EDISON

Context Therapeutics

Earnings update

A catalyst-rich year ahead

Pharma & biotech

Context Therapeutics' FY21 results echoed previously highlighted progress on its novel women's oncology franchise. With all four clinical programs expected to have initial read-outs in 2022, the next few months could be instrumental in shaping the outlook for the company. The share price, which has remained range bound in recent months, could potentially see an uplift on positive data readouts. Importantly, the cash position remains robust with the year-end cash balance of $50m sufficient to extend the runway into 2024. In the nearer term, we expect the upcoming presentations at the AACR (April 2022) to likely catalyze a momentum shift, contingent on the quality of the data. Pending upcoming read-outs, our valuation remains largely unchanged at $134.1m or $8.40/share.

Year end	Revenue ($m)	PBT* ($m)	EPS* ($)	DPS ($)	P/E (x)	Yield (%)
12/20	0.0	(3.2)	(9.28)	0.0	N/A	N/A
12/21	0.0	(10.6)	(3.74)	0.0	N/A	N/A
12/22e	0.0	(16.1)	(1.01)	0.0	N/A	N/A
12/23e	0.0	(22.3)	(1.40)	0.0	N/A	N/A

Note: *PBT and EPS are normalized, excluding exceptional items.

The pipeline is approaching key inflection points

Enrollment remains on track across all clinical programs (three Phase II and one Phase Ib/II trials evaluating lead asset ONA-XR in multiple hormone-driven cancers). With preliminary data expected from two studies (first line HR+/HER2- mBC and recurrent endometrial cancers) by mid-2022 (and in H222 for the other two), investors have plenty to look out for in the near term. Positive data from any one study could potentially trigger an upswing in the stock price, in our view. For the second asset, CLDN6xCD3, the company anticipates the selection of a candidate in 2022.

Upcoming AACR data a potential near-term catalyst

In March 2022, Context announced plans to present five abstracts highlighting new preclinical data on the ONA-XR and CLDN6xCD3 programs at the upcoming American Association for Cancer Research Annual Meeting (AACR) in April 2022. We look forward to these data-readouts and believe that the quality and strength of this data could underpin near-term momentum for the company.

Cash balance offers headroom to 2024

Context reported $49.7m cash at year-end 2021, and we estimate these funds should extend the company's operating runway into 2024. Nevertheless, in the absence of ensuing partnerships/out-licensing deals, we continue to estimate the need to raise a further $110m (modelled as illustrative debt) between FY24 and FY26, as discussed in our recent initiation report dated 24 February 2022.

Valuation: $134.1m or $8.40 per basic share

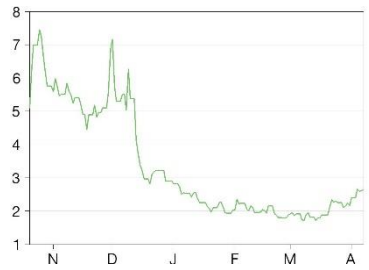
We have incorporated the reported FY21 results and have added another year to our estimates (FY24). After adjusting for the estimated (end Q122e) cash balance of $46.4m, our valuation remains largely unchanged at $134.1m (or $8.40 per basic share), from $134.9m (or $8.45 per basic share) previously.

8 April 2022

Price	**$2.4**
Market cap	**$38.3m**

Net cash ($m) at 31 December 2021	49.7
Shares in issue	15.97m
Free float	67%
Code	CNTX
Primary exchange	Nasdaq
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	52.3	4.7	N/A
Rel (local)	42.2	8.9	N/A
52-week high/low	US$7.5		US$1.7

Business description

Context Therapeutics is a clinical-stage women's oncology company. Lead candidate ONA-XR is a 'full' progesterone receptor antagonist currently being evaluated in three Phase II clinical trials in hormone-driven breast, endometrial and ovarian cancer. Preliminary data from at least one trial are expected in mid-2022. The other asset is a bi-specific monoclonal antibody, CLDN6xCD3, currently undergoing preclinical development.

Next events

Preclinical data presentations at AACR	April 2022
ONA-XR 1st line HR+HER2-mBC and endometrial cancer Phase II preliminary data	Mid-2022

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Edison profile page

Pipeline momentum building

ONA-XR is poised to report preliminary data across programs

Context's clinical programs continue to progress towards their respective deadlines for preliminary data readouts and we expect the results to dictate investor sentiment in the near to medium term, provided there are no material delays in reporting the observations (a common concern with investigator-sponsored trials given that the company does not have full control of the study).

All clinical studies are evaluating the company's lead asset ONA-XR across a range of hormone-driven cancers (breast, ovarian and endometrial cancer). As a quick refresher, ONA-XR is an extended-release version of the progesterone receptor (PR) antagonist onapristone, the only 'full' PR antagonist (no agonist activity) to be tested in humans to date, to our knowledge. The drug is being evaluated as a combination therapy in hormone-driven cancers affecting women, including hormone receptor-positive (HR+)/human epidermal growth factor receptor 2 negative (HER2-) metastatic breast cancer (mBC) (Phase II trials in second-/third-line treatment and Phase Ib/II trials as first-line escalation therapy for a subset of patients), recurrent endometrial (uterine) cancer (Phase II) and a rare form of ovarian cancer termed granulosa cell tumor (GCT) of the ovary (Phase II). The company's pipeline is presented in Exhibit 1 below and discussed in greater detail in our recent initiation report.

