

PTC Therapeutics (PTCT)

Q4:13 Update: Buyers on Weakness PTCT Remains Undervalued 2014 Catalysts Ahead - New Indications for Ataluren Underappreciated - Reiterate OUTPERFORM

- PTCT reported full year EPS of (\$5.18) and revenues of \$35M. The company ended 2013 with \$260M in cash and equivalents. Current cash is est. to fund operations through 2016, we estimate a 2014 net cash burn of \$76M. We our estimates to come inline with guidance.
- The next event for PTCT is an update on conditional approval for ataluren in DMD in the EU potentially in Q2:14. PTCT is appealing the negative opinion issued by the CHMP in Jan. We see a positive opinion as unlikely and not priced in to the stock at current levels; it also represents upside to our current valuation.
- We estimate that the two primary value drivers coming out of a potentially positive opinion EMA include: 1) earlier than expected sales and 2) validation of ataluren's clinical benefit. However, we note that both early sales and validation are likely regardless of a conditional approval.
- We note that, regardless of a conditional approval decision by the EMA, it is possible that PTCT markets ataluren on a named patient/compassionate use in the EU and other territories in 2015. Recall, that the company had recently [announced](#) the expansion of their international commercial team with Dr. Schopen, General Manager and Head of Medical Affairs in the EU.
- PTCT intends to initiate trials for ataluren in new indications in 2014 with readouts ahead of the trial in DMD in 2015. We believe with a significant safety database and strong pre-clinical evidence of efficacy these are derisked opportunities that will warrant additional valuation. (page 3-6). Based upon comps with molecularly targeted therapies such as EPZM (OUTPERFORM) we believe that two new indications (Aniridia and Hurler's (MPS I)) for ataluren could represent as much as \$600M in MC in upside to PTCT. Published research provides promising evidence for ataluren's efficacy in Aniridia, a rare condition that severely limits the vision of ~5,000 pts the U.S (page 5).
- Data from a Phase I trial of RG7800 in SMA by YE:14 may, in addition to safety and PK data, confirm mechanistic action through the measurement of SMN transcript levels in the blood plasma of healthy patients.
- Upcoming catalysts for the stock include an update on conditional approval from the EMA Q2:14, complete enrollment in the nmDMD trial, and start of enrollment in a Phase III trial for ataluren in cystic fibrosis (nmCF) in H1:14.
- We reiterate OUTPERFORM rating and 12-month price target of \$55/share. Our \$55 price target is derived by applying an 8X multiple to estimated 2017 revenues for ataluren in nmDMD and nmCF, discounted 25% and 35% annually, respectively. New indications for ataluren and the SMA candidate remain upside.

| FYE Dec | 2013E | 2014E | | | 2015E | | |
|---------|----------------|-----------|-----------|-----------|-----------|-------|-----------|
| REV | ACTUAL | CURR. | PREV. | CONS. | CURR. | PREV. | CONS. |
| Q1 Mar | \$7.1A | \$8.5E | \$3.6E | \$9.4E | \$1.0E | -- | -- |
| Q2 Jun | 6.9A | 1.0E | 7.5E | \$9.4E | 1.0E | -- | -- |
| Q3 Sep | 16.3A | 1.0E | 7.5E | \$9.4E | 1.0E | -- | -- |
| Q4 Dec | 4.4E | \$1.0E | \$7.5E | \$9.4E | \$1.0E | -- | -- |
| Year* | \$34.7E | \$11.5E | \$26.1E | \$9.4E | \$4.0E | -- | -- |
| Change | -- | -- | -- | -- | -- | -- | -- |
| EPS | 2013E | 2014E | | | 2015E | | |
| | ACTUAL | CURR. | PREV. | CONS. | CURR. | PREV. | CONS. |
| Q1 Mar | (\$3,244.59) A | (\$0.49)E | (\$0.65)E | (\$0.46)E | (\$0.73)E | -- | (\$0.24)E |
| Q2 Jun | (5.51)A | (\$0.70)E | (\$0.51)E | (\$0.46)E | (\$0.66)E | -- | (\$0.24)E |
| Q3 Sep | (0.19)A | (\$0.71)E | (\$0.53)E | (\$0.46)E | (\$0.65)E | -- | (\$0.24)E |
| Q4 Dec | (0.75)E | (\$0.73)E | (\$0.55)E | (\$0.46)E | (\$0.68)E | -- | (\$0.24)E |
| Year* | (\$5.18)E | (\$2.64)E | (\$0.55)E | (\$0.46)E | (\$2.72)E | -- | (\$0.24)E |
| P/E | -- | -- | -- | -- | -- | -- | -- |
| Change | -- | -- | -- | -- | -- | -- | -- |

Consensus estimates are from Thomson First Call.

