EDISON

Allarity Therapeutics

Earnings update

The end of a challenging year

Pharma & biotech

Like virtually all other businesses, the defining feature of 2020 for Allarity has been COVID-19 and its response to it. However, we believe the company has been able to deliver on two of its strategic objectives, albeit with delays: to clean up its capital structure and advance its new focused pipeline. Allarity now fully owns all of its lead assets and all three are progressing, either in clinical studies (stenoparib and Ixempra) or towards NDA filing (dovitinib).

Year end	Revenue (DKKm)	PBT* (DKKm)	EPS* (DKK)	DPS (DKK)	P/E (x)	Yield (%)
12/19	0.8	(174.9)	(2.08)	0.0	N/A	N/A
12/20	0.0	(59.1)	(0.29)	0.0	N/A	N/A
12/21e	0.0	(70.9)	(0.31)	0.0	N/A	N/A
12/22e	0.0	(248.2)	(0.97)	0.0	N/A	N/A

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

Making the story clearer

Before the new management took up the reigns in summer 2019, Allarity had seven assets in development. These assets were spread across three different, partially owned subsidiaries. The new management believed that this capital structure discouraged investment in the parent company and its goal was to bring all of the company's key assets under one roof, which it has been able to achieve, now with 100% ownership of each of its three lead assets.

Gearing back up for 2021

Management also believed that it could be more effective if it focused its clinical development efforts on a smaller number of assets. This process has been more difficult than expected due to the impact of COVID-19. Allarity has only been able to enrol two patients in its Phase II clinical study of stenoparib since November 2019, and we have had to adjust our expected timeline for dovitinib based on delays to that programme. We expect COVID-19 related delays to diminish in 2021, which is perhaps reflected in the recent initiation of the Ixempra Phase II study.

PMA submitted for the dovitinib DRP

The company has announced that it has submitted a PMA for the DRP companion diagnostic to the FDA for approval. Although the company is optimistic on the approval process, we consider it highly likely that the company will need to do additional clinical studies to support the PMA approval of the DRP and to have useful marketing claims for it and dovitinib. This initial submission process will likely provide useful information to the company to guide these future studies.

Valuation: Slightly lower at SEK1,007m or SEK4.21

We have lowered our valuation to SEK1,007m or SEK4.21 per share from SEK1,029m or SEK5.18 per share, which is driven by delays in the timeline for dovitinib and lower net cash, but offset by rolling forward our NPVs. We expect the company to need SEK850m in additional capital to reach profitability in 2025.

19 April 2021

Price	**SEK0.88**
Market cap	**SEK210m**
	SEK8.88/DKK6.32/US$
Net debt (DKKm) at 31 December 2020	7.9
Shares in issue	239.0m
Free float	92.4
Code	ALLR
Primary exchange	Nasdaq First North Stockholm
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	211.0	2.16	0.64
Rel (local)	(21.0)	1.4	(31.5)
52-week high/low	SEK2.16	SEK0.64	

Business description

Allarity Therapeutics is a Denmark-based biopharmaceutical company focused on oncology. Its patent-protected mRNA-based drug response predictor platform enables the identification of patients with gene expression highly likely to respond to treatment. The company is advancing the PARP inhibitor stenoparib (2X-121), the TKI dovitinib and microtubule inhibitor Ixempra.

Next events

Dovitinib NDA submission	2021
Stenoparib Phase II results	2022
Ixempra Phase II results	2022

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Recovering from a year of COVID-19

2020 was a complex year for Allarity because the new management had a mandate to revitalise the company, but many of its plans were stymied by the COVID-19 pandemic. Management's strategic objectives were to focus and relaunch the company's clinical development programme and to realign its capital structure to improve its chances of attractive new development. The timelines for both of these goals have been extended due to the impact of COVID-19.