Exhibit 1: Context Therapeutics pipeline

Cancer	Clinical Indication	Research	Phase 1	Phase 2	Phase 3	Upcoming Milestones	FDA Fast Track
ONA-XR (PR antagonist)[1]							
Breast Cancer	1L ER+,PR+,HER2- ctDNA^{high}		Phase 1b/2 Trial			• Phase 1b data Mid 2022	
	2L/3L ER+,PR+,HER2- Post-CDK4/6 inhibitor		Phase 2 Trial			• Preliminary data 2H 2022	
Ovarian Cancer	Recurrent PR+ Granulosa Cell		Phase 2 Trial			• Preliminary data 2H 2022	✓
Endometrial Cancer	Recurrent PR+ Endometrioid		Phase 2 Trial			• Preliminary data Mid 2022	
CLDN6xCD3 bispecific antibody							
	Ovarian & Endometrial Cancer					• IND enabling studies 2022	

Source: Context Therapeutics

Although two of the four clinical programs are expected to report preliminary data by mid-2022 (first line HR+/HER2- mBC – Phase Ib and recurrent endometrial – Phase II cancers), we continue to expect the second-/third-line HR+/HER2- mBC opportunity to be the lynchpin for driving future value for Context. Results for this study are expected in H222. In our last note, we also highlighted potential competition from the newer-generation oral selective estrogen receptor degraders (SERDs), four of which were in advanced-stage clinical development at that time. We note that since we last wrote, Sanofi's oral SERD amcenestrant has failed its Phase II Ameera-3 clinical trial and the fate of Roche's Giredestrant (results expected in Q222) remains uncertain given its similarity in study design and endpoints to amcenestrant. While this may make for a clearer path for Context, it also highlights the risks inherent in the space.

Upcoming AACR presentations could be a potential catalyst

In March 2022, the company announced that it will be presenting five separate abstracts highlighting new preclinical data on its assets ONA-XR and CLDN6xCD3 at the upcoming AACR scheduled for the second week of April 2022, followed by an R&D webinar. AACR is a leading global academic conference for oncology research, and we expect that these presentations, if compelling, could swing the momentum in the company's favor. We will be covering the results from the AACR and subsequent R&D meet in a note following the event on 13 April.

CLDN6xCD33 inching closer to the clinic

Looking beyond ONA-XR, for the second asset, the bispecific monoclonal antibody (BsAb) CLDN6xCD3, the company expects to select a clinical candidate in the second half of 2022 to support IND-enabling studies. CLDN6, a protein coding gene, part of the claudin family of tight junction proteins, is enriched in several cancer cells (rarely in healthy tissue), but accurate selectivity remains a challenge. While several pharmaceutical companies are developing CLDN6 targeting antibodies, Context claims best in-class potential with a 10x selectivity over competitors and potentially improved efficacy through CD3 facilitated T-cell recruitment. The asset is currently not included in our valuation, with potential to add upside on clinical progression.

Valuation

Since no material developments have taken place since our initiation note, our overall valuation remains largely unchanged at $134.1m or $8.40 per basic share (Exhibit 2), down marginally from $134.9m or $8.45 per basic share. The slight decrease is primarily due to updating the net cash figure to reflect our Q122 estimate of $46.4m. We will reassess our valuation following data read-outs from the four ONA-XR studies.

Exhibit 2: Context Therapeutics valuation (risk-adjusted NPV)

Program	Indication	Status	Probability of success	Launch year	Peak sales ($m)	Economics	Risked NPV ($m)
ONA-XR	Second-line HR+/HER2- mBC	Phase II	15%	2026	498	US (fully owned) Europe (out-licensed)	40.7
	First-line escalation therapy for HR+/HER2- mBC (ctDNA+)	Phase Ib	7.5%	2027	222	US (fully owned) Europe (out-licensed)	7.0
	Recurrent PR+ endometrial cancer	Phase II	10%	2027	583	US (fully owned) Europe (out-licensed)	28.5
	Advanced GCT of the ovary	Phase II	10%	2027	292	US (fully owned) Europe (out-licensed)	11.5
Net cash (estimated at the end of Q122) $m							46.4
Total firm value							**134.1**
Total basic shares (m)							16.0
Value per basic share ($)							**8.40**
Total diluted shares (m)							1.6
Value per diluted share ($)							**7.65**

Source: Edison Investment Research

Financials

Context's FY21 results were broadly in line with our expectations. While R&D expenses ($3.8m, excluding the one-time costs of $3.1m associated with the acquisition of the CLDN6 asset) were slightly lower than our estimated figure of $4.6m, the G&A expenses were higher ($3.6m vs our estimate of $2.8m), resulting in the reported operating loss figure of $10.5m matching our forecast for the year. For FY22–24, we have tweaked our R&D and G&A expectations based on the FY21 trend, resulting in revised net loss figures that are slightly lower than our previous estimates. Our

cash burn projections have been marginally modified ($13.2m and $22.3m in FY22 and FY23, respectively, versus $10.9m and $24.8m), with the current cash balance ($49.7m at the end of December 2021) adequate to extend the runway into 2024. We continue to estimate another $110m capital raise before Context reaches profitability in 2027. We have modelled the required fund-raising as illustrative debt, according to Edison policy ($40m each in FY24 and FY25 and an additional $30m in FY26).

