

## Rani Therapeutics

## Our thoughts on RT-111 phase 1 data

Maintain Rating: BUY | PO: 17.00 USD | Price: 3.60 USD

## Positive data warrants phase 2 study

Today, Rani reported top-line data from the phase 1 RT-111 (RaniPill capsule containing Ustekinumab) study. Overall, the data provided additional evidence to de-risk RT-111 and Rani's proprietary technology platform (RaniPill) which delivers biologics orally. Indeed, doses of RT-111 were generally well tolerated, with no serious adverse events reported. However, one patient (5% of study) reported a burning sensation in their stomach after taking the .5 mg dose, however Rani notes that there no drug levels present during the burning sensation, suggesting the AE was not related to the drug or RaniPill deployment in the gut. Further, high bioavailability (84% relative to SC) and device delivery success rate were achieved. While we view today's results as a positive, we think there is still a lot of wood to chop given the early status of the development. Indeed, questions remain about the optimization of dose level requiring a larger scale phase 2 trial to address which Rani plans to initiate upon the end of its exclusive rights negotiation period with its biosimilar partner Celltrion. That said, we continue to view the RaniPill as offering a differentiated approach to ease administration and capture economics from proven biologics (Humira, Forteo, insulins, etc.) in the >\$400B injectable market. And while we recognize the need for further development of Rani's platform, we see today's update as a step in the right direction. We reiterate our Buy rating and \$17 PO.

## Rani enters exclusive negotiation period with Celltrion

Following the successful execution of RT-111's phase 1 study, Rani has entered an exclusive window to negotiate commercial rights with its Biosimilar provider Celltrion. Celltrion has until 2/21 to exercise its right of first negotiation, and exclusive negotiating rights for 90 days following its exercise. Management has indicated positive interest from Celltrion and expects to commence its phase 2 RT-111 study following the completion of a commercial rights deal.

Estimates (Dec) (US\$)	2021A	2022A	2023E	2024E	2025E
EPS	(1.11)	(1.29)	(1.25)	(1.20)	(1.20)
EPS Change (YoY)	-208.3%	-16.2%	3.1%	4.0%	0%
Consensus EPS (Bloomberg)			(1.39)	(1.27)	(0.86)
DPS	0	0	0	0	0
Valuation (Dec)					
Free Cash Flow Yield*	-18.2%	-26.7%	-37.7%	-48.1%	-57.1%

\* For full definitions of *IQmethod*<sup>SM</sup> measures, see page 5.

05 February 2024

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## Stock Data

Price	3.60 USD
Price Objective	17.00 USD
Date Established	18-Aug-2023
Investment Opinion	C-1-9
52-Week Range	1.82 USD - 6.89 USD
Mrkt Val (mn) / Shares Out (mn)	180 USD / 50.0
Free Float	66.0%
Average Daily Value (mn)	0.28 USD
BofA Ticker / Exchange	RANI / NAS
Bloomberg / Reuters	RANI US / RANI.OQ
ROE (2023E)	-40.9%
Net Dbt to Eqty (Dec-2022A)	3.7%
ESGMeter™	NLA

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See p. 3 for abbreviation definitions

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Timestamp: 05 February 2024 02:38PM EST

# iQprofile<sup>SM</sup> Rani Therapeutics

## iQmethod<sup>SM</sup> – Bus Performance\*

(US\$ Millions)	2021A	2022A	2023E	2024E	2025E
Return on Capital Employed	-47.1%	-49.6%	-30.6%	-26.1%	-21.6%
Return on Equity	-1,290.4%	-64.8%	-40.9%	-34.7%	-28.7%
Operating Margin	-1,899.1%	NA	NA	NA	NA
Free Cash Flow	(33)	(48)	(68)	(87)	(103)

## iQmethod<sup>SM</sup> – Quality of Earnings\*

(US\$ Millions)	2021A	2022A	2023E	2024E	2025E
Cash Realization Ratio	NM	NM	NM	NM	NM
Asset Replacement Ratio	1.0x	3.0x	3.0x	3.0x	3.0x
Tax Rate	NM	NM	NM	NM	NM
Net Debt-to-Equity Ratio	-96.6%	3.7%	-72.2%	-55.5%	-76.6%
Interest Cover	-44.3x	NM	-39.0x	-26.5x	-18.7x