The biggest impact of the pandemic has been on Allarity's development programmes, which all experienced delays in 2020. On the company's 2020 earnings conference call, management guided towards the ongoing Phase II clinical studies for Ixempra (in metastatic breast cancer) and stenoparib (in ovarian cancer) completing in 2022, which is consistent with our current timeline. A total of 10 patients have been enrolled to date in the stenoparib study (out of a target of 30), compared to eight in November 2019. The company has not reported on the enrolment to date for the Ixempra Phase II, which started in March 2021.

In addition to these clinical programmes, Allarity plans to submit an NDA application for dovitinib and a PMA for DRP diagnostic in 2021, which would position it for an initial approval decision in 2022. This timeline has continually been pushed out by COVID-19 related delays, and we have consequently extended our timelines for its development. We expect the company to need to carry out additional clinical studies to support marketable claims with dovitinib and its DRP, and we have delayed the initiation of these studies until 2022 after receipt of the initial approval decision (from initiation of studies in 2021 previously).

PMA submitted for dovitinib companion DRP

The company announced on 2 April 2021 that it has submitted a PMA application to the FDA for approval of the dovitinib DRP. This is ahead of the company's planned NDA submission of dovitinib later this year in 2021, for approval. The goal is that the DRP can serve as a companion diagnostic for dovitinib to diagnose patients with renal cell carcinoma (RCC) who are likely to be responders to the drug.

The current marketing submission is using data and patient samples gathered during the pivotal Phase III study of dovitinib performed by Novartis. We should note that the DRP was not used during this study to guide the treatment of patients, so this data is fundamentally retrospective in nature. The FDA has not historically approved PMA applications for new diagnostics intended to diagnose or guide the treatment of a disease on the basis of retrospective data. The approval of a drug/companion diagnostic combination normally requires both the drug and the diagnostic to be examined together in a prospective clinical study, ie one in which the determination of the DRP is gathered before treatment. Approvals outside of this (prospective trial) paradigm are generally limited to updates to existing drug device combinations once the utility of the biomarker has been established. An example of this would be an update to a HER2 test kit for Herceptin, where the change to the kit is minor and HER2 has been established as an effective biomarker for decades. In the case of the DRP, the utility of the biomarkers it is examining has not been established yet, and therefore prospective clinical studies will likely be needed, in our view.

We do not know the exact contents of the application the company has submitted to the FDA, and we do not know the precise claims the company is making. The application could be phrased in such a way as to avoid making claims that the DRP is designed to diagnose or guide the treatment of a disease. It may be possible (albeit still unlikely, in our view) to receive marketing approval with sufficiently diluted claims in the application, but then the company would be limited to only using

these same claims in its marketing for the product. Although the product would be approved in this case, it is unlikely to be commercially viable without sufficiently establishing the utility of the drug device combination and being able to present such evidence in its claims and/or marketing materials. This scenario is comparable to the upcoming NDA submission for dovitinib being made on the basis of non-inferiority to Nexavar: if approved although it would establish the legal marketability of the product, it would establish no benefit over Nexavar or any other TKI for the treatment of RCC. We remain consistent in our assumption that additional clinical studies will be needed regardless of the outcoming of the current PMA submission (dovitinib DRP) and the upcoming dovitinib NDA submission to support the commercially necessary marketing claims for dovitinib and the dovitinib DRP.

However, a benefit of the current PMA submission is that the FDA is likely to provide very useful feedback that can be used to effectively guide future clinical trial design. The agency will outline any deficiencies in the data for the current application, which can provide useful insight into its thinking regarding which parameters will be important for a registration-enabling clinical study. Moreover, the PMA process is a relatively inexpensive (as low as $91k if Allarity can qualify as a small business, $365k otherwise) way to gather such information.

