

Portola Pharmaceuticals, Inc.

(PTLA)

SMALL & MID CAP RESEARCH



Rating **OUTPERFORM* [V]**
Price (22 Nov 13, US\$) 23.89
Target price (US\$) 32.00¹
52-week price range 29.01 - 15.15
Market cap. (US\$ m) 948.66
Enterprise value (US\$ m) 658.54

*Stock ratings are relative to the coverage universe in each analyst's or each team's respective sector.
¹Target price is for 12 months.

[V] = Stock considered volatile (see Disclosure Appendix).

Research Analysts

Jason Kantor, PhD

415 249 7942

jason.kantor@credit-suisse.com

Jeremiah Shepard, PhD

415 249 7933

jeremiah.shepard@credit-suisse.com

Ravi Mehrotra PhD

212 325 3487

ravi.mehrotra@credit-suisse.com

Lee Kalowski

212 325 9683

lee.kalowski@credit-suisse.com

Koon Ching PhD

212 325 6286

koon.ching@credit-suisse.com

Anuj Shah

212 325 6931

anuj.shah@credit-suisse.com

Breakthrough Therapy Designation, An Unexpected Upside Surprise

- **Breakthrough therapy:** FDA granted PTLA's andexanet alfa (PRT4445) breakthrough therapy designation as an antidote for Factor Xa inhibitors. We believe its very well described mechanism of action, the unmet need, and its clear efficacy all contributed to FDA's designation.
- **Accelerated clinical path affirmed.** The designation reaffirms PTLA's previous statements regarding FDA's advice for an accelerated approval path not requiring a formal outcomes study prior to approval.
- **Faster regulatory timeline.** FDA typically reviews drugs with breakthrough designation faster than other drugs. While there is no formal guidance for an earlier approval, FDA has a track record of approving drugs with this designation within 3-4 months of filing.
- **Unexpected upside.** We did not expect FDA to grant breakthrough designation, nor do we believe that this was a focus for investors. According to FDA, breakthrough therapy designation is intended for drugs that treat serious or life-threatening conditions where the drug has demonstrated a clear benefit over existing therapies. Andexanet alfa clearly meets these criteria.
- **Reiterate Outperform rating and a \$32 price target:** Our positive view is based on the large market opportunity for factor Xa inhibitors for clot prevention in acute medically ill patients and for its factor Xa inhibitor antidote for bleeding or surgery.

Financial and valuation metrics

| Year | 12/12A | 12/13E | 12/14E | 12/15E |
|---------------------------------|--------|--------------------------|--------|--------|
| EPS (CS adj.) (US\$) | 0.44 | -3.20 | -3.01 | -0.98 |
| Prev. EPS (US\$) | — | — | — | — |
| P/E (x) | 54.8 | -7.5 | -7.9 | -24.3 |
| P/E rel. (%) | 316.7 | -45.6 | -53.6 | -181.6 |
| Revenue (US\$ m) | 72.0 | 8.5 | — | 65.0 |
| EBITDA (US\$ m) | 12.2 | -88.8 | -120.3 | -43.9 |
| OCFPS (US\$) | -1.89 | -0.14 | -2.66 | -0.87 |
| P/OCF (x) | — | -169.6 | -9.0 | -27.5 |
| EV/EBITDA (current) | 59.9 | -8.3 | -6.1 | -16.7 |
| Net debt (US\$ m) | -54 | -290 | -172 | -276 |
| ROIC (%) | 14.92 | 382.33 | 549.25 | 239.57 |
| Number of shares (m) | 39.71 | IC (current, US\$ m) | | 72.78 |
| BV/share (Next Qtr., US\$) | — | EV/IC (x) | | -27.9 |
| Net debt (Next Qtr., US\$ m) | -290.1 | Dividend (current, US\$) | | — |
| Net debt/tot cap (Next Qtr., %) | -108.9 | Dividend yield (%) | | — |

Source: Company data, Credit Suisse estimates

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From FDA's Website

What is breakthrough therapy designation?

Breakthrough therapy designation is intended to expedite the development and review of drugs for serious or life-threatening conditions. The criteria for breakthrough therapy designation require preliminary clinical evidence that demonstrates the drug may have substantial improvement on at least one clinically significant endpoint over available therapy. A breakthrough therapy designation conveys all of the fast track program features, as well as more intensive FDA guidance on an efficient drug development program. The FDA also has an organizational commitment to involve senior management in such guidance. Section 902 of FDASIA requires the following actions, as appropriate:

- holding meetings with the sponsor and the review team throughout the development of the drug
- providing timely advice to, and interactive communication with, the sponsor regarding the development of the drug to ensure that the development program to gather the nonclinical and clinical data necessary for approval is as efficient as practicable
- taking steps to ensure that the design of the clinical trials is as efficient as practicable, when scientifically appropriate, such as by minimizing the number of patients exposed to a potentially less efficacious treatment
- assigning a cross-disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the cross-discipline members of the review team (i.e., clinical, pharmacology-toxicology, chemistry, manufacturing and control (CMC), compliance) for coordinated internal interactions and communications with the sponsor through the review division's Regulatory Health Project Manager
- involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review

Exhibit 1: PTLA News Flow

| Timing | Expected News Flow | Program |
|--|--|------------|
| Andexanet alfa (PRT4445) - Factor Xa antidote | | |
| Q4:13 | Additional Phase II data (Xarelto reversal) | PRT4445 |
| Q4:13/Q1:14 | Additional Phase II data (enoxaparin reversal) | PRT4445 |
| H1:14 | Phase III First-Patient-In | PRT4445 |
| Late 2015/2016 | BLA filing | PRT4445 |
| Betrixaban - Factor Xa inhibitor | | |
| 2014 | Futility analysis | Betrixaban |
| Mid:15 | Complete enrollment | Betrixaban |
| Q3:15 | Phase III Data | Betrixaban |
| PRT2070 - SYK/JAK inhibitor | | |
| 2014 | Phase I Proof-of-Concept Data | PRT2070 |
| Mid:15 | Phase II Proof-of-Concept Data | PRT2070 |

Source: Company data, Credit Suisse estimates

Exhibit 2: PTLA Earnings Model

| | 2011A | 2012A | Q1:13A | Q2:13A | Q3:13A | Q4:13E | 2013E | 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 | 3.1 | 2.6 | 2.8 | | 8.5 | | 65.0 | | | | | |
| Total revenue | 78.0 | 72.0 | 3.1 | 2.6 | 2.8 | | 8.5 | | 65.0 | 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 | 17.7 | 20.8 | 18.1 | 27.5 | 84.1 | 105.6 | 93.7 | 70.1 | 65.3 | 65.5 | 70.7 | 75.8 |
| SG&A | 12.1 | 11.5 | 3.0 | 3.7 | 3.9 | 3.9 | 14.6 | 16.2 | 18.7 | 87.2 | 80.0 | 83.6 | 88.7 | 94.3 |
| Total operating expenses | 58.2 | 61.2 | 20.8 | 24.5 | 22.0 | 31.4 | 98.7 | 121.8 | 110.5 | 144.3 | 145.3 | 149.1 | 159.4 | 170.1 |
| Income (loss) from operations | 19.9 | 10.9 | (17.7) | (21.9) | (19.2) | (31.4) | (90.2) | (121.8) | (45.5) | (114.9) | 40.9 | 132.1 | 219.5 | 323.5 |
| Interest and other income, net | 0.1 | 0.5 | (0.5) | 0.3 | 0.7 | 0.3 | 0.8 | 0.7 | 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 | (18.1) | (21.6) | (18.6) | (31.1) | (89.4) | (121.1) | (45.1) | (114.7) | 41.0 | 132.4 | 220.0 | 324.5 |
| Provision for income taxes | | | | | | | | | | 0.8 | 2.6 | 4.4 | 64.7 | |
| Net income (loss) | 20.0 | 11.4 | (18.1) | (21.6) | (18.6) | (31.1) | (89.4) | (121.1) | (45.1) | (114.7) | 40.2 | 129.8 | 215.6 | 259.8 |
| Diluted EPS - (proforma) | | \$0.44 | (\$0.71) | (\$1.47) | (\$0.53) | (\$0.86) | (\$3.20) | (\$3.01) | (\$0.98) | (\$2.47) | \$0.78 | \$2.50 | \$4.12 | \$4.91 |
| Basic | | 25.4 | 25.4 | 14.7 | 35.2 | 36.4 | 27.9 | 40.3 | 46.0 | 46.4 | 46.9 | 47.4 | 47.8 | 48.3 |
| Diluted | | 26.1 | 25.4 | 14.7 | 2,018.0 | 40.3 | 524.6 | 44.4 | 50.3 | 50.8 | 51.3 | 51.8 | 52.3 | 52.9 |

Source: Company data, Credit Suisse estimates

Companies Mentioned (Price as of 25-Nov-2013)**Portola Pharmaceuticals** (PTLA.OQ, \$23.89, OUTPERFORM[V], TP \$32.0)**Disclosure Appendix****Important Global Disclosures**

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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 | |

* Asterisk signifies initiation or assumption of coverage.



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|--------------------|---------------------|------------------------------|
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| Underperform/Sell* | 15% | (40% banking clients) |
| Restricted | 3% | |

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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 use 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 PTLA are (1) betrixaban Phase III APEX study fails to demonstrate clinical significance, (2) one or more factor Xa products enter the Clinically III 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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