

## Intra-Cellular Therapies

## 4Q23 EPS: Strong 2024 Caplyta guidance; adj. MDD push immaterial

Reiterate Rating: BUY | PO: 82.00 USD | Price: 71.93 USD

## FY24 guide in line with cons; up next: adj. MDD readout

Intra-Cellular's (ITCI) 4Q update included FY24 Caplyta revenue guidance that bracketed cons (~\$645-\$675m guide vs cons at \$658m) with ~40% Y/Y growth at the mid-point driven by continued growth in the bipolar depression indication. On the call, the focus was on the pending Ph3 (study 501) Caplyta adjunctive MDD study which is expected to readout in April (vs 1Q24) while the second Ph3 will readout closer to the end of 2Q24. We view the timeline tweaks as immaterial and still model a 2H24 sNDA filing for the aMDD indication. Furthermore, we continue to see Caplyta-MDD as a high probability label add-on (70% odds) which reflects prior studies demonstrating Caplyta's benefit on mood, risk-mitigation (3 Ph3's) somewhat offset by inherent MDD-related trial risks. We update our model for 4Q financials and pipeline updates, and reiterate Buy on favorable risk/reward in '24+ catalysts.

## Adj. MDD + MF regulatory path: levers for optionality

In 1Q, ITCI will be in a position to convey its development plans for the mixed features regulatory path post receiving official meeting minutes from 'constructive' FDA meeting discussing positive study 403. Separately, ITCI outlined potential scenarios for MDD studies 501 and 502, where the strength of the two datasets will dictate whether both need to be positive vs. split outcome. Note, AbbVie's Vraylar secured MDD approval provides an encouraging analog for regulatory latitude. Mgmt sounded bullish on ABBV's recent Vraylar launch inflection in aMDD indicating room for new treatment options.

## Other pipeline: no major updates

On mid-stage pipeline, ITCI remains on track to begin enrollment in three Ph2 trials of deuterated-lumateperone in GAD, ADA, and ADP by 1H24, citing deuterated's differentiated tolerability as an encouraging aspect of product profile. Progress continues on LAI formulations (announced doing work on 4 novel formulations) after prior Ph1 SAD was unable to get > 1 month duration dosing in subQ form of administration. Progress on early-stage pipeline continues as planned, including: 1) ITI-333 (pain, opioid disorder) Ph1 MAD study progressing, 2) ITI-1549 (non-hallucinogenic) Ph1 initiation in 2H24/1H25, 3) topline data from ITI-214 Ph2 trial in Parkinson's in 1H25. **Note continued on page 3 for model updates.**

Estimates (Dec) (US\$)	2022A	2023A	2024E	2025E	2026E
EPS	(2.72)	(1.75)	(0.29)	1.69	7.52
EPS Change (YoY)	22.3%	35.7%	83.4%	NM	345.0%
Consensus EPS (Bloomberg)			(0.56)	1.51	4.22
DPS	0	0	0	0	0
<b>Valuation (Dec)</b>					
P/E	NM	NM	NM	42.6x	9.6x
EV / EBITDA*	NM	NM	NM	34.7x	7.6x
Free Cash Flow Yield*	-3.9%	-2.0%	0.2%	2.8%	11.0%

\* For full definitions of *IQmethod™* measures, see page 5.

22 February 2024

## Equity

## Key Changes

(US\$)	Previous	Current
2025E Rev (m)	1,217.6	939.5
2026E Rev (m)	1,788.0	1,730.5
2025E EPS	3.80	1.69
2026E EPS	7.95	7.52

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## Stock Data

Price	71.93 USD
Price Objective	82.00 USD
Date Established	2-Jan-2024
Investment Opinion	C-1-9
52-Week Range	42.01 USD - 76.11 USD
Mkt Val (mn) / Shares Out (mn)	6,922 USD / 96.2
Free Float	92.8%
Average Daily Value (mn)	60.46 USD
BofA Ticker / Exchange	ITCI / NAS
Bloomberg / Reuters	ITCI US / ITCIOQ
ROE (2024E)	-5.2%
Net Dbt to Eqty (Dec-2023A)	-2.5%
<b>ESGMeter™</b>	<b>Low</b>

Please refer to "BofA ESGMeter Methodology".

