EDISON

Cellular Biomedicine Group

CBMG and Novartis sign manufacturing partnership

Business development update

Pharma & biotech

Cellular Biomedicine Group (CBMG) announced it has signed an exclusive partnership with Novartis to manufacture the CAR-T therapy Kymriah in China. Novartis retains all marketing responsibility and CBMG will be entitled to both a mark-up on manufacturing costs and an escalating single-digit royalty on sales. Additionally, Novartis will take an equity stake in CBMG of approximately 9%: $40m at $27.43/share. Our valuation is lifted to $535m (from $353.1m).

Year end	Revenue ($m)	PBT* ($m)	EPS* ($)	DPS ($)	P/E (x)	Yield (%)
12/16	0.6	(18.1)	(1.34)	0.0	N/A	N/A
12/17	0.3	(20.1)	(1.40)	0.0	N/A	N/A
12/18e	0.1	(27.1)	(1.43)	0.0	N/A	N/A
12/19e	5.3	(21.6)	(1.09)	0.0	N/A	N/A

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

Manufacturing in China a necessity

The other major companies involved in CAR-T have already established relationships with companies in China to bring their products to that market: Gilead with Fosun and Celgene with WuXi AppTec. This is in part necessary because the manufacturing of cell-based products for the Chinese market must be in China due to legislation, as well as for practical logistics concerns. CBMG has one of the most advanced CAR-T manufacturing footprints in the country, so was a natural choice for Novartis, which had no prior commercial Chinese CAR-T arrangement.

Reforms lead to a faster pathway to profitability

There have been numerous changes in China regarding both the treatment of cell based products as well as other pharmaceutical products. Cell therapies are now considered drugs, which allow them to be approved through similar pathways. These include expedited pathways for drugs that have been previously approved overseas, and priority review for novel products. With these factors combined, we believe that Kymriah could enter the Chinese market as early as 2019.

Resources opened up for other internal programs

We assume that development will stop on CBMG's internal CD19 CAR-T programs as this would pose a conflict of interest for the new Novartis deal. However, this should free up significant capital for the company's other internal development programs. It has stated that it should have first-in-human studies for the company's anti-BCMA and anti-CD22 CAR-T product initiated by the end of 2018.

Valuation: Increased to $535m or $29.07

We have increased our valuation to $535m or $29.07 per basic share from $353.1m or $20.76 per basic share. We have replaced the company internal C-CAR011 program with Kymriah in our models, which has a much higher probability of success (90%), and much sooner revenue ramp (manufacturing revenue in 2019). We also assume higher total sales ($396m vs $283m) considering the increased resources of Novartis.

5 October 2018

Price	**US$17.29**
Market cap	**US$318m**

Net cash ($m) at Q218 + Novartis investment	74.8
Shares in issue	18.4m
Free float	73%
Code	CBMG
Primary exchange	NASDAQ
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	(20.7)	(13.3)	64.7
Rel (local)	(20.8)	(19.0)	44.0
52-week high/low	US$23.6		US$9.2

Business description

Cellular Biomedicine Group (CBMG) is a biotechnology company developing cell-based therapeutics with operations primarily in China. It has completed Phase II clinical trials of ReJoin, an autologous progenitor cell therapy for osteoarthritis, and Phase I for a similar allogeneic product (AlloJoin). It is also the exclusive manufacturing partner for Norvartis's CAR-T therapy Kymriah in China.

Next events

Kymriah Chinese regulatory progress	Upcoming
Anti-BCMA initiated	Q418
Andi-CD22 initiated	Q418

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CBMG to manufacture Kymriah for Novartis in China

CBMG announced on 27 September 2018 that it entered into a licensing agreement with Novartis to manufacture the CAR-T therapy Kymriah (tisagenlecleucel) in China. Kymriah was the first CAR-T therapy to be approved and is currently marketed in the US, Canada and Europe for the treatment of diffuse large B-cell lymphoma (DLBCL) and pediatric acute lymphoblastic leukemia (ALL). CBMG will be entitled to an undisclosed mark-up on manufacturing costs as well as an escalating single-digit royalty on sales. CBMG will also provide a royalty free, worldwide license of some of its intellectual property to Novartis. Finally, Novartis is taking a 9% equity position in CBMG worth $40m (at $27.43 per share).

