



30 September 2021

Pharmaceuticals & Biotechnology



Source: Refinitiv

Market data

EPIC/TKR	CIZ
Price (p)	4.7
12m high (p)	10.0
12m low (p)	4.4
Shares (m)	253.4
Mkt cap (£m)	11.8
EV (£m)	10.9
Free float	72%
Country of listing	UK
Market	LSE Main

Description

Cizzle is a medical device company developing a companion diagnostic biomarker for the early detection of lung cancer. The blood test will be used alongside a positive chest scan to confirm presence of lung cancer and reduce the high rate of false positives.

Company information

Executive Chair	Allan Syms
NED/Founder	Dawn Coverley
CFO	Nigel Lee
NED	John Treacy

www.cizzlebiotechnology.com

Key shareholders

Directors	5.3%
Yorkshire Cancer Research	12.8%
Finance Yorkshire	9.6%
University of Leeds	4.4%
University of Sheffield	4.4%
University of York	3.2%

Diary

4Q'21	SGSC agreement
Apr'22	Final results

Analyst

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CIZZLE BIOTECHNOLOGY

Keeping on-track

Cizzle Biotechnology (Cizzle), focused on cancer diagnostics, was spun out of the University of York to exploit the biomarker, variant CIZ1b, for early detection of different forms of lung cancer. There is high medical need for a simple blood test that allows early detection of lung cancer and potentially improve patient outcomes. Since listing, Cizzle has expanded this concept to develop a broader screening test, with the possibility of testing for other cancers and, in addition, developing a companion diagnostic for autoimmune disease. Cizzle continues to make progress on a number of fronts, most of which have come after the reporting period.

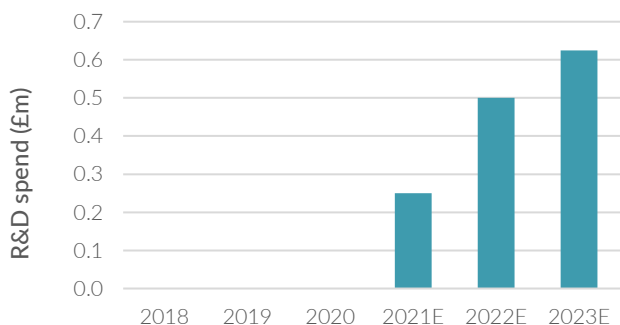
- **Strategy:** Cizzle is a diagnostic company that is progressing a biomarker diagnostic assay, which aims to deliver a simple blood test for lung cancer that can pick up the disease earlier to improve the chances of survival, and to greatly reduce the need for unnecessary follow-up tests and tissue biopsies.
- **Interims:** Results for 1H'21 were in line with expectations, after taking account of the £65k pre-payment for the MoU with SGSC (see below). Cizzle incurred modest administration costs of -£119k, compared with our forecast of -£200k, including the MoU payment. Net cash at 30 June was almost as forecast, at £1,425k.
- **SGSC:** Initially, Cizzle signed an MoU with St. George Street Capital (SGSC), a UK-based medical charity, to develop a companion diagnostic for one of its clinical assets, also with the potential to earn royalties. This has evolved into two deals, with the commercial and royalty deal signed, giving potential royalties of up to £5m.
- **FairJourney:** In July, Cizzle signed a collaboration deal with FairJourney Biologics (FJB) for the development and supply of proprietary monoclonal antibodies and reagents that will be the foundation for protein detection in its ELISA-based test. This was a key step highlighted in its admission document in May.
- **Investment summary:** Since Cizzle's listing, its shares have drifted while the market awaits news. Since the period-end, Cizzle has announced two new collaborations, which have the potential to expand the number and timing of income streams. Trading on an EV of just £10.9m, the market seems to be ignoring these deals, which suggests that Cizzle has considerable upside potential when investors become aware of these and as development progress is made.

