Chimeric Therapeutics Ltd

Company Update

Adding to the pipeline with a clinical platform technology

Biotechnology

17h December 2021

Chimeric Therapeutics (ASX:CHM) is a clinical-stage cell therapy company focused on developing and commercialising a range of chimeric antigen receptor T (CAR T) cell therapies targeting haematological cancers and solid tumours. CHM has recently announced its exclusive option to license a platform technology from Case Western Reserve University (CWRU), the CORE-NK platform. In parallel with finalising the option, CHM will be preparing a research collaboration, likely with Dr. David Wald's lab at CWRU. We have not adjusted our valuation for this new opportunity, as it is not yet a completed deal. We have valued CHM at a mid-case of A$243m or A$0.74/share (A$0.67/share fully diluted for all options), using a risked NPV based on our assumptions for CLTX CAR T therapy for recurrent glioblastoma (GBM), which is currently in Phase I trials. Our valuation range is from A$0.50/share to A$0.93/share on the current share count. We expect to revisit the portfolio valuation as CHM advances its existing technologies and its potential new platform technology.

Three world-class partners in discovery

With the new option to license the Clinically Validated, Off the Shelf, Robust, Enhanced, Natural Killer Cell Platform (CORE-NK) with CWRU, CHM has the opportunity to add a third partnership to its portfolio, including its partnerships with The University of Pennsylvania (Penn) for its CHM 2101 pre-clinical stage CAR T and City of Hope (COH) Cancer Center in Los Angeles for its CHM 1101 clinical-stage CAR T technology. This technology is more clinically validated than its CLTX and CDH17 CAR T technologies, as there has been a Phase I trial completed, with results pending (expected 2022). The platform technology can be leveraged for multiple new therapies, and CHM has several new clinical programmes planned for 2023 in blood cancer and solid tumours. The platform is a complement to its existing technologies, as it is allogeneic, meaning it can be used "off the shelf" for patients, rather than autologous, which is specific to each patient. CHM's pipeline will now expand to seven unique assets with eight clinical trials planned by 2023. Diversification of its portfolio with stages of development, partners and therapies for both solid tumours and now blood cancers enhances opportunities and its pipeline.

New therapy pipeline to enhance CAR T

We believe this deal positions CHM well for future partnerships, out-licensing and collaborations. An expansion of the pipeline across both autologous and allogeneic technologies, and from early pre-clinical to late Phase I clinical therapies, is significant. If CHM licenses the CORE-NK platform, its pipeline will be expanded to include five new cell therapy assets, and will extend the clinical development programme with eight total trials by 2023. CHM has identified multiple programmes for its technologies, with its CAR research combining with the platform to create new potential CAR NK therapies as well as potential therapies from the CORE-NK platform. As a result of the expansion of the programmes, CHM has reorganised its team, including adding a Programme Manager, elevating Dr. Eliot Bourk to Chief Business Officer and Head of External Innovation, and adding a Head of Clinical Development role. The new pipeline will broaden CHM's ability to find partners or out-licensing opportunities, including in blood cancers and solid tumours.

Mid-case valuation remains $0.74/share

Our valuation remains unchanged as CHM has secured an exclusive option to negotiate a license agreement. CHM has not disclosed the quantum of upfront funding and any future milestone and royalty payments, however it has indicated that the upfront fees are fully funded from its cash reserves. We would expect more news flow from the company based on its significantly expanded milestone timeline, with a particularly busy 2022. We have looked at a potential value for the platform technology being used as a treatment for acute myeloid leukaemia (AML), just one of the several therapies under investigation, and have arrived at a potential value of US$41m or A$56m, or $0.17/share (this is discussed on page 4 of this report). This exercise serves to highlight the additional value the leadership team is bringing to the table. Our existing valuation utilises a risk-weighted valuation to our forecasts for the GBM opportunity, arriving at a valuation range of $0.50-$0.93/share with the mid-point at $0.74/share, based on the current share count. On a fully diluted basis for all options on issue, the mid-point valuation is $0.69/share. Our valuation is solely based on the opportunity for CHM 1101 for recurrent glioblastoma. As we highlighted in our 29 November initiation report **Building a pipeline of expertise**, further upside could be obtained from the advancement of CHM 1101 to Phase II with GBM; the commencement of a Phase I frontline GBM study; the application of CHM 1101 to other indications; the advancement of CDH17 CAR T from pre-clinical to Phase I and from the acquisition of other portfolio opportunities.