We view this as a very favourable relationship for all parties involved. It allows both CBMG and Novartis to leverage some of the regulatory reforms in China to quickly bring the product to market. Manufacturing based in China is obligatory for all cell-based products, because of legislation that limits the transport of human tissue out of China's borders. The other major western CAR-T companies have already established similar relationships with Chinese companies: Gilead has an agreement with Fosun and Celgene has an agreement with Wuxi AppTec (although neither currently market product). We should note that the structure of these agreements is fundamentally different from thos between Novartis and CBMG. The Gilead-Fosun joint venture is largely a technology transfer, in which Fosun supplies all upfront costs as well as profit sharing and milestones to Gilead in exchange for its IP. The Celgene-Wuxi agreement is the formation of a new company (JW Therapeutics) jointly owned by both parties.

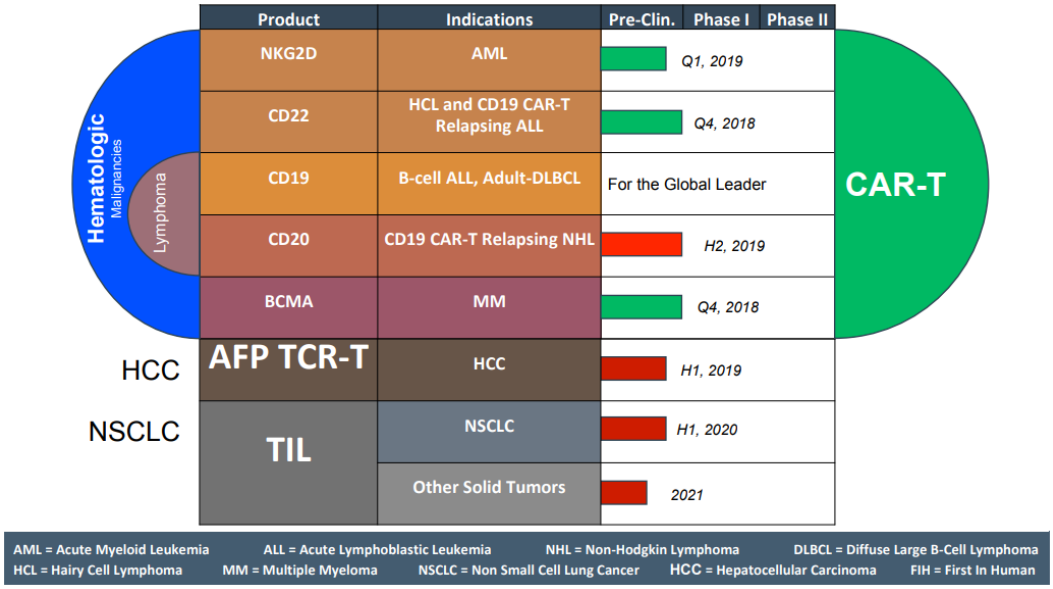
Additionally, there have been a series of regulatory changes in China that should enable treatments developed under such agreements to quickly enter the Chinese market. In December 2017, the National Medical Products Administration (NMPA, formerly the CFDA) announced that it would regulate cell therapies as drugs. Before this point, there was little clarity on how these products would be regulated and approved. Additionally, it opened up priority designations designed to enable quicker review and quicker market entry. In October 2017, the State Council announced a draft proposal that would allow foreign clinical data to be used for the approval of drugs in China. Previously, drugs approved overseas were required to perform at minimum Phase III studies in China. Under the new regime, applications are only required to include clinical data on 'the existence of ethnic differences'. Additionally, we should expect Kymriah to qualify as an innovative drug product and therefore be entitled to priority review at the NMPA. According to the government's audit of review times for 2017, the average review time for a priority review NDA application was 59 days. These pathways have not yet been tested for cell therapies, but the Chinese government has shown considerable initiative in promoting the development and approval of CAR-T and other cell therapies through these and other regulatory measures.