* Numbers may not add up due to rounding.

March 7, 2014

Price
\$30.42

Rating
OUTPERFORM

12-Month Price Target
\$55

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Company Information

| | |
|----------------------|-------------------|
| Shares Outst (M) | 30.1 |
| Market Cap (M) | \$914.9 |
| 52-Wk Range | \$13.04 - \$34.65 |
| Book Value/sh | \$29.59 |
| Cash/sh | \$8.31 |
| Enterprise Value (M) | \$664.9 |
| LT Debt/Cap % | 0.0 |
| Cash Burn (M) | \$77.8 |
| Current Cash (M) | \$250.0 |

Company Description

PTC Therapeutics is a biopharmaceutical company focused on the development of orally administered, proprietary, small molecule drugs that target post-transcriptional control processes for orphan and orphan disorders including DMD and CF.



Source: Thomson Reuters

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Risks to the attainment of our price target include 1) failure of ataluren in the clinic in DMD or CF; 2) regulatory failure of ataluren; and 3) inability to fund the development or execute on the commercializing of ataluren globally

Investment Thesis

PTC is a biotechnology company focused on the development of ataluren, a molecularly targeted, orally delivered treatment for rare and ultra-rare diseases including Duchenne muscular dystrophy and cystic fibrosis caused by nonsense mutations. Ataluren may also be effective in treating 2500 other rare diseases and certain cancers caused by nonsense mutations since its mechanism of action is broadly applicable to these molecular lesions. PTC is also developing a candidate for spinal muscle atrophy a fatal and rare disease that most severely impacts infants. We believe that ataluren will be shown to be safe and efficacious in ongoing Phase III trials in nmDMD as well as those set to begin (H1:14) in nmCF. In our opinion, the Street is overly discounting their lead Phase III program for ataluren in nmDMD, which showed mixed results overall in a Phase II trial, but positive trends and nominal statistically significant benefit in the current subgroups being evaluated in the Phase III trial. We believe that, given lessons learned from prior pioneering trials of ataluren in DMD, PTC has enriched their Phase III trial for success and that it is highly likely to show positive results in mid:2015. Final read-outs from a soon to be initiated (H1:14) trial for ataluren CF are anticipated by mid:16. PTC's SMA program, partnered with Roche, remains additional upside to our estimates. We believe that this program likely be accelerated through the clinic due to significant unmet medical need in this devastating disease and that breakthrough results in Phase I/II trials could form the basis for a registration filing as early as 2015.

Valuation Methodology

Our \$55 price target is derived by applying an 8X multiple to estimated 2017 revenues for ataluren in nmDMD and nmCF, discounted 25% and 35% annually, respectively. Conditional approval of ataluren in the EU by Q1:14 remains upside to our price target and would yield a 12-month price target of \$75/share. We project that approval and commercialization of ataluren could generate ~\$550 million in annual worldwide revenues in 2017 (our valuation year) in nmDMD and nmCF and potential peak global sales of >\$1.5 billion. Success of PTC/Roche's SMA candidate RG7800 remains upside to our estimates. Similarly we arrive at our \$55 price target by applying a 15x multiple to PTC's fully taxed EPS in 2017 discounted back 20% annually.