Financial update

The above adjustments to our dovitinib timeline have significantly reduced our expected loss in 2021 (DKK69.6m from DKK189.1m), albeit these costs will be incurred in later years. Operating losses were lower in 2020 (DKK60.0m) than in 2019 (DKK174.9m), but this is largely the effect of a SEK81.6m impairment charge in FY19 when the company pared down its pipeline. On an EBITDA basis, expenses were lower in 2020 (DKK58.9m) compared to 2019 (DKK66.5m), we assume because the COVID-19 disruptions also led to some cost reductions.

Under previous management, Allarity had a large number of assets held under multiple, different, partially held subsidiaries. The new management has simplified this structure by focusing on the company's three lead assets (stenoparib, dovitinib and Ixempra), and converting former subsidiary shareholders into general shareholders. The goal has been to make the simplified structure and focused programmes more attractive to new investors, and for the company to move away from the debt-based financing on which it had relied. Allarity has relied primarily on two financing facilities (convertible note programme with Negma Group and Park Partners, and an equity line with Global Corporate Finance separately) to finance operations, which have been highly dilutive. It reported 239m shares as of March 2021 in the annual report, compared to 121m at end 2019 and 50m at end 2018. Furthermore, the company announced in March 2021 that it was initiating a SEK100m rights offering (up to 119,520,759 units at SEK0.85 per unit with each unit comprising one share and one warrant, pending shareholder approval). The goal is that this offering will be able to finance Allarity through 2021 and into 2022. The company ended 2020 with DKK7.9m (SEK11.2m) in net debt (DKK1.81m gross cash offset by DKK9.75m debt) and subsequently called on a SEK10m tranche of convertible debt from Negma, and converted SEK0.5m in separate debt to equity.

Based on the above adjustments to our timelines, we have also adjusted the financing schedule for the company. We expect it to need DKK850m in additional capital to reach profitability in 2025. This is a slight reduction from previous estimates (DKK870m) because some of the costs of developing and launching dovitinib have been delayed until after our projection for profitability. We include these financings as illustrative debt in our forecasts (DKK100m in 2021, followed by DKK250m in each of 2022, 2023 and 2024).

Valuation

We have lowered our valuation to SEK1,007m or SEK4.21 per share from SEK1,029m or SEK5.18 per share previously. This reduction is driven by adjustments in the timeline for the commercial launch of dovitinib described above. However, we have adjusted some of our assumptions regarding the clinical study we forecast after the NDA approval; we are encouraged by the FDA's recent approval of Fotivda (tivozanib, AVEO Pharmaceuticals) for renal cancer. The pivotal study for this programme used progression free survival as the primary endpoint and enrolled 350 patients. We have adjusted our assumptions regarding the dovitinib clinical study to match this (350 patients and a PFS endpoint, from 490 patients previously, and an overall survival endpoint). The smaller patient count was possible with Fotivda because it was supported by a large safety database from previous clinical studies, and dovitinib should also have a large safety database from its prior studies. These changes reduce the total cost of this clinical programme (to $35m from $49m) and offset most of the other delays to our timeline (less than one-year net delay after considering all factors). We expect the programme to be launched in 2025 (regardless of the outcome of the upcoming non-inferiority NDA) compared to 2024–25 previously (2024 if the non-inferiority NDA were granted, or 2025 if it were declined). For more information regarding our contingency model for the product, please see our recent Outlook note.

Additionally, we include lower net cash: SEK10.7m pro forma adjusted net debt (FY20) compared to SEK6.1m net cash previously (at Q320 pro forma). These factors are offset by rolling forward our NPVs. If the ongoing rights offering (SEK100m for 119.5m shares) were fully subscribed, this would increase the company valuation to SEK1,107m, while reducing the valuation per basic share to SEK3.09.

