Portola Pharmaceuticals (PTLA)

SMALL & MID CAP RESEARCH

Q1 Earnings: Two Steps Forward and One Step Back

We remain confident in the multiple clinical programs at PTLA and expect significant clinical news flow in the remainder of 2014. Manufacturing yield at Lonza marked a setback for andexinet alfa supply at launch, but should not impact the longer-term outlook. Our 2014 EPS increases to ($3.29) from ($3.67) on lower R&D and higher revenue from partners. PTLA remains well capitalized with $306M and all retained commercial rights to its three products.

- **Betrixaban on track:** APEX is 40% enrolled, and is on track for a futility analysis in early 2015 and full enrollment by year-end 2015 (consistent with prior guidance).
- **Oral lymphoma drug progressing.** Cerdulatinib data at ASCO will likely only include initial PK (half-life) and PD (inhibition of the target). Clinical data from the ongoing trial should come at ASH in December, and expansion to Phase II is expected prior to ASH.
- **Significant clinical data for Andexanet alfa:** In 2014, we expect Phase II data with edoxaban, Eliquis, and Lovenox. Initial Phase III data is also expected by year-end. The Phase III and Lovenox data are most impactful.
- **Manufacturing issue with Andexanet alfa:** Lower than expected yield at Lonza has PTLA shifting plans to launch with material from its current supplier CMC Biologics. As a result, PTLA projects lower supply during the first year of launch, but believes that the initial BLA may be lower risk because the current supplier is providing the clinical trial material. We believe the manufacturing issue creates an overhang and increases overall risk for its most advanced program.

Rating	**OUTPERFORM* [V]**
Price (12 May 14, US$)	23.95
Target price (US$)	32.00[1]
52-week price range	30.25 - 15.15
Market cap. (US$ m)	984.15
Enterprise value (US$ m)	970.82

**Stock ratings are relative to the coverage universe in each analyst's or each team's respective sector.*
[1]Target price is for 12 months.
[V] = Stock considered volatile (see Disclosure Appendix).

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Financial and valuation metrics

Year	12/13A	12/14E	12/15E	12/16E
EPS (CS adj.) (US$)	-3.65	-3.29	-2.07	-3.32
Prev. EPS (US$)	—	-3.67	-2.23	—
P/E (x)	-6.6	-7.3	-11.6	-7.2
P/E rel. (%)	-38.2	-45.7	-81.2	-56.2
Revenue (US$ m)	10.5	11.4	73.0	58.4
EBITDA (US$ m)	-82.8	-134.9	-97.9	-159.3
OCFPS (US$)	-2.78	-2.17	-1.83	-2.84
P/OCF (x)	-9.2	-11.0	-13.1	-8.4
EV/EBITDA (current)	-10.5	-6.4	-8.9	-5.5
Net debt (US$ m)	-115	-13	-163	-16
ROIC (%)	-46.30	-86.56	-103.02	-173.06

Number of shares (m)	41.09	IC (current, US$ m)	181.82
BV/share (Next Qtr., US$)	—	EV/IC (x)	5.0
Net debt (Next Qtr., US$ m)	-92.4	Dividend (current, US$)	—
Net debt/tot cap (Next Qtr., %)	-34.3	Dividend yield (%)	—

Source: Company data, Credit Suisse estimates

Manufacturing Andexanet alfa

PTLA announced a change to its manufacturing strategy for Andexanet alfa which includes both near-term and long-term supply plans. Overall, the near-term plans have changed, while the long-term plans have not.

The problem: PTLA had hoped to transfer manufacturing from its current clinical supplier (CMC Biologics) to its planned commercial supplier (Lonza) ahead of the projected BLA filing at year-end 2015. This plan has changed because recent technology transfer and scale up was did not result in sufficiently high yields at Lonza.

The solution: PTLA now plans to file the BLA based on material made at CMC Biologic at lower scale and to try to make up some of the difference by increasing the number of manufacturing runs.

The ramifications of this change include:

No change in the timing of the BLA filing (still year-end 2015)

- **Reduced regulatory risk for the initial BLA filing** because the material will be made using the exact same process and scale used for the clinical material.
- **Reduced supply for the first 6-9 months of the launch**. It is unclear how big the impact will be or whether this will be commercially limiting. We have not changed our model, but will monitor this situation closely.
- **Cost of goods may be impacted**, but it is unclear by how much. We assume it will be more expensive at CMC Biologics, though the long-term plan for increased yield and scale at Lonza is unchanged, so any impact to COGS would only be in the first two years of launch.