Share Details

ASX code	CHM
Share price (16-Dec)	$0.25
Market capitalisation	$82.8M
Shares on issue	331M
Net cash 30-Sept-2021	$17.4M
Free float	~25.8%

Share Performance (since listing)

Upside Case

- Positive result from Phase I trial with CHM1101
- Approval to commence Phase I trial with CHM2101
- Success with additional pre-clinical studies to advance an indication for IND approval

Downside Case

- Underperformance in safety or efficacy of CHM1101 in Phase I trial
- Not receiving IND approval for CHM2101
- Patent applications rejected for pipeline IP

Board of Directors

Paul Hopper	Executive Chairman/ Founder
Jennifer Chow	Managing Director/CEO
Leslie Chong	Non-Executive Director
Dr Lesley Russell	Non-Executive Director
Cindy Elkins	Non-Executive Director
Dr George Matcham	Non-Executive Director

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Origins of Chimeric Therapeutics

CHM was originally formed as a company and listed on the ASX to fund its License Agreement with City of Hope Cancer Center in Los Angeles, as well as Phase I clinical trials for the CLTX CAR T cell therapy targeting glioblastoma. COH has clinical care, research and production facilities all on one campus, with resources available to enable discovery, translational research, clinical development, manufacturing, quality assurance and delivery of treatments for patients. Professors Christine Brown and Michael Barish at COH have been developing CLTX CAR T for more than five years. In November 2019, the FDA allowed the IND (Investigational New Drug) application, enabling the initiation of a clinical trial in treating glioblastoma. In September 2020, COH commenced dosing of patients with glioblastoma as part of Phase I clinical trials. Since then, Chimeric has licensed the University of Pennsylvania technology, 3rd generation CDH17 CAR T, with worldwide exclusivity. CHM has also recently announced (1 December 2021) an exclusive option to negotiate a license deal with Case Western Reserve University for its CORE NK platform, which was studied in a Phase I clinical trial completed in June 2021 in both solid tumours and blood cancers.

Case Western Reserve University CORE-NK Platform – Key Details

Chimeric has entered into an exclusive option to negotiate a license agreement for the Clinically Validated, Off the Shelf, Robust, Enhanced Natural Killer Cell Platform (CORE-NK) from Case Western Reserve University. CHM plans to engage in a collaboration to continue the scientific research, likely with Dr. David Wald and his lab at CWRU which developed the CORE-NK platform. CHM paid an upfront fee to secure the option, which has not been disclosed, but is funded fully from existing funds according to company announcements (1 December 2021). The CORE-NK platform has completed a Phase I dosing trial, with results expected in 2022.

Potential expanded portfolio and pipeline with CWRU licensing deal

If CHM licenses the CORE-NK platform, its pipeline will be expanded, including into blood cancers and additional solid tumors. At present, CHM is planning eight clinical trials by 2023 in 10+ disease areas.

Exhibit 1: Chimeric Therapeutics' pipeline

	CHM Pipeline	Pre-Clinical	Phase 1	Phase 2/3*
CHM 1101 (CLTX CAR T)	Glioblastoma	Stage 2 dose trial		
	Melanoma	Preclinical		
	Colorectal	Preclinical		
	Prostate	Preclinical		
CHM 2101 (CDH17 CAR T)	Neuroendocrine	Preclinical		
	Colorectal	Preclinical		
	Pancreatic	Preclinical		
	Gastric	Preclinical		
NK Cell Derived Therapies	CHM 0201 (CORE NK Platform)	Solid Tumours and Hematological Malignancies		
	CHM 0301 (Next Gen CORE-NK Platfm)	Blood Cancers		
	CHM 1301 (CLTX CAR NK)	Solid Tumours		
	CHM 2301 (CDH17 CAR NK)	Solid tumours		
	CHM 3301 (Undisclosed Target)			

Source: Company data

CHM will continue to develop its autologous CLTX CAR T therapies and its CDH17 CAR T therapies in addition to the blended CAR NK therapies utilising CLTX and CDH17 in combination with the CORE-NK platform. The CORE-NK platform itself will also be developed for next-gen therapies targeting blood cancers. The CORE-NK platform being licensed will target opportunities in solid tumours and hematological malignancies.

CHM Strategy and Development Plan

CHM has a strategy for its CORE-NK platform to leverage its existing CAR T technologies in addition to the CORE-NK platform. The strategy includes:

1) Further enhance the CORE-NK platform with next-generation technologies for development as a combination therapy.

   Potential targets include acute myeloid leukemia, B cell malignancies and multiple myeloma.

2) Develop CAR-NK products using the CLTX and CDH17 chimeric antigen receptors.
3) Identify collaborations or out-licensing opportunities to further expand the utilisation of the CORE-NK platform.

