

PepGen Inc

FDA grants PGN-EDODM1 program Fast Track Designation for DM1; Maintain Buy

Maintain Rating: BUY | PO: 21.00 USD | Price: 13.89 USD

Initial phase 1 DM1 data expected in 2024

PepGen (ticker: PEPG) announced the FDA granted PGN-EDODM1 for myotonic dystrophy 1 (DM1) Fast Track Designation. Recall, the FDA previously granted the program Orphan Drug Designation in September 2023. We are encouraged by the FDA's understanding of the high unmet need associated with DM1 given no approved disease modifying therapies. We note the regulatory designations will allow PEPG to have earlier and more frequent interactions with the FDA for a more streamlined development process, which could lead to earlier drug approval. The company reported the first patient in the phase 1 FREEDOM-DM1 trial evaluating PGN-EDODM1 in DM1 was diagnosed in December with initial data expected in 2024 (see our [December 18th note](#)). The trial will enroll ~24 adult DM1 patients and will provide an early look at safety, mis-splicing correction, oligonucleotide muscle concentration and clinical outcomes at day 28 and later. We continued to be encouraged by PEPG's DM1 program given its differentiated mechanism of action aiming to liberate MBNL1 (Musclebind Like Splicing Regulator 1) instead of knocking down the protein. We await clinical validation before assigning standalone value for the program and currently include PGN-EDODM1 as part of our \$500mn pipeline value. We maintain our Buy with \$21 PO.

Estimates (Dec) (US\$)	2021A	2022A	2023E	2024E	2025E
EPS	(30.27)	(4.44)	(3.70)	(3.50)	(3.31)
EPS Change (YoY)	-545.4%	85.3%	16.7%	5.4%	5.4%
Consensus EPS (Bloomberg)			(3.50)	(3.66)	(3.53)
DPS	0	0	0	0	0
Valuation (Dec)					
Free Cash Flow Yield*	-7.0%	-20.5%	-26.6%	-31.8%	-36.4%

* For full definitions of *IQmethod*SM measures, see page 4.

20 February 2024

Equity

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Stock Data

Price	13.89 USD
Price Objective	21.00 USD
Date Established	13-Nov-2023
Investment Opinion	C-1-9
52-Week Range	3.72 USD - 20.00 USD
Mkt Val (mn) / Shares Out (mn)	331 USD / 23.8
Free Float	36.6%
Average Daily Value (mn)	2.21 USD
BofA Ticker / Exchange	PEPG / NAS
Bloomberg / Reuters	PEPG US / PEPG.OQ
ROE (2023E)	-73.1%
Net Dbt to Eqty (Dec-2022A)	-99.6%
ESGMeter TM	NLA

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FDA: Food and Drug Administration

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Timestamp: 20 February 2024 09:34AM EST

iQprofileSM PepGen Inc

iQmethodSM – Bus Performance*

(US\$ Millions)	2021A	2022A	2023E	2024E	2025E
Return on Capital Employed	-34.1%	-39.3%	-65.7%	-130.9%	-198.5%
Return on Equity	-38.2%	-46.2%	-73.1%	-145.7%	-221.2%
Operating Margin	NA	NA	NA	NA	NA
Free Cash Flow	(23)	(68)	(88)	(105)	(120)

iQmethodSM – Quality of Earnings*

(US\$ Millions)	2021A	2022A	2023E	2024E	2025E
Cash Realization Ratio	NM	NM	NM	NM	NM
Asset Replacement Ratio	2.8x	3.1x	3.3x	3.6x	4.0x
Tax Rate	NM	NM	NM	NM	NM
Net Debt-to-Equity Ratio	-99.9%	-99.6%	-98.7%	-97.6%	-94.3%
Interest Cover	NA	NA	NA	NA	NA

Income Statement Data (Dec)

(US\$ Millions)	2021A	2022A	2023E	2024E	2025E
Sales	0	0	0	0	0
% Change	NA	NA	NA	NA	NA
Gross Profit	0	0	0	0	0
% Change	NA	NA	NA	NA	NA
EBITDA	(27)	(68)	(92)	(110)	(125)
% Change	NM	-152.9%	-35.5%	-19.1%	-14.2%
Net Interest & Other Income	0	3	3	3	3
Net Income (Adjusted)	(27)	(69)	(90)	(107)	(123)
% Change	-569.1%	-153.3%	-29.6%	-19.7%	-14.5%