Exhibit 3: Financial summary

$000s	2020	2021	2022e	2023e	2024e
Year end 31 December	US GAAP	US GAAP	US GAAP	US GAAP	US GAAP
INCOME STATEMENT					
Revenue	0	0	0	0	0
Cost of Sales	0	0	0	0	0
Gross Profit	0	0	0	0	0
Research and Development Expenses	(1,642)	(6,893)	(12,336)	(16,904)	(30,786)
Sales, General and Administrative Expenses	(931)	(3,633)	(4,723)	(6,140)	(7,982)
EBITDA	(2,572)	(10,526)	(17,059)	(23,044)	(38,768)
Operating profit (before amort. and excepts.)	(2,572)	(10,526)	(17,059)	(23,044)	(38,768)
Amortization of acquired intangibles	0	0	0	0	0
Exceptionals	0	0	0	0	0
Share-based payments	0	0	0	0	0
Reported operating profit	(2,572)	(10,526)	(17,059)	(23,044)	(38,768)
Net Interest	(661)	(64)	994	730	283
Joint ventures & associates (post tax)	0	0	0	0	0
Exceptionals	9,878	133	0	0	0
Profit Before Tax (norm)	(3,233)	(10,590)	(16,065)	(22,314)	(38,485)
Profit Before Tax (reported)	6,644	(10,457)	(16,065)	(22,314)	(38,485)
Reported tax	0	0	0	0	0
Profit After Tax (norm)	(3,233)	(10,590)	(16,065)	(22,314)	(38,485)
Profit After Tax (reported)	6,644	(10,457)	(16,065)	(22,314)	(38,485)
Minority interests	0	0	0	0	0
Discontinued operations	0	0	0	0	0
Net income (normalized)	(3,233)	(10,590)	(16,065)	(22,314)	(38,485)
Net income (reported)	6,644	(10,457)	(16,065)	(22,314)	(38,485)
Average Number of Shares Outstanding (m)	0	3	16	16	16
EPS - basic normalized ($)	(9.28)	(3.74)	(1.01)	(1.40)	(2.41)
EPS - normalized fully diluted ($)	(9.28)	(3.74)	(1.01)	(1.40)	(2.41)
EPS - basic reported ($)	3.07	(3.69)	(1.01)	(1.40)	(2.41)
Dividend ($)	0	0	0	0	0
BALANCE SHEET					
Fixed Assets	118	0	0	0	0
Intangible Assets	0	0	0	0	0
Tangible Assets	0	0	0	0	0
Investments & other	118	0	0	0	0
Current Assets	350	51,306	37,123	14,806	17,549
Stocks	0	0	0	0	0
Debtors	0	0	0	0	0
Cash & cash equivalents	341	49,686	36,475	14,157	16,901
Other	9	1,620	648	648	648
Current Liabilities	(9,548)	(3,033)	(4,916)	(4,913)	(6,141)
Creditors	(2,708)	(1,826)	(2,960)	(2,799)	(3,296)
Tax and social security	0	0	0	0	0
Short term borrowings	(5,884)	0	0	0	0
Other	(956)	(1,207)	(1,956)	(2,114)	(2,845)
Long Term Liabilities	(69)	0	0	0	(40,000)
Long term borrowings	(69)	0	0	0	(40,000)
Other long-term liabilities	0	0	0	0	0
Net Assets	(9,150)	48,272	32,207	9,893	(28,592)
Convertible preferred stock	(7,771)	0	0	0	0
Minority interests	0	0	0	0	0
Shareholders' equity	(16,921)	48,272	32,207	9,893	(28,592)
CASH FLOW					
Op Cash Flow before WC and tax	(2,572)	(10,526)	(17,059)	(23,044)	(38,768)
Working capital	1,318	(2,225)	2,855	(3)	1,228
Exceptional & other	219	3,951	994	730	283
Tax	0	0	0	0	0
Operating Cash Flow	(1,035)	(8,799)	(13,210)	(22,318)	(37,256)
Capex	0	(250)	0	0	0
Equity financing	0	58,394	0	0	0
Dividends	0	0	0	0	0
Other	0	0	0	0	0
Net Cash Flow	(1,035)	49,345	(13,210)	(22,318)	(37,256)
Opening net debt/(cash)	21,742	13,384	(49,686)	(36,475)	(14,157)
FX	0	0	0	0	0
Other non-cash movements	9,393	13,725	0	0	0
Closing net debt/(cash)	13,384	(49,686)	(36,475)	(14,157)	23,099

Source: Context Therapeutics reports, Edison Investment Research

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