Recent deals in the CAR NK space indicate potential for upfront payments plus milestone payments plus royalties.

CHM's planned timeline includes development of the CLTX CAR NK and CDH17 CAR NK products in 2022, and a Phase I clinical trial for the next-gen CORE-NK platform in 2023. A Phase I clinical trial for the CAR NKs is also anticipated in 2023.

Natural Killer Cell Technology

Natural Killer (NK) cells are a type of white blood cell (lymphocyte) and a component of the innate immune system. These cells have small particles with enzymes that can kill tumor cells or cells infected with a virus, but are naturally prevented from killing healthy cells. NK cells have a major role in the host-rejection of tumours and virally infected cells. NK cells serve to contain viral infections while the immune response is generating the T cells that can clear the infection. NK cells have the ability to recognise and kill stressed cells in the absence of antibodies and major histocompatibility complex presented on the cell surfaces, allowing for a much faster immune reaction. NK cells do not require activation to kill cells that are missing the markers that T cells and other immune cells need to detect and destroy harmful cells.

In anti-cancer therapy, the use of allogeneic NK cells is currently being investigated. Blood is taken from a healthy donor, expanded in the lab up to 10,000 times from a single donor unit, and then utilised in multiple different patients.

Risks

In addition to the safety, efficacy and commercialisation risks identified in the RaaS's Initiation Report (**29 November 2021**), there have been several risks identified in the NK platform technology, which are under investigation as it a relatively new technology. With respect to safety, graft vs host disease has been investigated in the Phase I study of the CORE-NK platform, as a blood product from one donor is being used in another patient. One way of mitigating the risk that is under investigation is the removal of T cells from the donor material, to reduce the risk of this happening.

In manufacturing, potential risks include the success rate of the expansion and the sourcing of the materials. In addition, each product will need to be characterised for stability.

Benefits

The costs of the NK platform therapies are thought to be lower than the autologous (ie. CAR) therapies, as the number of expanded cells from a single donor unit is significantly higher. In addition, these doses can be stored for months to years after being cryopreserved.

The allogeneic therapies can be provided to patients who may not be able to wait for the autologous solution to be manufactured, as the NK platform therapies would be "off the shelf". These therapies would be available to patients quickly, and can be infused into many more patients due to wider compatibility than autologous, personalised, therapies.

Blue Sky Potential Value for the NK Platform

We have looked at potential values for the NK platform and associated therapies. We modelled the treatment for one potential indication, AML. Using the assumptions in Exhibit 2, we arrived at a potential value of US$41m or A$56m. Note that this is for just one potential indication of at least five potential indications that have been flagged for the platform. In addition, CHM is looking to combine CAR NK for additional therapies. None of these are explored in this exercise. The assumptions we have used and the valuation we have reached for AML are a broad approximation, as the first indication has not yet been identified. In addition, until the therapy is developed for clinical study, the costs are not known. We have utilised a standard chance of success for biotechnology therapies at 10% and a discount rate of 10.3%. We have assumed that CHM brings the therapy to market in 2025, without out-licensing. As this has not been integrated into our financial model for CHM, we have not accounted for any additional funding that might be needed to bring this to market. We believe it is likely that CHM will collaborate or out-license its therapies once the indication has been chosen and the design is further developed.

Exhibit 2: Key assumptions for potential upside for the NK platform

Parameters	Value
#/100,000 AML patients per year	4.3
Population (millions)	1,060
% of patients that meet criteria for treatment	50%
% of patients that can afford and attend treatment	52%
% growth/year of patient population	0.50%
CHM AML market penetration 1st year	5%
CHM peak market penetration	9%
Treatment price per patient (US$)	$250,000
Cost to CHM per treatment (US$)	$75,000
Chance of success	10%
AUD/USD	0.73
Discount Rate used on free cashflows	10.3%

Source: RaaS estimates

Summary

We believe this deal positions CHM well for future partnerships, out-licensing and collaborations. An expansion of the pipeline across both autologous and allogeneic technologies, and from early pre-clinical to late Phase I clinical therapies, is significant. A diversified pipeline, particularly in the CAR NK space, has seen deal activity. The expanded pipeline would also position CHM more in line with listed peers in the US market. We expect CHM to leverage its team's depth of experience and networks in the cell therapy space to advance clinical trials and identify collaborators. This deal is not yet finalised, as it is only an option to license the platform and therefore we haven't included any value for this in our company valuation either utilising cash-flow modelling or through comparables or recent deal flow.

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