

## Rocket Pharmaceuticals, Inc.

# PDUFA extension delays commercial transition but attention remains on Danon

Reiterate Rating: BUY | PO: 37.00 USD | Price: 29.99 USD

## Company remains prepared to commercialize KRESLADI

Rocket announced the FDA has extended the priority review period for the BLA for KRESLADI in LAD-1 by three months (new PDUFA date June 30<sup>th</sup>) in order to review clarifying CMC information submitted by Rocket in response to FDA information requests. With the [submission supported by positive clinical data \(see report\)](#), we look for the FDA to complete its review process in June and model a launch of KRESLADI in mid-24 (PoS 90%). The company also noted an AdCom is not needed by the FDA for the review process of KRESLADI. With a notable [manufacturing process and capabilities \(see report\)](#), we remain confident in an approval of KRESLADI upon the new PDUFA date. Given the late-stage clinical progress and regulatory milestones anticipated across Rocket's pipeline we reiterate Buy, PO \$37.

## June 30 PDUFA moves launch to mid-year

With a new review timeline, we now model a launch of KRESLADI in mid-24 and 2024 sales of \$16.2M (from \$43.2M). We see the LAD-1 launch as a key program to lay the foundation for larger commercial launches by the company in the future including the Danon program. We look for additional commercial launch details upon approval of Kresladi.

## Pivotal progress still expected across pipeline

While the review extension today delays the commercial transition of the company by 3 months, Rocket is primed for important regulatory and clinical milestones in other pipeline programs, including interim data from the pivotal Danon trial (2024). We also look for the BLA-MAA filing of the RP-L102 program in Fanconi anemia (1H24) and the pivotal trial initiation of RP-L301 in PKD (2024).

### See our catalyst calendar below (Exhibit 1):

Estimates (Dec) (US\$)	2021A	2022A	2023E	2024E	2025E
EPS	(2.67)	(3.26)	(2.99)	(3.21)	(2.42)
EPS Change (YoY)	-6.0%	-22.1%	8.3%	-7.4%	24.6%
Consensus EPS (Bloomberg)			(3.09)	(2.84)	(1.48)
DPS	0	0	0	0	0
<b>Valuation (Dec)</b>					
Free Cash Flow Yield*	-4.8%	-6.9%	-8.2%	-9.9%	-7.3%

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

13 February 2024

### Equity

#### Key Changes

(US\$)	Previous	Current
2024E Rev (m)	43.2	16.2
2025E Rev (m)	166.1	169.1
2024E EPS	-2.98	-3.21
2025E EPS	-2.44	-2.42

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### Stock Data

Price	29.99 USD
Price Objective	37.00 USD
Date Established	12-Nov-2023
Investment Opinion	C-1-9
52-Week Range	14.89 USD - 32.53 USD
Mkt Val (mn) / Shares Out (mn)	2,704 USD / 90.2
Free Float	77.1%
Average Daily Value (mn)	19.90 USD
BofA Ticker / Exchange	RCKT / NAS
Bloomberg / Reuters	RCKT US / RCKT.QQ
ROE (2023E)	-48.9%
Net Dbt to Eqty (Dec-2022A)	-28.7%
ESGMeter™	Low

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### Glossary

BLA: Biologics License Application  
CMC: Chemistry, Manufacturing, and Controls  
LAD-1: Leukocyte Adhesion Deficiency-1  
MAA: Marketing Authorization Application  
PDUFA: Prescription Drug User Fee Act

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Timestamp: 13 February 2024 09:02AM EST

# iQprofile<sup>SM</sup> Rocket Pharmaceuticals, Inc.

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

(US\$ Millions)	2021A	2022A	2023E	2024E	2025E
Return on Capital Employed	-29.0%	-40.9%	-49.1%	-83.6%	-132.1%
Return on Equity	-29.2%	-40.4%	-48.9%	-90.0%	-150.9%
Operating Margin	NA	NA	NA	-1,919.3%	-146.1%
Free Cash Flow	(129)	(187)	(222)	(268)	(197)

## 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	2.4x	2.0x	1.4x	0.8x	0.4x
Tax Rate	NM	NM	NM	NM	NM
Net Debt-to-Equity Ratio	-51.2%	-28.7%	-68.8%	-24.2%	-4.0%
Interest Cover	NM	NM	NM	NM	NM