Upcoming Milestones

| | |
|--------------|---|
| March 16-19 | Poster presentation at the Muscular Dystrophy Association conference, Chicago, IL |
| Apr 26-May 3 | AAN Meeting (Philadelphia, PA), potential ataluren updates. |
| Apr 26-May 3 | AAN Meeting (Philadelphia, PA) ISIS/BIB updates on SMNrx Phase I results |
| Q2:14 | Feedback from CHMP SAG meeting regarding request for reconsideration of conditional approval for ataluren for nmDMD in the EU |
| Q2:14 | Potential MAA filing for conditional approval of ataluren for nmCF in the EU |
| Q2:14 | Potential new opinion following a re-examination of the negative opinion regarding conditional approval of ataluren for nmDMD in the EU |
| Q2:14 | Full enrollment in the confirmatory Phase III trial of ataluren in nmDMD |
| H1:14 | Initiation of a Phase III trial of ataluren in nmCF |
| 2014 | Nomination of one or two new indications for ataluren (likely Aniridia and/or MPS I) |
| 2014 | Open label trial updates for ataluren as nmDMD at a scientific conference (US study safety only, EU efficacy at 0, 6,12,18 months) |
| H2:14 | Potential data from the Phase IIb open-label extension study of ataluren in the EU |
| YE:14/Q1:15 | Potential start of proof-of-concept Phase II trials (potentially pivotal) for ataluren in one or two indications (ahead of ataluren in nmDMD) |
| YE:14 | Potential conditional approval of ataluren for nmCF in the EU |
| YE:14/Q1:15 | Potential top-line data and biomarker data from Roche/PTCT's Phase I healthy volunteers study of SMA candidate RG7800 |
| H1:15 | Top-line data from the confirmatory Phase III trial of ataluren in nmDMD |
| 2015 | Potential first commercial (named patient/compassionate use) sales of ataluren nmDMD in EU (or ROW) markets |
| H2:15 | FDA and MAA filing for full approval of ataluren for nmDMD |
| H2:15 | Top-line data from the confirmatory Phase III trial of ataluren in nmCF |
| 2015 | Potential initiation of pivotal Phase II/III trials RG7800 in patients with SMA |
| H1:16 | FDA and MAA filing for full approval of ataluren for nmCF |
| 2016 | First commercial sales of ataluren following potential approval on Phase III data |

Additional Indications Could Expand the Market for Ataluren

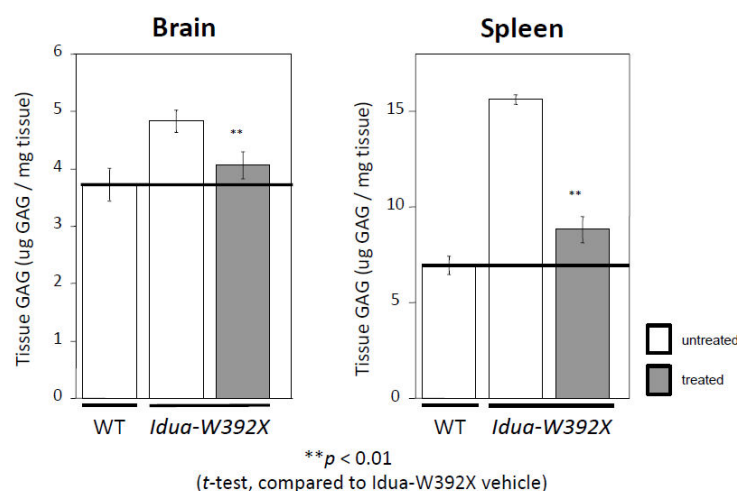
Figure 1: Additional Indications Under Study

| Author | Indication |
|---|--|
| Wang (2010) | Miyoshi myopathy |
| Yu (2014) | Long QT syndrome |
| Sarker (2011) | Infantile neuronal ceroid lipofuscinosis (INCL) |
| Miller (2013) | (Late) infantile neuronal ceroid lipofuscinosis (INCL) |
| Du (2013) | Ataxia telangiectasia |
| Goldman (2011 , 2012) | Usher syndrome (USCH1C) |
| Zhou (2013) | Pseudoxanthoma elasticum |
| Kuschal (2013) | Xeroderma pigmentosum |
| Moosajee (unpublished) | Choroideremia |
| Gregory-Evans (2014) | Aniridia |
| Drake (2013) | Heritable pulmonary arterial hypertension |
| Tan (2011) | Carnitine palmitoyltransferase 1A deficiency |
| Buck (2012) | Methylmalonic aciduria (MMA) |
| Sanchez-Alcudia (2012) | Propionic acidemia (PA) |
| Bartolomeo (2013) | Maroteaux-Lamy syndrome (MPS VI) |
| Keeling (unpublished) | Hurler's syndrome (MPS I) |

Source: Company data, Wedbush Securities, Inc.