## Income Statement Data (Dec)

(US\$ Millions)	2021A	2022A	2023E	2024E	2025E
Sales	3	0	0	0	0
% Change	488.1%	-100.0%	NA	NA	NA
Gross Profit	3	0	0	0	0
% Change	488.1%	NM	NA	NA	NA
EBITDA	(51)	(63)	(83)	(101)	(118)
% Change	-220.3%	-23.1%	-31.6%	-22.4%	-16.6%
Net Interest & Other Income	(1)	0	1	1	2
<b>Net Income (Adjusted)</b>	<b>(53)</b>	<b>(63)</b>	<b>(83)</b>	<b>(101)</b>	<b>(117)</b>
<b>% Change</b>	<b>-217.8%</b>	<b>-19.3%</b>	<b>-30.8%</b>	<b>-22.0%</b>	<b>-15.8%</b>

## Free Cash Flow Data (Dec)

(US\$ Millions)	2021A	2022A	2023E	2024E	2025E
Net Income from Cont Operations (GAAP)	(53)	(63)	(83)	(101)	(117)
Depreciation & Amortization	0	1	1	1	1
Change in Working Capital	(3)	1	1	1	0
Deferred Taxation Charge	NA	NA	NA	NA	NA
Other Adjustments, Net	24	15	16	16	16
Capital Expenditure	(1)	(2)	(2)	(3)	(3)
<b>Free Cash Flow</b>	<b>-33</b>	<b>-48</b>	<b>-68</b>	<b>-87</b>	<b>-103</b>
<b>% Change</b>	<b>-102.7%</b>	<b>-47.0%</b>	<b>-41.1%</b>	<b>-27.4%</b>	<b>-18.9%</b>
Share / Issue Repurchase	80	0	325	4	418
Cost of Dividends Paid	0	0	0	0	0
Change in Debt	7	0	10	9	8

## Balance Sheet Data (Dec)

(US\$ Millions)	2021A	2022A	2023E	2024E	2025E
Cash & Equivalents	117	28	279	188	491
Trade Receivables	NA	NA	NA	NA	NA
Other Current Assets	2	73	90	109	129
Property, Plant & Equipment	5	7	7	9	11
Other Non-Current Assets	0	0	0	0	0
<b>Total Assets</b>	<b>124</b>	<b>108</b>	<b>377</b>	<b>305</b>	<b>631</b>
Short-Term Debt	0	1	1	2	2
Other Current Liabilities	3	4	5	6	7
Long-Term Debt	0	29	38	47	55
Other Non-Current Liabilities	0	0	0	0	0
<b>Total Liabilities</b>	<b>3</b>	<b>34</b>	<b>45</b>	<b>55</b>	<b>64</b>
<b>Total Equity</b>	<b>122</b>	<b>74</b>	<b>332</b>	<b>250</b>	<b>567</b>
<b>Total Equity &amp; Liabilities</b>	<b>124</b>	<b>108</b>	<b>377</b>	<b>305</b>	<b>631</b>

\* For full definitions of iQmethod<sup>SM</sup> measures, see page 5.

## Company Sector

Biotechnology

## Company Description

Rani Therapeutics is a clinical-stage biotech company with a differentiated drug delivery platform, the 'RaniPill', which promises oral administration of complex biologics historically limited to needle injection, with the global market for injectable drugs reaching >\$400B in 2020. The company was founded in 2012 by Mir Imran, an established inventor and serial entrepreneur, with the RaniPill created and fully developed to date in-house.

## Investment Rationale

We are positive on Rani's differentiated approach to oral delivery of biologics (broad applicability, flexible manufacturing, solid IP), which has long been considered the 'holy grail' of drug delivery. And while there is still more derisking left to go for the company's pipeline, initial applications (octreotide, teriparatide, adalimumab, insulin/GLP-1) could cumulatively provide >\$5B in peak sales if approved. Ongoing (Novartis, Takeda) and future partnerships offer additional upside.

## Stock Data

Average Daily Volume 77,075

## Quarterly Earnings Estimates

	2022	2023
Q1	-0.28A	-0.34A
Q2	-0.32A	-0.38A
Q3	-0.33A	-0.30E
Q4	-0.35A	-0.34E

Abbreviations:

SAE: Severe Adverse Event

AE: Adverse Event

SC: Subcutaneous Injection

## Price objective basis & risk

### Rani Therapeutics (RANI)

Our \$17/share price objective is based on a probability adjusted NPV of RT-101 (\$3/sh), RT-102 (\$5/sh), RT-103/106 (\$1/sh), RT-105 (\$4/sh), early pipeline and platform revenues (\$3/sh), and cash (\$1/sh). We apply a WACC of 11-13% and -2% terminal growth, which is comparable to our valuation methodology for other biotech companies of similar size and stage of clinical development.