ABBV: AbbVie (covered by Geoff Meacham)  
 ADA: alzheimer's disease agitation  
 Adj: adjunctive  
 ADP: alzheimer's disease psychosis  
 BPD: bipolar disorder  
 Cons: consensus  
 FDA: food & drug administration  
 GAD: generalized anxiety disorder  
 LAI: long acting injectable  
 MAD: multiple ascending dose  
 (a)MDD: (adjunctive) major depressive disorder  
 MF: mixed features  
 SAD: single ascending dose  
 sNDA: supplementary new drug application  
 Stat-sig: statistically significant

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Timestamp: 22 February 2024 05:39PM EST

# iQprofile<sup>SM</sup> Intra-Cellular Therapies

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

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Return on Capital Employed	-42.8%	-24.6%	-5.0%	24.9%	64.6%
Return on Equity	-49.3%	-28.1%	-5.2%	25.5%	65.5%
Operating Margin	-105.3%	-37.6%	-6.3%	21.0%	52.5%
Free Cash Flow	(271)	(137)	15	195	760

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

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Cash Realization Ratio	NM	NM	NM	1.3x	1.1x
Asset Replacement Ratio	1.2x	14.2x	7.4x	6.9x	9.6x
Tax Rate	NM	NM	18.0%	20.0%	20.0%
Net Debt-to-Equity Ratio	-22.7%	-2.5%	-5.3%	-30.3%	-65.8%
Interest Cover	NA	NA	NA	NA	NA

## Income Statement Data (Dec)

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Sales	250	464	662	939	1,731
% Change	198.7%	85.5%	42.6%	41.9%	84.2%
Gross Profit	230	427	609	864	1,590
% Change	203.4%	85.8%	42.6%	41.7%	84.1%
EBITDA	(263)	(174)	(40)	199	911
% Change	7.7%	33.7%	76.9%	NM	357.0%
Net Interest & Other Income	7	7	7	7	7
<b>Net Income (Adjusted)</b>	<b>(256)</b>	<b>(167)</b>	<b>(28)</b>	<b>164</b>	<b>733</b>
<b>% Change</b>	<b>9.8%</b>	<b>34.7%</b>	<b>83.3%</b>	<b>NM</b>	<b>347.1%</b>

## Free Cash Flow Data (Dec)

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Net Income from Cont Operations (GAAP)	(256)	(167)	(28)	164	733
Depreciation & Amortization	1	0	1	2	3
Change in Working Capital	(58)	(11)	13	13	27
Deferred Taxation Charge	0	0	0	0	0
Other Adjustments, Net	44	46	37	30	24
Capital Expenditure	(1)	(6)	(9)	(13)	(26)
<b>Free Cash Flow</b>	<b>-271</b>	<b>-137</b>	<b>15</b>	<b>195</b>	<b>760</b>
<b>% Change</b>	<b>0.5%</b>	<b>49.5%</b>	<b>NM</b>	<b>NM</b>	<b>289.5%</b>
Share / Issue Repurchase	434	0	0	0	0
Cost of Dividends Paid	0	0	0	0	0
Change in Debt	0	0	0	0	0

## Balance Sheet Data (Dec)

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Cash & Equivalents	149	14	29	224	984
Trade Receivables	NA	NA	NA	NA	NA
Other Current Assets	146	146	146	146	146
Property, Plant & Equipment	2	7	15	26	49
Other Non-Current Assets	458	458	458	458	458
<b>Total Assets</b>	<b>755</b>	<b>625</b>	<b>648</b>	<b>854</b>	<b>1,637</b>
Short-Term Debt	0	0	0	0	0
Other Current Liabilities	83	73	86	99	125
Long-Term Debt	0	0	0	0	0
Other Non-Current Liabilities	15	15	15	15	15
<b>Total Liabilities</b>	<b>99</b>	<b>88</b>	<b>101</b>	<b>114</b>	<b>141</b>
<b>Total Equity</b>	<b>656</b>	<b>537</b>	<b>546</b>	<b>740</b>	<b>1,497</b>
<b>Total Equity &amp; Liabilities</b>	<b>755</b>	<b>625</b>	<b>648</b>	<b>854</b>	<b>1,637</b>