Hurler's syndrome (MPS I) is a severe disease caused by a lack of lysosomal α -L-iduronidase which helps break down glycosaminoglycans (GAG's). GAG's accumulate and cause organ damage, particularly in the heart and brain. In mouse models, ataluren inhibits the accumulation of GAG's in both the brain and the spleen.

Figure 2: Ataluren has a Promising Effect in Mouse Models of Hurler's Syndrome



Source: Company data, Wedbush Securities, Inc.

Hurler's syndrome is treated with Bone Marrow Transplants (BMT) and Aldurazyme (Genzyme/BioMarin), an IV delivered enzyme replacement therapy approved on a single 26-week pivotal trial enrolling 45 patients with endpoints of FVC and 6MWT. Naglazyme (BioMarin) is a similar IV delivered enzyme replacement therapy also approved on a small pivotal trial in MPS VI.

Figure 3: Clinical Trial's Submitted with BLA Applications for Aldurazyme (MPS I) and Naglazyme (MPS VI)

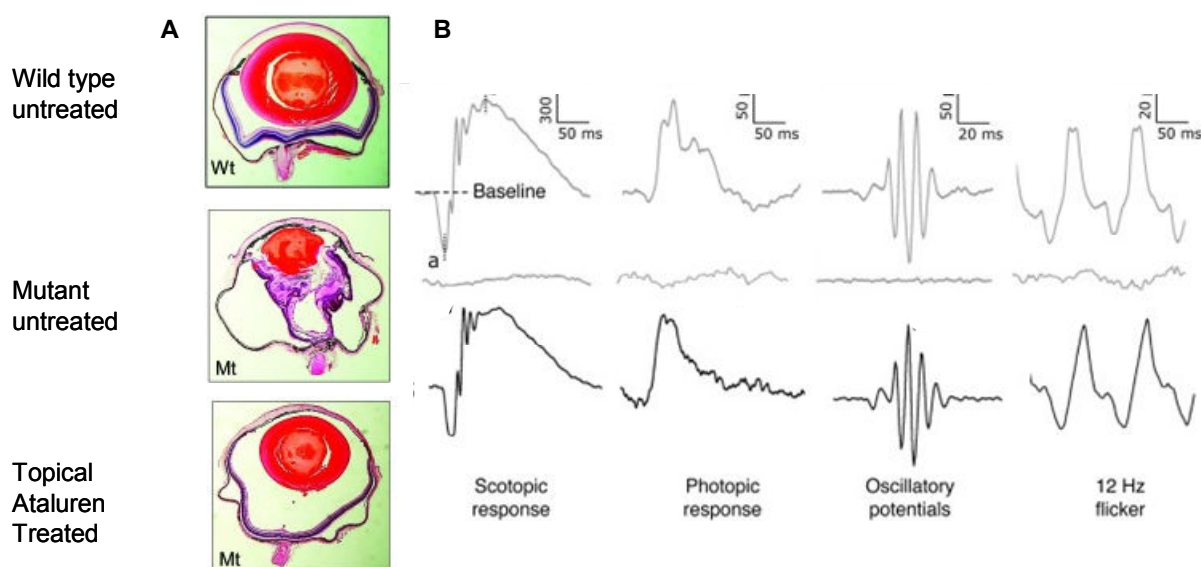
| | N | Length | Primary Endpoints | Design | NCT |
|--------------------------------|----------|--------------------|--|------------|-------------|
| Aldurazyme Phase I/II | 10 | 2 years (extended) | Urinary GAG excretion, liver and spleen size | Open-label | NCT01173016 |
| Aldurazyme pivotal | 45 (1:1) | 26 weeks | FVC and 6MWT | RCT | NCT00912925 |
| Aldurazyme long-term extension | 45 | 24 weeks | FVC and 6MWT | Open-label | NCT00146770 |
| Naglazyme Phase I/II | 7 | 24 weeks | Urinary GAG secretion, 6MWT | Open-label | NCT00048620 |
| Naglazyme Phase II | 10 | 48 weeks | Urinary GAG secretion, 12MWT | open-label | NCT00048711 |
| Naglazyme pivotal | 39 (1:1) | 24 weeks | 12MWT | RCT | NCT00067470 |

Source: Company data, Wedbush Securities, Inc.

