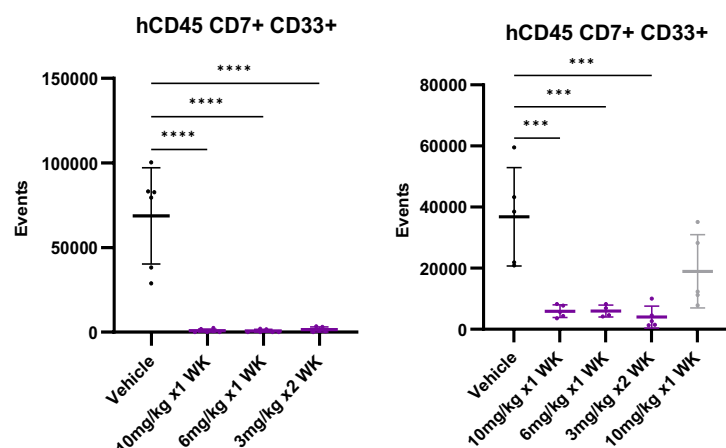
We continue to drawdown the Innovate UK grant for this program which provides us with reimbursement of 70% of eligible costs. The grant runs until the end of September 2025 and we will be evaluating whether there is further grant support available for the next phase of this program.

BVX001

In our December 2024 update, we reported promising in-vitro efficacy data in primary patient samples taken from a diverse array of AML patients from diagnosis to relapse. We also reported that we had generated promising data from a rodent toxicity study demonstrating the improved safety profile of BVX001 versus other ADC's using the same payload.

Since the last update, we now have excellent data generated in 2 independent patient-derived xenograft ("PDX") studies – These mouse studies are viewed as gold standard for assessing efficacy preclinically for different cancer types. The data that we have generated (in the two figures below) demonstrates that BVX001 causes statistically significant reduction in CD33+ CD7+ AML blasts at doses that are not toxic to healthy cells.

Figure 2: BVX001 efficacious in AML PDX models at doses not toxic to healthy myeloid cells, neutrophils & healthy lymphoid cells in humanized mouse models.



Furthermore these studies also demonstrate that BVX001 can significantly reduce CD33+ and CD7+ blasts in both homogeneous and heterogeneous AML models.

While the Board views this data as very positive, we have recently made the strategic decision to focus our funds on our solid tumour assets where we are seeing greater investor and corporate interest. Therefore, we will be exploring opportunities to partner this program with potential licensors or collaborators who may have an active interest and knowledge in the AML space.

As mentioned in the most recent Shareholder update, the next key stage for BVX001's progression would be to commence the manufacture of materials in preparation for a Phase1 trial in humans and would be dependent upon securing significant further external funding. The Board believes that current funds are best prioritised for our BVX002 asset and hence the strategic decision to seek to partner this program.

BVX004

The Board have reviewed our current allocation of available funds and, given the current funding environment, we have paused development on this asset to focus on BVX002. If further external funding is secured, we will expedite the development of this program and also review our target discovery library to ensure our funds are focused on our most promising and commercially lucrative assets.

Financial and cash position

We have recently completed our audit for the year-ended December 2024 and a copy of the full Annual Report will be added to our website as soon as signed off by the Board.

Total expenditure for the year was £2.9m versus £3.0m in the prior year with £2.0m of this being spent on direct Research & Development.

In order to maximise our current runway and to ensure as much of our resources are directed to developing our programs, we have not replaced staff who have left during the year.

We will shortly be submitting our claim to HMRC for repayable tax credits under both the R&D and RDEC schemes. Our claim will be for £377,000 which is in addition to the Innovate UK grant receipts that we continue to receive on a quarterly basis.

Proposed Board Changes

Since delisting from AIM, we have maintained the same Board of Directors who have provided invaluable support and challenge to the business both during and after our time on AIM. Now that we are a private company we feel that it is the right time to make some amendments to our Board.

On completion of the fundraising, Robert Hawkins, Susan Lowther and Drummond Paris will be resigning from their positions as Non-Executive Directors at the General Meeting on 23rd May 2025. Michael Kauffman will continue as Non-Executive Chair and Tiffany Thorn will continue as CEO. The remaining Board members would like to thank Robert, Susan and Drummond for their invaluable contributions since their appointment.

We look forward to communicating further business updates including the results of our ongoing BVX002 trial shortly.