Free Cash Flow Data (Dec)

(US\$ Millions)	2021A	2022A	2023E	2024E	2025E
Net Income from Cont Operations (GAAP)	(27)	(69)	(90)	(107)	(123)
Depreciation & Amortization	0	0	0	0	0
Change in Working Capital	3	0	0	0	0
Deferred Taxation Charge	NA	NA	NA	NA	NA
Other Adjustments, Net	2	2	2	3	3
Capital Expenditure	(1)	(1)	(1)	(1)	(1)
Free Cash Flow	-23	-68	-88	-105	-120
% Change	NM	-192.9%	-29.9%	-19.7%	-14.4%
Share / Issue Repurchase	149	100	0	94	94
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	133	166	78	67	40
Trade Receivables	5	5	6	6	7
Other Current Assets	2	3	3	3	3
Property, Plant & Equipment	1	1	2	2	3
Other Non-Current Assets	3	3	4	4	4
Total Assets	144	178	92	82	58
Short-Term Debt	0	0	0	0	0
Other Current Liabilities	10	11	12	14	15
Long-Term Debt	0	0	0	0	0
Other Non-Current Liabilities	0	0	0	0	0
Total Liabilities	11	12	13	14	15
Total Equity	133	166	79	68	43
Total Equity & Liabilities	144	178	92	82	58

* For full definitions of iQmethodSM measures, see page 4.

Company Sector

Biotechnology

Company Description

PepGen Inc (PEPG) is a clinical-stage biotechnology company developing a pipeline of enhanced delivery oligonucleotides (EDOs) focusing on neuromuscular and neurologic disorders. Its lead programs target Duchenne muscular dystrophy (DMD) amenable to exon 51 skipping and myotonic dystrophy type 1 (DM1). The company is planning to expand to other DMD subtypes including exon 53, exon 44 and exon 45.

Investment Rationale

We rate PEPG at Buy. We believe its enhanced delivery oligonucleotide (EDO) platform using cell-penetrating peptides to enhance tissue delivery and uptake of therapeutic oligonucleotides has the potential to show improved clinical efficacy over currently approved drugs. Preclinical data is supportive of the superior biodistribution profile showing delivery to key tissues. However, extensive clinical validation is needed and initial data in patients is not expected until 2024.

Stock Data

Average Daily Volume 158,972

Quarterly Earnings Estimates

	2022	2023
Q1	-18.94A	-0.69A
Q2	-1.23A	-0.82A
Q3	-0.79A	-0.98A
Q4	-0.63A	-1.19E

Price objective basis & risk

PepGen Inc (PEPG)

Our \$21 price objective (PO) is based on a probability-adjusted net present value (NPV) analysis. Our valuation includes PGN-EDO51 in DMD amenable to exon 51 skipping (\$4/share). The remainder of our valuation comes from pipeline and cash. Our discounted cash flow (DCF)-based model goes out to 2040 and assumes a 14% WACC for EDO51 and pipeline expenses and no terminal value.

Upside risks to our PO are 1) positive clinical trial data for lead indications, 2) accelerated approval of lead assets, 3) positive data from unmodeled, early-stage assets, 4) better-than-expected market penetration, and 5) partnerships to accelerate clinical development.

Downside risks to our PO are 1) negative results from clinical trials, 2) unexpected safety signals in clinical trials, 3) failure to obtain regulatory approval for lead assets, 4) failure of EDO51 to differentiate from similar assets in the pipeline, 5) lower-than-expected uptake in target indications.

Analyst Certification

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US - Biotechnology Coverage Cluster