Downside risks: 1) initial clinical data for pipeline programs fails to demonstrate a meaningful benefit in patients, 2) pipeline therapies fail to differentiate from similar competing products, 3) regulatory/reimbursement environment weighs on commercial economics, 4) patent litigation invalidates or otherwise undermines the IP portfolio, 5) funding is insufficient to move forward pipeline aspirations or manufacturing buildout.

## Analyst Certification

I, Geoff Meacham, hereby certify that the views expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the specific recommendations or view expressed in this research report.

### US - Biopharmaceuticals Coverage Cluster

Investment rating	Company	BofA Ticker	Bloomberg symbol	Analyst
<b>BUY</b>				
	89bio, Inc	ETNB	ETNB US	Geoff Meacham
	Acumen Pharma	ABOS	ABOS US	Geoff Meacham
	Agios Pharmaceuticals	AGIO	AGIO US	Greg Harrison, CFA
	Amylyx Pharmaceuticals	AMLX	AMLX US	Geoff Meacham
	BioMarin	BMRN	BMRN US	Geoff Meacham
	BioXcel Therapeutics	BTAI	BTAI US	Greg Harrison, CFA
	BridgeBio Pharma	BBIO	BBIO US	Greg Harrison, CFA
	Caribou	CRBU	CRBU US	Geoff Meacham
	CRISPR Therapeutics	CRSP	CRSP US	Geoff Meacham
	Eli Lilly and Company	LLY	LLY US	Geoff Meacham
	Gilead Sciences Inc.	GILD	GILD US	Geoff Meacham
	HUTCHMED	HCM	HCM US	Alec W. Stranahan
	Immatics	IMTX	IMTX US	Alec W. Stranahan
	Insmed Incorporated	INSM	INSM US	Jason Zemansky
	Intellia Therapeutics	NTLA	NTLA US	Greg Harrison, CFA
	Janux Therapeutics	JANX	JANX US	Geoff Meacham
	Keros	KROS	KROS US	Greg Harrison, CFA
	Kiniksa Pharmaceuticals, Ltd.	KNSA	KNSA US	Geoff Meacham
	Krystal Biotech	KRYS	KRYS US	Alec W. Stranahan
	Kura Oncology	KURA	KURA US	Jason Zemansky
	Liquidia Corporation	LQDA	LQDA US	Greg Harrison, CFA
	Lyell Immunopharma	LYEL	LYEL US	Geoff Meacham
	MeiraGTx	MGTX	MGTX US	Alec W. Stranahan
	Mineralys Therapeutics	MLYS	MLYS US	Greg Harrison, CFA
	Neumora Therapeutics	NMRA	NMRA US	Geoff Meacham
	Rani Therapeutics	RANI	RANI US	Geoff Meacham
	Regenxbio, Inc.	RGNX	RGNX US	Alec W. Stranahan
	Revolution Medicines	RVMD	RVMD US	Alec W. Stranahan
	Rocket Pharmaceuticals, Inc.	RCKT	RCKT US	Greg Harrison, CFA
	Royalty Pharma	RPRX	RPRX US	Geoff Meacham
	Sana Biotechnology	SANA	SANA US	Geoff Meacham
	SpringWorks	SWTX	SWTX US	Alec W. Stranahan
	Syndax Pharmaceuticals	SNDX	SNDX US	Jason Zemansky
	Traverse Therapeutics Inc	TVTX	TVTX US	Greg Harrison, CFA
	Turnstone Biologics	TSBX	TSBX US	Geoff Meacham
	Vertex Pharmaceuticals Inc.	VRTX	VRTX US	Geoff Meacham
	Werewolf Therapeutics	HOWL	HOWL US	Jason Zemansky