Long-term plan is not changed: PTLA still expects to file an sBLA by year-end 2017 with an improved process at larger scale at Lonza. This timeline is unchanged by the announcement. However, it is unclear to us whether the risk of achieving this higher yield larger scale process has increased. We assume this will be an overhang on the stock until the company can provide better visibility.

Q1 Results

PTLA reported lower than expected net loss driven by slightly better revenue and lower R&D expenses versus our forecast. We have reduced our outlook for near-term expenses and slightly increased our collaborative revenue. Our new estimate is slightly below guidance for operating expenses, and slightly above year-end cash guidance.

Exhibit 1: 2014 guidance

	CS estimate	Guidance
GAAP operating expenses	$148	$153-$168M
Stock based comp	$8	$8M
Non-GAAP operating expenses	$140	$145-160M
Cash at year-end 2014	$221	$185-200M

Source: Company data, Credit Suisse estimates

Exhibit 2: Q1:14 Variance Table

Income Statement	1Q:14 Act.	CS 1Q:14 Est	Delta
Royalty revenue	0.0	0.0	0.0
Collaboration and license revenue	2.4	2.0	0.4
Total revenue	**2.4**	**2.0**	**0.4**
Cost of goods sold	0.0	0.0	0.0
Milestone expense	0.0	0.0	0.0
R&D	28.2	34.2	-6.0
SG&A	5.2	5.1	0.1
Total operating expenses	33.4	39.3	-5.9
Income (loss) from operations	(31.0)	(37.3)	6.24
Interest and other income, net	0.3	0.2	0.1
Interest expense	0.0	0.0	0.0
Income (loss) before income taxes	(30.7)	(37.0)	6.3
Provision for income taxes	0.0	0.0	0.0
Net income (loss)	**(30.7)**	**(37.0)**	**6.3**
Diluted EPS - (proforma)	**($0.75)**	**($0.91)**	**$0.16**
Basic	41.0	40.9	0.1
Diluted	45.0	45.0	0.0

Source: Company data, Credit Suisse estimates

Exhibit 3: PTLA pipeline

Product	Mechanism of Action	Indication	Stage	Partner
Betrixaban	Oral Factor Xa inhibitor	VTE prophylaxis	Phase III	Proprietary
Andexanet alfa (PRT4445)	Antidote for Factor Xa inhibitors	Reversal of Factor Xa inhibition	Phase II	Proprietary
PRT2070	Oral Dual Syk and Jak inhibitor	B-cell malignancies	Phase I	Aciex (topical only)
PRT2607	Syk inhibitor	Asthma and Inflammation	Pre-clinical	Proprietary

Source: Company data, Credit Suisse estimates

Exhibit 4: PTLA News Flow

Product/Event	Indication	Catalyst	Expected Date
Andexanet alfa (PRT4445)	Factor Xa antidote	Phase II data (enoxaparin reversal) - ISTH meeting	Jun-14
Cerdulatinib (PRT2070)	Hematologic malignancies	Preliminary Phase I data at ASCO	Jun-14
Andexanet alfa (PRT4445)	Factor Xa antidote	Phase II data (edoxaban reversal)	H2:14
Andexanet alfa (PRT4445)	Factor Xa antidote	Phase II data (prolonged Eliquis reversal) - ESC	Aug. 2014
Andexanet alfa (PRT4445)	Factor Xa antidote	Data from first part of Phase III	Q4:14
Cerdulatinib (PRT2070)	Hematologic malignancies	Updated Phase I data at ASH	Dec-14
Betrixaban	Factor Xa inhibitor	Futility analysis	Early 2015
Andexanet alfa (PRT4445)	Factor Xa antidote	Phase 3b/4 initiation	YE:14/ Q1:15
Andexanet alfa (PRT4445)	Factor Xa antidote	Phase III full data	H1:15
Andexanet alfa (PRT4445)	Factor Xa antidote	BLA filing	YE:15
Betrixaban	Factor Xa inhibitor	Complete enrollment of APEX Phase III study	YE:15
Betrixaban	Factor Xa inhibitor	Phase III Data	H1:16