Investment rating	Company	BofA Ticker	Bloomberg symbol	Analyst
BUY				
	4D Molecular Therapeutics, Inc.	FDMT	FDMT US	Tazeen Ahmad
	Alnylam Pharmaceuticals	ALNY	ALNY US	Tazeen Ahmad
	Amicus Therapeutics	FOLD	FOLD US	Tazeen Ahmad
	Annexon Biosciences	ANNX	ANNX US	Tazeen Ahmad
	Apellis Pharmaceuticals	APLS	APLS US	Tazeen Ahmad
	Argenx SE	ARGX	ARGX US	Tazeen Ahmad
	Arvinas	ARVN	ARVN US	Tazeen Ahmad
	Ascendis Pharma	ASND	ASND US	Tazeen Ahmad
	Biocryst Pharmaceuticals Inc	BCRX	BCRX US	Tazeen Ahmad
	BioNTech	BNTX	BNTX US	Tazeen Ahmad
	Denali Therapeutics	DNLI	DNLI US	Tazeen Ahmad
	Inozyme Pharma, Inc.	INZY	INZY US	Tazeen Ahmad
	Merus	MRUS	MRUS US	Tazeen Ahmad
	Neurocrine Biosciences	NBIX	NBIX US	Tazeen Ahmad
	Ocular Therapeutix	OCUL	OCUL US	Tazeen Ahmad
	PepGen Inc	PEPG	PEPG US	Tazeen Ahmad
	Rhythm Pharmaceuticals	RYTM	RYTM US	Tazeen Ahmad
	Sarepta Therapeutics	SRPT	SRPT US	Tazeen Ahmad
	Ultragenyx Pharmaceuticals	RARE	RARE US	Tazeen Ahmad
NEUTRAL				
	Acadia Pharmaceuticals	ACAD	ACAD US	Tazeen Ahmad
	Incyte Corporation	INCY	INCY US	Tazeen Ahmad
	Prothena Corporation	PRTA	PRTA US	Tazeen Ahmad
	SAGE Therapeutics	SAGE	SAGE US	Tazeen Ahmad



US - Biotechnology Coverage Cluster

Investment rating	Company	BofA Ticker	Bloomberg symbol	Analyst
UNDERPERFORM	Achilles Therapeutics	ACHL	ACHL US	Tazeen Ahmad
	Fate Therapeutics	FATE	FATE US	Tazeen Ahmad
	Fulcrum Therapeutics	FULC	FULC US	Tazeen Ahmad
	Pharvaris	PHVS	PHVS US	Tazeen Ahmad
	PTC Therapeutics	PTCT	PTCT US	Tazeen Ahmad

iQ^{method}™ 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

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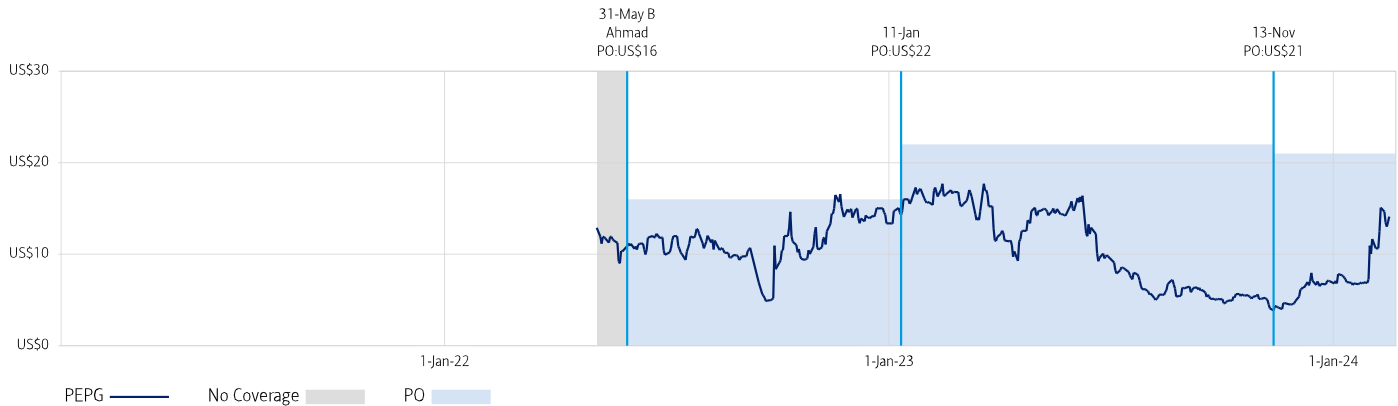
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PepGen Inc (PEPG) Price Chart



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 ^{R1}	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 ^{R1}	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%

^{R1} 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 ^{R2}
Buy	≥ 10%	≤ 70%
Neutral	≥ 0%	≤ 30%
Underperform	N/A	≥ 20%

^{R2} Ratings dispersions may vary from time to time where BofA Global Research believes it better reflects the investment prospects of stocks in a Coverage Cluster.

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