Aniridia is an eye disorder characterized by complete or partial absence of the iris caused by mutations in the *PAX6* gene. *PAX6* protein is involved in the early development of the eyes, brain, spinal cord and pancreas. Without *PAX6*, patients develop involuntary eye movements and underdevelopment of the fovea, responsible for sharp central vision.

Gregory-Evans et al. (2014) investigated the use of ataluren in a mouse model with a nonsense mutation in the *PAX6* gene. Mutant mouse eyes demonstrated significant deformation and ERG abnormalities. A topical formulation of ataluren dubbed, START, was developed to increase viscosity and thus surface contact time and reduce the irritation associated with water based eye drops. START application was initiated 14 days after birth (when the eyes open), and continued until sacrifice and analysis at day 60. Ataluren treatment normalizes eye histology (Figure 4A) and nerve response as assessed by ERG after light pulse (Figure 4B) and brings the amplitude of the low-light (scotopic) and high light (photopic) responses up to levels not significantly different from wild type mice.

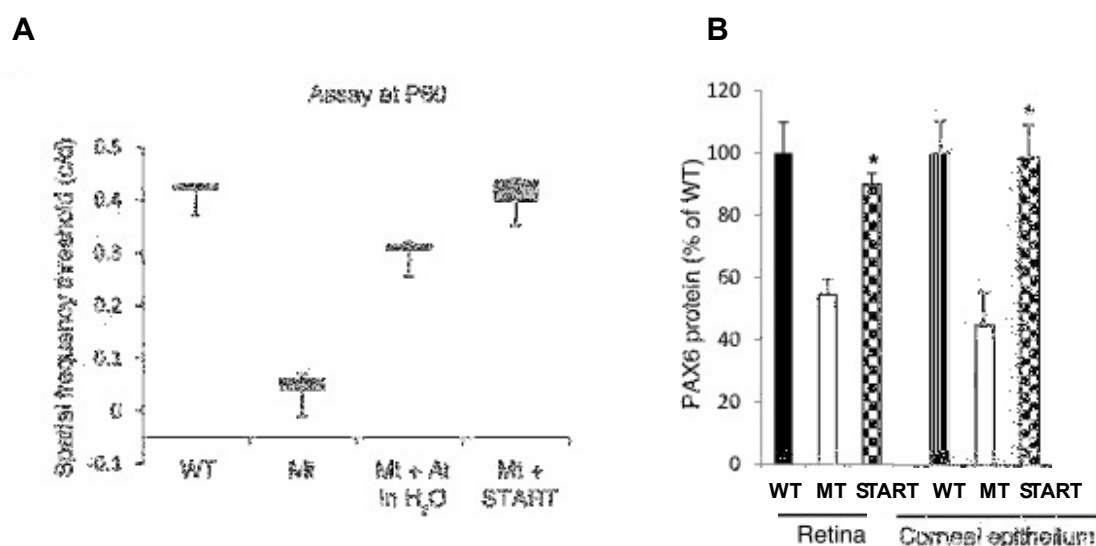
Figure 4: Ataluren Normalizes Nerve Firing in a Mouse Model of Nonsense Mutation Aniridia



Source: Gregory-Evans et al. *J Clin Invest.* Jan 2, 2014; 124(1): 111–116.

The researchers measured optokinetic tracking response in a virtual reality system to approximate visual acuity. Ataluren treated mice had much better tracking response than mutant (Mt) or ataluren in water treated mice (Figure 5A) and were not significantly different from responses seen in wild type animals ($p = 0.42$). Mice treated with Ataluren had increased levels of PAX6 protein in the retina and corneal epithelium (Figure 5B).

Figure 5: Ataluren Increased Nerve Amplitude and PAX6 Protein Expression



Source: Gregory-Evans et al. *J Clin Invest.* Jan 2, 2014; 124(1): 111–116.

Aniridia is a rare disease with no current treatment options. It could potentially be approved on a single pivotal trial, supported by PTC's large safety database. Although an optical formulation is technically not comparable to systemic formulation, it is reasonable to propose that an optical formulation with low systemic exposure would have a lower safety risk than a systemic administration. We highlight previous trials in rare eye disorders, though we note that Ligneous Conjunctivitis is an extremely rare disease with roughly 200 cases ever reported.