Financial summary and valuation

Year-end Dec (£000)	2018	2019	2020	2021E	2022E	2023E
Sales	0	0	0	0	0	0
COGS	0	0	0	0	0	0
SG&A	-54	-22	-15	-300	-500	-550
R&D	0	0	0	-250	-500	-625
Underlying EBIT	-3	-22	-15	-370	-250	-1,425
Statutory EBIT	-3	-22	-15	-3,594	-250	-1,425
Underlying PBT	-3	-22	-15	-371	-251	-1,426
Statutory PBT	-3	-22	-15	-3,595	-251	-1,426
Underlying EPS (p)	-0.9	-6.9	-4.8	-0.2	-0.1	-0.5
Statutory EPS (p)	-0.9	-6.9	-4.8	-2.2	-0.1	-0.5
Net cash/(debt)	20	13	-3	855	535	-684
Equity issues	0	0	0	2,200	0	0

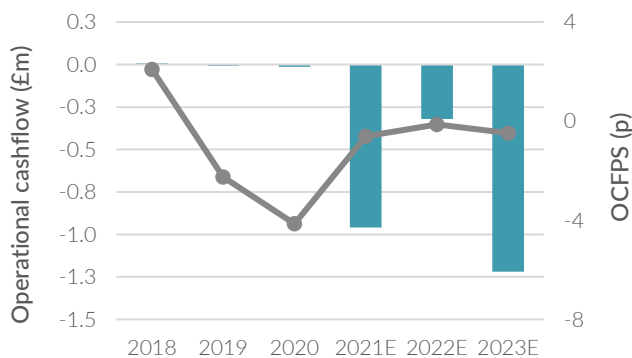
Source: Hardman & Co Life Sciences Research

R&D investment



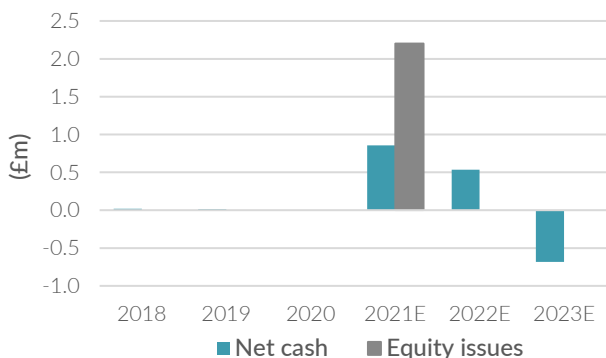
- ▶ Cizzle has successfully developed a prototype CIZ1b biomarker test on very limited resources.
- ▶ Much of the elucidation and understanding of CIZ1 was undertaken with grant funding.
- ▶ R&D investment will ramp up once funding is in place to develop the commercial CIZ1b biomarker test based on mAb direct-ELISA.

Operational cashflow and OCFPS (rhs)



- ▶ Cizzle will have two costs: R&D investment and the general corporate overhead.
- ▶ Some R&D tax credits can be expected, but payment by HMRC is usually six to 12 months in arrears.
- ▶ Given that much of the work will be outsourced, Cizzle will have only modest working capital requirements.
- ▶ The underlying cash burn during 1H'21 was a modest £119k.

Net cash and equity issues



- ▶ As part of its admission, Cizzle raised gross new capital of £2.2m (£1.97m net) through an institutional placing.
- ▶ At 30 June 2021, Cizzle had gross (and net) cash of £1.43m.
- ▶ Forecasts suggest that this will provide a cash runway of 18-24 months and that further funds will be required towards the end of 2022.

rhs=right hand scale
Source: Company data, Hardman & Co Life Sciences Research

2021 interim results

These are the inaugural results for Cizzle in its current form, largely reflecting the activities of the group since its listing on the London Stock Exchange (LSE) in May 2021.