Development focus shifts to other internal products

CBMG was previously developing its own CAR-T product C-CAR011 for the treatment of DLBCL and ALL, which were in Phase I clinical trial and expected to produce results in mid-2018. This product was based on similar technology to Kymriah, an anti-CD19 CAR-T receptor, and therefore presents a conflict of interest with the new agreement. The company has not explicitly disclosed the status of these programs, but we hypothesize that the intellectual property transfer included in the agreement is in regards to these products. We do not expect further clinical development of CD19-based CAR-T products, but the company did state that it will continue to develop its immunoncology assets (Exhibit 1). The company has communicated accelerated timelines with these programs: its anti-BCMA CAR-T program and anti-CD22 CAR-T programs are slated to initiate first-in-human

trials in Q418, with many following in 2019. We expect that this is made possible by the capital freed up by discontinuing C-CAR011, and we expect it to be further supported by the revenue from Novartis in the future. Additionally, the company intends to file INDs with the NMPA to initiate pivotal trials for both AlloJoin and ReJoin in Q418.

Exhibit 1: CBMG pipeline



Source: Cellular Biomedicine Group

Valuation

We have increased our valuation to $535m or $29.07 per basic share from $353.1m or $20.76 per basic share. This increase is driven by a number of factors relating to the Novartis deal. We predict a 90% probability of approval in China for Kymriah, compared to the 20% probability for C-CAR011. We expect a low regulatory hurdle for the product, with few or no additional clinical data needed, although we may revise this in the future based on company feedback. We initial manufacturing revenue in 2019 to prepare for a launch in 2019 or 2020, although we admit that the pace of an NDA review for a cell product in China is untested. We have increased our peak sales estimates ($396m total from $283m) compared to C-CAR011 as well, due to Novartis's greater resources. Our pricing model remains unchanged, albeit at a lower launch price ($76,000 vs $84,000) as it will now occur before future price growth. Likewise, our market estimates remain unchanged, and we only consider patients covered by urban insurance schemes a viable market. CBMG is entitled to a mark-up over manufacturing costs, which we estimate at 50%, and we model a sales royalty of 4-8%, which corresponds to an average payment to the company of 17% of sales. Finally, we also include the $40m in equity investment from Novartis, although this includes 1.5m additional shares. We may revise some aspects of this model in the future if more information regarding the agreement is released, or a more detailed commercial timeline is presented.

Exhibit 2: Valuation of Cellular Biomedicine Group

Development Program	Region	Prob. of success	Launch year	Peak sales ($m)	Margin/license and royalties	rNPV ($m)
Kymriah (DLBCL)	China	90%	2019	253	17%	146.3
Kymriah (ALL)	China	90%	2019	143	17%	82.8
ReJoin	China	40%	2021	144	31%	44.3
AlloJoin	China	40%	2022	431	58%	222.6
AlloJoin/ReJoin cannibalism	China					-35.3
Total						**460.7**
Net cash and equivalents (Q218 + Novartis purchase) ($m)						74.8
Total firm value ($m)						535.5
Total shares (m)						18.4
Value per basic share ($)						**29.07**
Options (m)						1.9
Value per diluted share ($)						27.49

Source: Cellular Biomedicine Group reports, Edison Investment Research

Financials

The Novartis agreement has substantially affected the financial outlook for the company. Given the combination of the $40m equity investment, much sooner revenue generation from the manufacturing agreement and reduced costs, we do not expect CBMG to require additional capital before profitability in 2021 (previously $90m in capital needed to reach profitability in 2022). We no longer include development costs associated with C-CAR011 in our forecasts, although we have increased development of the company's other pipeline products, a trend that has already been reflected in Q218 financials: $9.2m in R&D costs vs $6.7m in Q217 due to 'pick-up in our development work and new talents recruited for anti-BCMA target for multiple myeloma, and other solid tumor indications.' Otherwise our forecasts, including those for the AlloJoin and ReJoin programs, remain unchanged.