## Income Statement Data (Dec)

(US\$ Millions)	2021A	2022A	2023E	2024E	2025E
Sales	0	0	0	16	169
% Change	NA	NA	NA	NA	943.8%
Gross Profit	0	0	0	13	139
% Change	NA	NA	NA	NA	943.8%
EBITDA	(164)	(220)	(265)	(306)	(243)
% Change	-23.2%	-34.2%	-20.2%	-15.8%	20.8%
Net Interest & Other Income	(2)	2	8	0	(1)
<b>Net Income (Adjusted)</b>	<b>(140)</b>	<b>(191)</b>	<b>(230)</b>	<b>(279)</b>	<b>(215)</b>
<b>% Change</b>	<b>-15.4%</b>	<b>-36.5%</b>	<b>-20.3%</b>	<b>-21.4%</b>	<b>22.8%</b>

## Free Cash Flow Data (Dec)

(US\$ Millions)	2021A	2022A	2023E	2024E	2025E
Net Income from Cont Operations (GAAP)	(169)	(222)	(261)	(311)	(248)
Depreciation & Amortization	3	4	4	4	4
Change in Working Capital	(3)	6	9	11	16
Deferred Taxation Charge	NA	NA	NA	NA	NA
Other Adjustments, Net	48	34	32	32	33
Capital Expenditure	(8)	(8)	(6)	(4)	(2)
<b>Free Cash Flow</b>	<b>-129</b>	<b>-187</b>	<b>-222</b>	<b>-268</b>	<b>-197</b>
<b>% Change</b>	<b>-35.2%</b>	<b>-44.8%</b>	<b>-19.1%</b>	<b>-20.5%</b>	<b>26.5%</b>
Share / Issue Repurchase	38	155	189	0	160
Cost of Dividends Paid	0	0	0	0	0
Change in Debt	0	0	0	0	0

## Balance Sheet Data (Dec)

(US\$ Millions)	2021A	2022A	2023E	2024E	2025E
Cash & Equivalents	233	141	309	41	5
Trade Receivables	NA	NA	NA	NA	NA
Other Current Assets	159	224	24	24	24
Property, Plant & Equipment	22	29	29	29	26
Other Non-Current Assets	83	159	159	159	159
<b>Total Assets</b>	<b>497</b>	<b>552</b>	<b>520</b>	<b>252</b>	<b>213</b>
Short-Term Debt	0	0	0	0	0
Other Current Liabilities	22	39	47	57	72
Long-Term Debt	0	0	0	0	0
Other Non-Current Liabilities	20	23	25	25	26
<b>Total Liabilities</b>	<b>42</b>	<b>62</b>	<b>71</b>	<b>82</b>	<b>98</b>
<b>Total Equity</b>	<b>455</b>	<b>490</b>	<b>449</b>	<b>170</b>	<b>115</b>
<b>Total Equity &amp; Liabilities</b>	<b>497</b>	<b>552</b>	<b>520</b>	<b>252</b>	<b>213</b>

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

## Company Sector

Biotechnology

## Company Description

RCKT is a clinical stage company that develops gene therapies for severe genetic diseases including rare blood, bone, and cardiac diseases including Fanconi anemia, Danon disease, leukocyte adhesion deficiency type 1, pyruvate kinase disorder, and infantile osteopetrosis.

## Investment Rationale

RCKT targets rare genetic diseases with significant unmet medical needs that offer meaningful commercial opportunities if drug treatments can be developed and approved. We also believe the company is positioned to benefit from advancements in gene therapies. Encouraging pre-clinical and clinical data along with positive clinical updates from other next-gen gene therapy programs using lentiviral and AAV vectors provide us with greater confidence in the likelihood of success in these programs.

## Stock Data

Average Daily Volume 663,569

## Quarterly Earnings Estimates

	2022	2023
Q1	-0.67A	-0.73A
Q2	-0.83A	-0.82A
Q3	-0.87A	-0.78A
Q4	-0.92A	-0.87E

Exhibit 1: Rocket Catalyst Calendar

We update our LAD-1 model for a launch in mid-24.