Key features

Operational

- ▶ **Reverse takeover:** During the period, Bould Opportunities completed the reverse takeover of Cizzle Biotechnology Ltd, and renamed the company Cizzle Biotechnology Holdings plc. Concomitantly, its shares were listed on the Main market of the LSE.
- ▶ **FairJourney collaboration:** Post the period-end, Cizzle entered into a collaboration with FJB to develop proprietary antibodies for use, among other things, in the detection of CIZ1b, a fundamental part of its biomarker test for the early detection of lung cancer.
- ▶ **SGSC relationship:** Also post the period-end, Cizzle entered, initially, into an MoU with SGSC to collaborate on the development of a companion diagnostic for certain therapeutic assets licensed to SGSC by AstraZeneca (AZN). Cizzle will receive up to £1m in development fees per asset. As part of the MoU, Cizzle paid £65k on signing in return for the granting of a potential royalty stream.
- ▶ **Royalty rights:** Following on from the MoU with SGSC, Cizzle has subsequently signed a royalty sharing agreement with SGSC from the commercialisation of AZD1656, up to a maximum of £5m. Cizzle paid a further £135k to SGSC in September 2021 to secure these rights.

Financial

- ▶ **Cash raise:** At the time of its listing, Cizzle raised gross new capital of £2.2m (£1.97m net) for working capital purposes.
- ▶ **Underlying EBIT:** Given that Cizzle only became operational in its current guise on 14 May, the underlying EBIT loss reflects the modest level of administration costs that were incurred during the period.
- ▶ **Exceptional items:** The large exceptional item reflects the non-cash "share-based expense" of £2.82m related to the reverse takeover and transaction costs of £0.3m.
- ▶ **Net cash/(debt):** Cizzle has no debts or financial leases, so its gross (and net) cash position at the end of the period was £1.43m.

Cizzle interim results – actual vs. forecasts					
Half-year to June (£000)	1H'20 actual	1H'21 actual	Growth %	1H'21 forecast	Delta Δ
Sales	0	0	-	0	
Operating costs	-8	-119	n/m	-135	+16
R&D	0	0	n/m	-65	+65
Underlying EBIT	-8	-119	n/m	-200	+81
Exceptional items	0	-3,119	-		
Statutory EBIT	-8	-3,238	-		
Underlying EPS (p)	-2.5	-0.1	n/m	-0.2	+0.1
Net cash/(debt)	10	1,425	-	1,430	-5

*Comparative results are for Cizzle Biotechnology Limited
n/m=not meaningful*

*Figures may not add up exactly due to rounding
Source: Hardman & Co Life Sciences Research*

Corporate update

The primary goal of Cizzle is to expand on the scientific work originally undertaken by Professor Coverley and her team at the University of York regarding the role and understanding of variants of Cdkn1A-interacting zinc finger protein 1 (CIZ1) in many common cancers, through the development of diagnostic tests – in particular, variant CIZ1b, for the early detection of different forms of lung cancer.

Antibody development

A key step highlighted in its recent admission document was the identification and development of an antibody for the detection of CIZ1b in its diagnostic test. In July, Cizzle announced that it had signed a collaboration with FJB for the development and supply of proprietary monoclonal antibodies and reagents that will be used for protein detection in its ELISA-based test. This agreement expanded on the original plan, in that a licensable antibody-complex could arise, which could be used by research scientists to further the global knowledge and understanding of the role of CIZ1 and its variants, and thereby provide Cizzle with the opportunity to generate additional income streams and to increase value.

FJB is a Portuguese-based biologics clinical research organisation, which acquired IONTAS, a Cambridge-based antibody company, in 2020. FJB has a >99% record of developing antibodies for a specific target in a timely manner, using phage display technology.

SGSC

On 22 June 2021, Cizzle announced that it had signed an MoU with SGSC, a UK-based biomedical charity, whereby the two parties would collaborate to develop certain therapeutic assets already licensed to SGSC by AZN. The MoU is divided into two separate parts, each of which are subject to full agreements between Cizzle and SGSC.