Exhibit 3: Financial summary

$'000s	2016	2017	2018e	2019e
31-December	US GAAP	US GAAP	US GAAP	US GAAP
INCOME STATEMENT				
Revenue	627.9	336.8	128.3	5,256.6
Cost of Sales	(860.4)	(162.2)	(76.7)	0.0
Gross Profit	(232.5)	174.6	51.6	5,256.6
EBITDA	(15,716.2)	(19,245.4)	(22,703.0)	(17,545.8)
Normalised operating profit	(18,351.2)	(22,231.4)	(27,404.9)	(22,247.7)
Amortisation of acquired intangibles	(4,611.7)	0.0	0.0	0.0
Exceptionals	0.0	0.0	(29.4)	0.0
Share-based payments	(5,452.4)	(5,345.2)	(5,345.2)	(5,345.2)
Reported operating profit	(28,415.3)	(27,576.6)	(32,779.6)	(27,593.0)
Net Interest	78.9	133.6	215.7	643.7
Joint ventures & associates (post tax)	0.0	0.0	0.0	0.0
Exceptionals	132.1	1,955.1	93.9	0.0
Profit Before Tax (norm)	(18,140.2)	(20,142.6)	(27,095.3)	(21,604.0)
Profit Before Tax (reported)	(28,204.3)	(25,487.9)	(32,470.0)	(26,949.3)
Reported tax	(4.1)	(2.5)	0.0	0.0
Profit After Tax (norm)	(18,140.2)	(20,142.6)	(27,095.3)	(21,604.0)
Profit After Tax (reported)	(28,208.4)	(25,490.3)	(32,470.0)	(26,949.3)
Minority interests	0.0	0.0	0.0	0.0
Discontinued operations	(1,000.6)	727.2	0.0	0.0
Net income (normalised)	(18,140.2)	(20,142.6)	(27,094.3)	(21,602.0)
Net income (reported)	(29,209.0)	(24,763.1)	(32,470.0)	(26,949.3)
Basic average number of shares outstanding (m)	14	14	19	20
EPS - basic normalised ($)	(1.34)	(1.40)	(1.43)	(1.09)
EPS - diluted normalised ($)	(1.34)	(1.40)	(1.43)	(1.09)
EPS - basic reported ($)	(2.16)	(1.73)	(1.71)	(1.35)
Dividend ($)	0.00	0.00	0.00	0.00
BALANCE SHEET				
Fixed Assets	27,936.4	36,635.4	36,872.4	36,507.8
Intangible Assets	21,771.4	20,098.5	19,217.7	19,217.7
Tangible Assets	4,117.7	12,973.3	12,608.7	12,244.1
Investments & other	2,047.3	3,563.5	5,046.0	5,046.0
Current Assets	40,692.1	24,526.9	67,063.0	46,020.1
Stocks	0.0	0.0	0.0	0.0
Debtors	452.7	1,105.8	284.0	284.0
Cash & cash equivalents	39,252.4	21,568.4	64,369.9	43,327.0
Other	987.0	1,852.7	2,409.1	2,409.1
Current Liabilities	(2,364.0)	(3,676.1)	(4,836.2)	(5,032.7)
Creditors	(216.2)	(225.3)	(428.2)	(624.7)
Tax and social security	(28.9)	(28.9)	(28.9)	(28.9)
Short term borrowings	0.0	0.0	0.0	0.0
Other	(2,119.0)	(3,422.0)	(4,379.1)	(4,379.1)
Long Term Liabilities	(370.5)	(183.6)	(87.6)	(87.6)
Long term borrowings	0.0	0.0	0.0	0.0
Other long term liabilities	(370.5)	(183.6)	(87.6)	(87.6)
Net Assets	65,894.0	57,302.5	99,011.6	77,407.6
Minority interests	0.0	0.0	0.0	0.0
Shareholders' equity	65,894.0	57,302.5	99,011.6	77,407.6
CASH FLOW				
Op Cash Flow before WC and tax	(15,716.2)	(19,245.4)	(22,703.0)	(17,545.8)
Working capital	(255.4)	(1,434.6)	488.6	196.5
Exceptional & other	103.9	2,086.6	312.3	643.7
Tax	0.0	0.0	0.0	0.0
Net operating cash flow	(15,867.7)	(18,593.4)	(21,902.1)	(16,705.5)
Capex	(2,733.4)	(10,192.9)	(4,371.5)	(4,337.3)
Acquisitions/disposals	0.0	0.0	0.0	0.0
Net interest	0.0	0.0	0.0	0.0
Equity financing	43,285.6	10,826.5	69,136.2	0.0
Dividends	0.0	0.0	0.0	0.0
Other	0.0	0.0	0.0	0.0
Net Cash Flow	24,684.4	(17,959.8)	42,862.6	(21,042.9)
Opening net debt/(cash)	(14,884.6)	(39,252.4)	(21,568.4)	(64,369.9)
FX	(316.6)	275.8	(61.2)	0.0
Other non-cash movements	0.0	0.0	0.0	0.0
Closing net debt/(cash)	(39,252.4)	(21,568.4)	(64,369.9)	(43,327.0)

Source: Cellular Biomedicine Group reports, Edison Investment Research

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