

Context Therapeutics

Q123 update

FY23 focus squarely on CTIM-76

Pharma and biotech

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Context Therapeutics reported Q123 results and its strategic priority for FY23 and beyond. The key highlight for the quarter was its decision to pivot its pipeline focus towards its novel bispecific CLDN6xCD3 antibody, CTIM-76 (IND-enabling studies ongoing) and terminate the development of its ONA-XR program. Operating expenses for the quarter were \$6.7m, an increase of 94% y-o-y (Q122: \$3.4m), driven by a more than 3x increase in R&D expenses to \$4.5m (Q122: \$1.4m). With no further R&D earmarked for ONA-XR (\$2.1m in Q123), we expect a lower run rate for operating expenses for the remainder of FY23. The period-end net cash balance was \$29.8m, which management has guided to last into late 2024, well past the Q124 timeline for the CTIM-76 investigational new drug (IND) filing. This implies a quarterly burn rate of c \$4.3m until Q424 (\$5.7m in Q123; \$3.6m ex-ONA-XR R&D expenses). We expect the IND filing for CTIM-76 to be the next share price catalyst for Context.

Year end	Revenue (\$m)	PBT* (\$m)	EPS* (\$)	Operating cash flow (\$m)	P/E (x)	Yield (%)
12/21	0.0	(10.6)	(3.74)	(10.5)	N/A	N/A
12/22	0.0	(14.8)	(0.93)	(15.4)	N/A	N/A

Note: *PBT and EPS are normalized, excluding amortization of acquired intangibles, exceptional items and share-based payments.

The first quarter of FY23 was marked by Context's decision to reprioritize its development focus away from the ONA-XR program ([March 2023](#)) and towards its other asset, CTIM-76, a novel bispecific CLDN6xCD3 antibody, targeting Claudin 6-expressing tumors. CLDN6 has emerged as a highly attractive therapeutic target in oncology, with expression across a variety of malignant tumor cells (but rarely in healthy tissue), although progress has been undermined by concerns around off-target toxicities. In [April 2023](#), Context presented preclinical data on CTIM-76 at the American Association for Cancer Research meeting, highlighting its strong selectivity and binding to CLDN6, alongside a potentially beneficial safety profile. The competitive landscape for this class of drugs is still evolving, but we view BioNTech (BNT211) and Amgen (AMG 794) as the closest competitors to CTIM-76. We believe that the latest [Phase I data](#) for BNT211 provide early validation of CLDN6's potential as a therapeutic target, but CTIM-76's strong selectivity and activity for CLDN6, if reproduced in clinical trials, could provide a competitive edge.

Higher R&D expenses in Q123 were driven by increased costs from ONA-XR (\$2.1m vs \$0.9m in Q122, due to initiation of the Phase Ib/II ELONA trial) and CTIM-76 (\$2.1m vs \$0.08m in Q122, related to higher contract manufacturing costs and IND-enabling studies). We expect costs to go down with the discontinuation of the ONA-XR program, although we anticipate some increase in CTIM-76-related R&D expenses in the run-up to the Q124 IND filing. General and administrative expenses for Q123 were broadly consistent with Q122 at \$2.1m; we expect a similar run rate for FY23.

We estimate that the Q123 cash balance (\$29.8m) is sufficient to initiate the Phase I clinical trial for CTIM-76, but foresee the need for additional funding to progress the asset further through the clinic. Management has communicated that it is open to exploring various options, including external fund-raising, partnership or asset sale.

Price **\$0.62**
Market cap **\$10m**

Net cash (\$m) at 31 March 2023	29.8
Shares in issue	15.97m
Free float	91%
Code	CNTX
Primary exchange	Nasdaq
Secondary exchange	N/A

Share price performance



Business description

Context Therapeutics is a clinical-stage biopharma company developing therapeutics for solid tumors. Following a strategic pivot, the core pipeline focus will be on CTIM-76, a selective Claudin 6 (CLDN6) x CD3 bispecific antibody for CLDN6 positive tumors, which is in preclinical development with plans for an IND application filing in Q124.

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