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

## Company Sector

Biotechnology

## Company Description

Intra-Cellular Therapies (ITCI) is an early commercial-stage biotech company focused on the treatment of central nervous system (CNS) disorders. ITCI's portfolio consists of three key drugs, with Caplyta launched in March 2020, while the other two pipeline assets are in early development. Caplyta is approved for schizophrenia and bipolar depression (BPD).

## Investment Rationale

We are Buy-rated on ITCI based on peak sales potential for Caplyta in approved and development-stage add-on indications. We believe the commercial opportunity for Caplyta in bipolar depression is substantial given limited approved therapies in this under-penetrated market. We are encouraged by recent MDD competitor launches and we view the 1H24 Ph3 updates for Caplyta in MDD as a meaningful upside opportunity.

## Stock Data

Average Daily Volume 840,541

## Quarterly Earnings Estimates

	2023	2024
Q1	-0.46A	NAE
Q2	-0.45A	NAE
Q3	-0.25A	NAE
Q4	-0.51A	NAE

# Model updates: 2034 LOE credit, pipeline updates

We update our model for 4Q23 financials, assign credit for Caplyta sales in 2034, and update expected year of revenue recognition based on pipeline progress. Specifically, we extend Caplyta LOE to 2034 (prior 2033). Our model now combines adj. MDD and mixed features into one sales revenue stream projection to reflect overlap in patient populations and similar timing for label expansion. Additionally, update our projections for revenue recognition for adj. MDD/MF to reflect 2026 launch (prior 2025) based on timing of sNDA submission in 2H24 and approval in 2025 timeframe. These changes are summarized in Exhibit 1.

## Exhibit 1: Summary of model changes

We summarize estimate changes made with this report

Ticker	PO (\$)		Revenue (\$m)						EPS (\$)					
			Old			Current			Old			Current		
	Old	New	2024E	2025E	2026E	2024E	2025E	2026E	2024E	2025E	2026E	2024E	2025E	2026E
ITCI	82	82	662	1,218	1,788	662	939	1,731	(0.29)	3.80	7.95	(0.29)	1.69	7.52

Source: BofA Global Research estimates

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## Price objective basis & risk

### Intra-Cellular Therapies (ITCI)

Our \$82 price objective (PO) is based on a risk-adjusted sum-of-the-parts analysis. 1) Caplyta risk-adjusted sales climb to \$1.9bn by 2027E, before loss-of-exclusivity (LOE) in 2034, 2) no terminal value, 3) operating margin reaching low-60s percentage, 4) 9% discount rate.

Downside risks to our PO: 1) lower-than-expected commercial uptake of Caplyta in schizophrenia, continued COVID disruption keeping a lid on script growth, 2) BPD commercial execution risk, 3) potential setbacks on ITCI's execution on pipeline clinical development plan, e.g. adjunctive MDD, mixed features.

Upside risks to our PO: 1) better-than-expected commercial uptake of Caplyta in schizophrenia, 2) bipolar depression launch significantly above our estimates, 3) further pipeline validation beyond our assumptions, for e.g. Caplyta in adjunctive MDD, mixed features

## Analyst Certification

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### US - Specialty Pharma & Biotechnology Coverage Cluster