Source: Company data, Credit Suisse estimates

Exhibit 3: PTLA Model

	2011A	2012A	2013A	Q1:14A	Q2:14E	Q3:14E	Q4:14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
US sales (prob. adjusted)														
Betrixaban										29.1	151.2	212.3	271.6	336.2
Andexanet alfa (PRT4445)										25.0	67.3	91.3	123.3	160.0
Total US sales										54.1	218.5	303.6	394.9	496.2
Royalty revenue										4.3	22.3	39.5	56.6	79.3
Collaboration and license revenue	78.0	72.0	10.5	2.4	3.0	3.0	3.0	11.4	73.0					
Total revenue	**78.0**	**72.0**	**10.5**	**2.4**	**3.0**	**3.0**	**3.0**	**11.4**	**73.0**	**58.4**	**240.8**	**343.2**	**451.5**	**575.5**
Cost of goods sold										29.1	54.6	62.0	72.7	81.9
Milestone expense									(2.0)	(13.0)				
R&D	46.1	49.7	79.3	28.2	30.2	32.2	34.2	124.6	145.7	112.8	78.5	74.2	74.8	75.5
SG&A	12.1	11.5	15.4	5.2	5.6	6.0	6.5	23.2	28.7	90.4	83.3	86.9	92.2	97.8
Total operating expenses	**58.2**	**61.2**	**94.7**	**33.4**	**35.7**	**38.2**	**40.7**	**147.8**	**172.5**	**190.3**	**161.8**	**161.1**	**167.0**	**173.3**
Income (loss) from operations	19.9	10.9	(84.2)	(31.0)	(32.7)	(35.2)	(37.7)	(136.5)	(99.5)	(160.9)	24.4	120.1	211.9	320.3
Interest and other income, net	0.1	0.5	0.8	0.3	0.2	0.2	0.1	0.8	0.3	0.3	0.2	0.3	0.5	1.0
Interest expense	(0.0)													
Income (loss) before income taxes	20.0	11.4	(83.4)	(30.7)	(32.5)	(35.0)	(37.5)	(135.7)	(99.1)	(160.7)	24.5	120.4	212.4	321.3
Provision for income taxes											0.5	2.4	4.2	8.4
Net income (loss)	**20.0**	**11.4**	**(83.4)**	**(30.7)**	**(32.5)**	**(35.0)**	**(37.5)**	**(135.7)**	**(99.1)**	**(160.7)**	**24.0**	**118.0**	**208.1**	**312.9**
Diluted EPS - (proforma)		**$0.44**	**($3.65)**	**($0.75)**	**($0.79)**	**($0.85)**	**($0.90)**	**($3.29)**	**($2.07)**	**($3.32)**	**$0.45**	**$2.19**	**$3.83**	**$5.69**
Basic		25.4	22.8	41.0	41.1	41.3	41.5	41.2	47.9	48.4	48.9	49.4	49.9	50.4
Diluted		26.1	22.8	45.0	45.2	45.5	45.8	45.4	52.3	52.8	53.3	53.9	54.4	54.9

Source: Company data, Credit Suisse estimates

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Companies Mentioned *(Price as of 12-May-2014)*

Portola Pharmaceuticals (PTLA.OQ, $23.95, OUTPERFORM[V], TP $32.0)

Disclosure Appendix

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3-Year Price and Rating History for Portola Pharmaceuticals (PTLA.OQ)

PTLA.OQ	Closing Price	Target Price	
Date	(US$)	(US$)	Rating
17-Jun-13	19.68	30.00	O *
15-Aug-13	21.86	32.00	
07-Oct-13	26.74		R
17-Oct-13	25.68	29.74	O
06-Nov-13	22.09	32.00	

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Price Target: (12 months) for Portola Pharmaceuticals (PTLA.OQ)

Method: Our $32 target for PTLA is derived using a probability-adjusted DCF, assigning a 65% probability of success to betrixaban and a 55% probability to PRT4445. We us a 12% discount rate and model through the entire lifecycle. We expect the company to be cash flow positive in 2017.

Risk: Risks to our $32 target price for PTL are (1) betrixaban Phase III APEX study fails to demonstrate clinical significance, (2) one or more factor Xa products enter the Clinically Ill market before betrixaban can capture a meaningful market share, (3) unexpected regulatory hurdles for PTLA's antidote program, (4) potential competition from other factor Xa antidote products, and (5) financing risk with a future capital raise.

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