Exhibit 1: Valuation of Allarity

Development programme	Indication	Clinical stage	Prob. of success	Launch year	Launch pricing	Peak sales ($m)	rNPV (SEKm)
Stenoparib	Recurrent ovarian cancer	Phase II	25%	2025	$138,000	51.3	142.3
Dovitinib	Renal cancer	NDA	35–50%	2025	$145,000	175.1	702.4
Ixempra	Metastatic breast cancer	Phase II	50%	2025	$41,000	56.4	172.5
Total							1,017.3
Pro forma net cash/(debt) (YE20 + subsequent transactions)							(10.7)
Total firm value (SEKm)							1,006.6
Total shares (m)							239.0
Value per basic share (SEK)							4.21
Dilutive securities (m)							22.5
Fully diluted shares in issue (m)							261.5
Fully diluted value per share (SEK)							3.97

Source: Allarity reports, Edison Investment Research

Exhibit 2: Financial summary

DKK000s	2019	2020e	2021e	2022
Year end 31 December	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS				
Revenue	801	0	0	0
Cost of Sales	0	0	0	0
Gross Profit	801	0	0	0
EBITDA	(66,502)	(58,958)	(69,877)	(247,181)
Operating Profit (before amort. and except.)	(148,102)	(60,017)	(70,936)	(248,240)
Intangible Amortisation	0	0	0	0
Exceptionals/Other	0	0	0	0
Operating Profit	(148,102)	(60,017)	(70,936)	(248,240)
Net Interest	(26,822)	932	0	0
Other	0	0	0	0
Profit Before Tax (norm)	(174,924)	(59,085)	(70,936)	(248,240)
Profit Before Tax (IFRS)	(174,924)	(59,085)	(70,936)	(248,240)
Tax	36,792	11,379	1,351	4,728
Deferred tax	0	0	0	0
Profit After Tax (norm)	(138,132)	(47,706)	(69,585)	(243,512)
Profit After Tax (IFRS)	(138,132)	(47,706)	(69,585)	(243,512)
Average Number of Shares Outstanding (m)	63.4	163.2	227.5	251.0
EPS - normalised (DKK)	(2.08)	(0.29)	(0.31)	(0.97)
EPS - IFRS (DKK)	(2.08)	(0.29)	(0.31)	(0.97)
Dividend per share (ore)	0.0	0.0	0.0	0.0
BALANCE SHEET				
Fixed Assets	158,895	162,973	161,933	160,893
Intangible Assets	155,978	155,720	155,720	155,720
Tangible Assets	2,917	2,134	1,094	54
Other	0	5,119	5,119	5,119
Current Assets	22,306	13,949	38,136	70,518
Stocks	0	0	0	0
Debtors	5,937	1,722	6,979	24,423
Cash	10,176	1,807	19,386	34,324
Other	6,193	10,420	11,771	11,771
Current Liabilities	(31,497)	(34,724)	(20,356)	(45,210)
Creditors	(27,919)	(24,971)	(10,603)	(35,457)
Short term borrowings	(3,578)	(9,753)	(9,753)	(9,753)
Long Term Liabilities	(8,370)	(1,615)	(108,715)	(358,715)
Long term borrowings	0	0	(107,100)	(357,100)
Other long term liabilities	(8,370)	(1,615)	(1,615)	(1,615)
Net Assets	141,334	140,583	70,998	(172,514)
CASH FLOW				
Operating Cash Flow	(54,511)	(55,391)	(89,502)	(235,043)
Net Interest	(26,846)	(1,085)	0	0
Tax	8,942	5,354	0	0
Capex	(56)	(19)	(19)	(19)
Acquisitions/disposals	0	0	0	0
Financing	62,715	24,737	0	0
Dividends	0	0	0	0
Other	(4,253)	(572)	0	0
Net Cash Flow	(14,009)	(26,976)	(89,521)	(235,062)
Opening net debt/(cash)	17,345	(6,598)	7,946	97,467
HP finance leases initiated	0	0	0	0
Exchange rate movements	(98)	(304)	0	0
Other	38,050	12,736	0	0
Closing net debt/(cash)	(6,598)	7,946	97,467	332,529

Source: Allarity reports, Edison Investment Research

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