- ▶ **Royalty:** In September 2021, Cizzle announced that the full agreement covering the royalty deal had been concluded (see research report¹). In return for a payment of £200k – £65k on signing the MoU and £135k on the full agreement – Cizzle will be entitled to receive royalties of up to £5m on net sales from the commercialisation of SGSC's therapeutic assets (AZD1656), plus further payments from the potential use of a companion diagnostic.
- ▶ **Companion diagnostic:** Cizzle and SGSC also agreed to collaborate for the development of a companion diagnostic platform for certain therapeutic assets already licensed to SGSC by AZN, which seek to address unmet clinical needs in autoimmune disease. This is pending the closure of a second full agreement, which is expected to follow shortly.

Cash position

At the period-end, Cizzle had a net cash position of £1.43m. During 2H'21, apart from the ongoing corporate overhead, the second payment of £135k to SGSC has been incurred. However, this will be countered by development income, estimated at £200k, likely to be received during 2H'21 as part of the companion diagnostic development programme when the second deal with SGSC is concluded. In addition, payments to FJB for the antibody development are expected to become due during 2H'21. Consequently, we are forecasting a net cash position of ca.£0.85m at the end of 2021.

¹ <https://www.hardmanandco.com/research/corporate-research/strategic-collaboration-with-sgsc/>

Financial summary

The income statement will be dominated by the investment in R&D and the corporate overhead during the forecast period. No income is expected other than recoverable development costs from SGSC. Therefore, these costs will drop straight through to the cashflow statement and determine the net cash position at the end of each financial year.

- ▶ **R&D:** The majority of the forecast R&D expense in 2021 is the payment to FJB for the antibody development work. In future years, the R&D will be a blend of the work for the Cizzle's ClZ1b diagnostic and the companion diagnostic for SGSC, but most of the latter will be recoverable.
- ▶ **Administration:** Given that most activities are outsourced, the general corporate overhead is forecast to be kept at a relatively low level.
- ▶ **Exceptional items:** In 2021, the large exceptional reflects the reverse takeover and transaction costs associated with the creation of the new entity, known as Cizzle.
- ▶ **Net cash/(debt):** Tight control of its limited resources suggests that Cizzle will end the current year with ca.£0.85m of cash, and no debts or lease liabilities.

Financial summary						
Year-end Dec (£000)	2018	2019	2020	2021E	2022E	2023E
Income statement						
Sales	0	0	0	0	0	0
COGS	0	0	0	0	0	0
SG&A	-54	-22	-15	-300	-500	-550
Share-based costs	0	0	0	-20	-50	-250
R&D	0	0	0	-250	-500	-625
Licensing/royalties	51	0	0	200	800	0
Underlying EBIT	-3	-22	-15	-370	-250	-1,425
Exceptional items	0	0	0	-3,224	0	0
Statutory EBIT	-3	-22	-15	-3,594	-250	-1,425
Net financials	0	0	0	-1	-1	-1
Underlying PBT	-3	-22	-15	-371	-251	-1,426
Statutory PBT	-3	-22	-15	-3,595	-251	-1,426
Tax liability/credit	0	0	0	50	100	125
Underlying net income	-3	-22	-15	-321	-151	-1,301
Underlying basic EPS (p)	-0.9	-6.9	-4.8	-0.2	-0.1	-0.5
Statutory basic EPS (p)	-0.9	-6.9	-4.8	-2.2	-0.1	-0.5
Balance sheet						
Share capital	3	3	3	25	25	25
Reserves	25	3	-12	1,846	1,695	395
Leases	0	0	0	0	0	0
Loans & borrowings	0	0	10	10	10	10
less: Cash & deposits	20	13	7	865	545	-674
Invested capital	8	-6	-5	1,017	1,186	1,105
Cashflow						
Underlying EBIT	-3	-22	-15	-370	-250	-1,425
Change in working capital	8	15	2	-199	-169	-144
Company op cashflow	7	-7	-13	-958	-369	-1,319
Capital expenditure	0	0	0	0	0	0
Equity issues	0	0	0	2,200	0	0
Change in net cash/(debt)	7	-7	-13	858	-320	-1,219
Opening net cash/(debt)	13	20	13	-3	855	535
Closing net cash/(debt)	20	13	-3	855	535	-684

Source: Hardman & Co Life Sciences Research

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