Company	Asset	Indication	Event	Timing	Importance
Rocket	RP-L201	LAD-1	PDUFA	30-Jun-24	High
Rocket	RP-L301	PKD	Pivotal phase 2 trial initiation	2024	Low
Rocket	RP-A501	Danon disease	Pivotal trial interim update	2024	High
Rocket	RP-L102	Fanconi anemia	BLA-MAA filing	1H24	High
Rocket	BAG3-association DCM	BAG3-DCM	IND filing	2024	Low

Source: BofA Global Research, company reports

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## Price objective basis & risk

### Rocket Pharmaceuticals, Inc. (RCKT)

Our \$37/share price objective is based on a probability-adjusted (35%-90%) net present value (NPV) analysis of its four programs under development. We use a weighted-average cost of capital (WACC) of 15%, similar to other early-stage companies in our coverage universe, and terminal growth rate of -2%. Given these assumptions, we estimate a value of \$9/share for RP-L102 (Fanconi anemia), \$21/share for RP-A501 (Danon disease), \$2/share for RP-L201 (LAD-1), \$1/share for RP-L301 (PKD), and \$4/share in net cash.

Risks: 1) failure of early clinical trials, 2) emergence of unacceptable safety signals, 3) shorter efficacy duration than expected, and 4) commercialization failures.

## Analyst Certification

I, Greg Harrison, CFA, 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
	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
	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
	Merck & Co.	MRK	MRK US	Geoff Meacham
	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
	Xencor	XNCR	XNCR US	Alec W. Stranahan

## US - Biopharmaceuticals Coverage Cluster

Investment rating	Company	BofA Ticker	Bloomberg symbol	Analyst
<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
<b>RSTR</b>	United Therapeutics Corporation	UTHR	UTHR US	Greg Harrison, CFA
	BioXcel Therapeutics	BTAI	BTAI US	Greg Harrison, CFA
	Gilead Sciences Inc.	GILD	GILD 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 &amp; 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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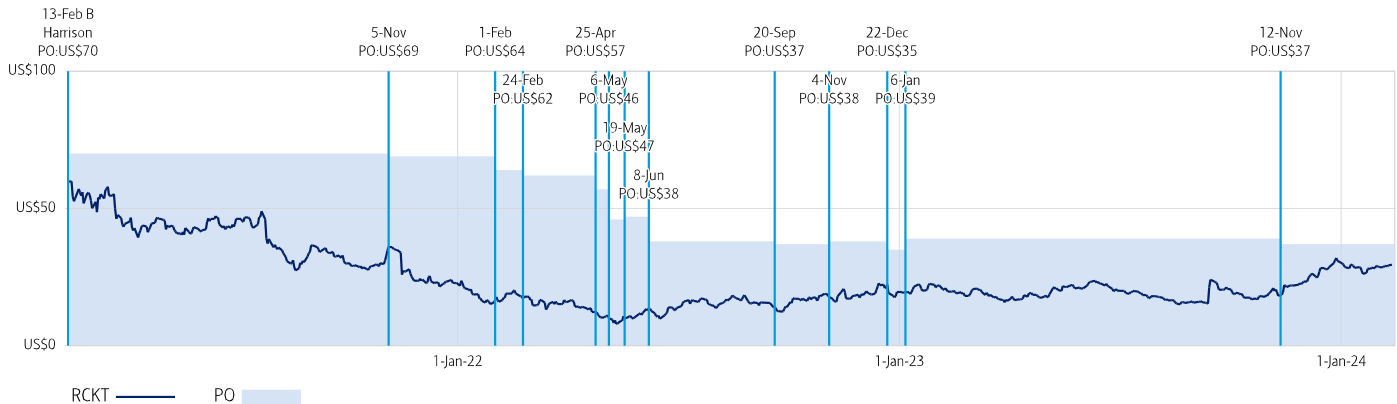
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## Important Disclosures

### Rocket Pharma (RCKT) Price Chart



B: Buy, N: Neutral, U: Underperform, PO: Price Objective, NA: No longer valid, NR: No Rating

The Investment Opinion System is contained at the end of the report under the heading "Fundamental Equity Opinion Key". Dark grey shading indicates the security is restricted with the opinion suspended. Medium grey shading indicates the security is under review with the opinion withdrawn. Light grey shading indicates the security is not covered. Chart is current as of a date no more than one trading day prior to the date of the report.

### 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>
Buy	≥ 10%	≤ 70%
Neutral	≥ 0%	≤ 30%
Underperform	N/A	≥ 20%

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