Investment rating	Company	BofA Ticker	Bloomberg symbol	Analyst
<b>BUY</b>				
	Arcellx, Inc.	ACLX	ACLX US	Jason M. Gerberry
	Arrowhead Pharmaceuticals	ARWR	ARWR US	Jason M. Gerberry
	bluebird bio	BLUE	BLUE US	Jason M. Gerberry
	Exelixis	EXEL	EXEL US	Jason M. Gerberry
	Immunovant, Inc.	IMVT	IMVT US	Jason M. Gerberry
	Intra-Cellular Therapies	ITCI	ITCI US	Jason M. Gerberry
	Ionis	IONS	IONS US	Jason M. Gerberry
	Jazz Pharmaceuticals	JAZZ	JAZZ US	Jason M. Gerberry
	Lyra Therapeutics	LYRA	LYRA US	Jason M. Gerberry
	Oculis Holding AG	OCS	OCS US	Jason M. Gerberry
	Relay Therapeutics	RLAY	RLAY US	Jason M. Gerberry
	Tarsus Pharmaceuticals	TARS	TARS US	Jason M. Gerberry
	Teva Pharmaceuticals	TEVA	TEVA US	Jason M. Gerberry
	Vaxcyte Inc	PCVX	PCVX US	Jason M. Gerberry
	Xenon Pharmaceuticals	XENE	XENE US	Jason M. Gerberry
<b>NEUTRAL</b>				
	Alkermes	ALKS	ALKS US	Jason M. Gerberry
	Amphastar Pharmaceuticals	AMPH	AMPH US	Jason M. Gerberry
	Axsome Therapeutics	AXSM	AXSM US	Jason M. Gerberry
	Galapagos	GLPG	GLPG US	Jason M. Gerberry
	ProKidney Corp	PROK	PROK US	Jason M. Gerberry
	Roivant	ROIV	ROIV US	Chi M. Fong
<b>UNDERPERFORM</b>				
	Bausch Health Cos Inc	BHC	BHC US	Jason M. Gerberry
	FibroGen Inc.	FGEN	FGEN US	Jason M. Gerberry
	Harmony Biosciences	HRMY	HRMY US	Jason M. Gerberry
	Organon	OGN	OGN US	Jason M. Gerberry
	Viatris Inc.	VTRS	VTRS US	Jason M. Gerberry

## 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

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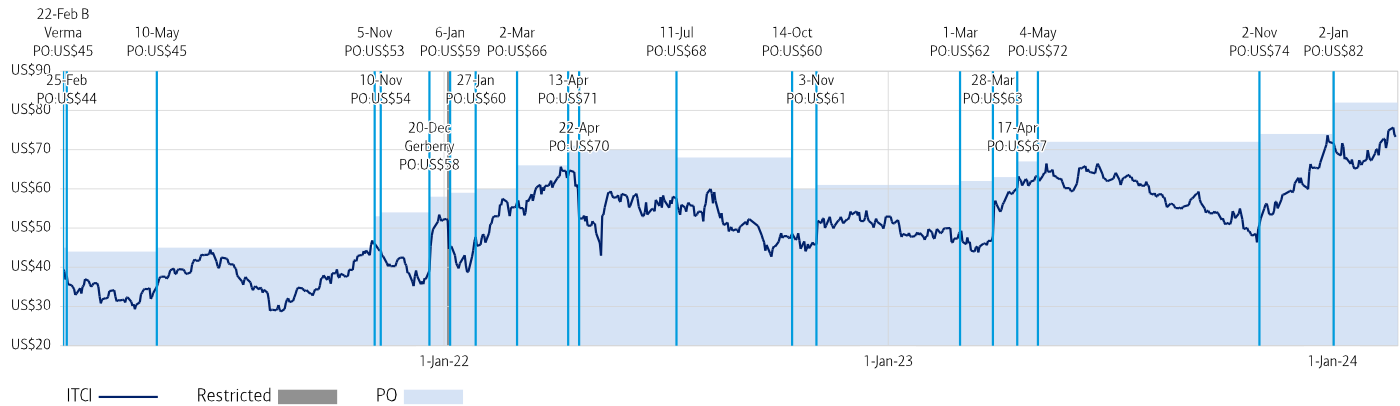
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### Intra-Cellular (ITCI) Price Chart



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.

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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%

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