## US - Biopharmaceuticals Coverage Cluster

Investment rating	Company	BofA Ticker	Bloomberg symbol	Analyst
	Xencor	XNCR	XNCR US	Alec W. Stranahan
<b>NEUTRAL</b>				
	AbbVie	ABBV	ABBV US	Geoff Meacham
	Alector, Inc	ALEC	ALEC US	Greg Harrison, CFA
	Amgen Inc.	AMGN	AMGN US	Geoff Meacham
	Arcus Biosciences	RCUS	RCUS US	Jason Zemansky
	Beam Therapeutics	BEAM	BEAM US	Greg Harrison, CFA
	Biogen Inc.	BIIB	BIIB US	Geoff Meacham
	Bristol-Myers Squibb	BMJ	BMJ US	Geoff Meacham
	Cytokinetics, Incorporated	CYTK	CYTK US	Jason Zemansky
	Editas Medicine	EDIT	EDIT US	Greg Harrison, CFA
	Erasca	ERAS	ERAS US	Alec W. Stranahan
	Esperion	ESPR	ESPR US	Jason Zemansky
	Exscientia	EXAI	EXAI US	Alec W. Stranahan
	IGM Biosciences	IGMS	IGMS US	Greg Harrison, CFA
	Johnson & Johnson	JNJ	JNJ US	Geoff Meacham
	Kymira Therapeutics	KYMR	KYMR US	Geoff Meacham
	Moderna	MRNA	MRNA US	Geoff Meacham
	Pfizer	PFE	PFE US	Geoff Meacham
	Recursion Pharmaceuticals, Inc.	RXR	RXR US	Alec W. Stranahan
	Tyra Biosciences	TYRA	TYRA US	Greg Harrison, CFA
	Vir	VIR	VIR US	Geoff Meacham
	Y-mAbs Therapeutics, Inc	YMAB	YMAB US	Alec W. Stranahan
<b>UNDERPERFORM</b>				
	AlloVir, Inc.	ALVR	ALVR US	Jason Zemansky
	CureVac	CVAC	CVAC US	Geoff Meacham
	Day One Biopharmaceuticals	DAWN	DAWN US	Alec W. Stranahan
	LianBio	LIAN	LIAN US	Geoff Meacham
	Novavax	NVAX	NVAX US	Alec W. Stranahan
	Regeneron Pharmaceuticals Inc.	REGN	REGN US	Geoff Meacham
	Reneo Pharmaceuticals	RPHM	RPHM US	Jason Zemansky
	TG Therapeutics	TGTX	TGTX US	Alec W. Stranahan
	United Therapeutics Corporation	UTHR	UTHR US	Greg Harrison, CFA
<b>RSTR</b>				
	Merck & Co.	MRK	MRK US	Geoff Meacham

IQmethod<sup>SM</sup> Measures Definitions

## Business Performance

Return On Capital Employed

Return On Equity  
Operating Margin  
Earnings Growth  
Free Cash Flow

## Quality of Earnings

Cash Realization Ratio  
Asset Replacement Ratio  
Tax Rate  
Net Debt-To-Equity Ratio  
Interest Cover

## Valuation Toolkit

Price / Earnings Ratio  
Price / Book Value  
Dividend Yield  
Free Cash Flow Yield  
Enterprise Value / Sales

EV / EBITDA

## Numerator

NOPAT = (EBIT + Interest Income) × (1 – Tax Rate) + Goodwill Amortization

Net Income  
Operating Profit  
Expected 5 Year CAGR From Latest Actual  
Cash Flow From Operations – Total Capex

## Numerator

Cash Flow From Operations  
Capex  
Tax Charge  
Net Debt = Total Debt – Cash & Equivalents  
EBIT

## Numerator

Current Share Price  
Current Share Price  
Annualised Declared Cash Dividend  
Cash Flow From Operations – Total Capex  
EV = Current Share Price × Current Shares + Minority Equity + Net Debt +  
Other LT Liabilities  
Enterprise Value

## Denominator

Total Assets – Current Liabilities + ST Debt + Accumulated Goodwill  
Amortization  
Shareholders' Equity  
Sales  
N/A  
N/A

## Denominator

Net Income  
Depreciation  
Pre-Tax Income  
Total Equity  
Interest Expense

## Denominator

Diluted Earnings Per Share (Basis As Specified)  
Shareholders' Equity / Current Basic Shares  
Current Share Price  
Market Cap = Current Share Price × Current Basic Shares  
Sales

Basic EBIT + Depreciation + Amortization



Valuation Toolkit

Numerator

Denominator

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### Equity Investment Rating Distribution: Health Care Group (as of 31 Dec 2023)

Coverage Universe	Count	Percent	Inv. Banking Relationships <sup>R1</sup>	Count	Percent
Buy	234	60.94%	Buy	115	49.15%
Hold	80	20.83%	Hold	36	45.00%
Sell	70	18.23%	Sell	29	41.43%

### Equity Investment Rating Distribution: Global Group (as of 31 Dec 2023)

Coverage Universe	Count	Percent	Inv. Banking Relationships <sup>R1</sup>	Count	Percent
Buy	1895	53.62%	Buy	1083	57.15%
Hold	832	23.54%	Hold	454	54.57%
Sell	807	22.84%	Sell	383	47.46%

<sup>R1</sup> Issuers that were investment banking clients of BofA Securities or one of its affiliates within the past 12 months. For purposes of this Investment Rating Distribution, the coverage universe includes only stocks. A stock rated Neutral is included as a Hold, and a stock rated Underperform is included as a Sell.

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Investment rating	Total return expectation (within 12-month period of date of initial rating)	Ratings dispersion guidelines for coverage cluster <sup>R2</sup>
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Neutral	≥ 0%	≤ 30%
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