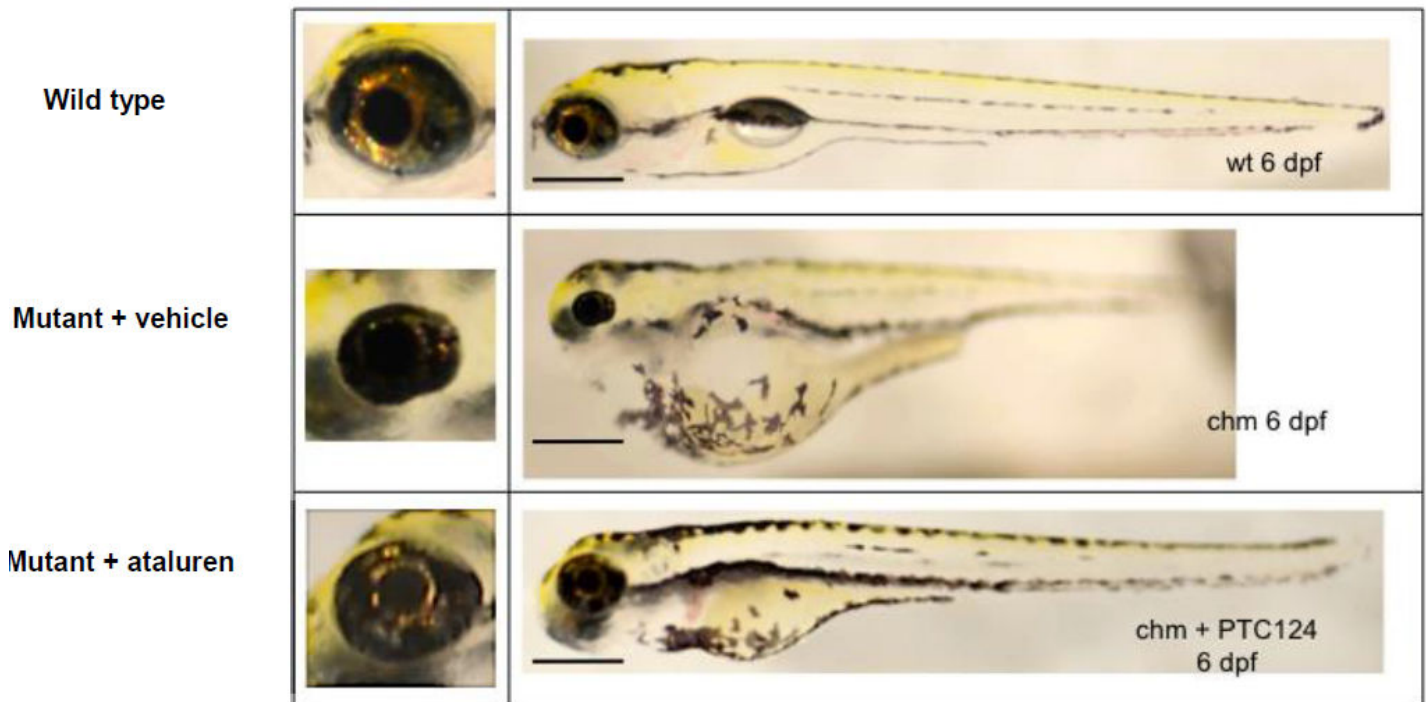
Figure 6: Current Trials in Rare Eye Disorders Highlight a Path Forward for Ataluren in Aniridia or Choroideremia

| Gene Therapy Trial in Choroideremia | | Human Plasminogen in Ligneous Conjunctivitis | |
|-------------------------------------|--|--|--|
| Phase | Phase I | Phase III | |
| N | 12 | 10 | |
| Efficacy Length | 6 months | 12 weeks | |
| Safety Length | 24 months | 26 weeks | |
| Primary Endpoint | Visual acuity | # of eyes with recurrent ligneous membranes, # of eyes with reduction of overall membrane surface area | |
| Secondary endpoints | Microperimetry, OCT and fundus autofluorescence | Safety | |
| Inclusion criteria | Vision 6/60 or better in the study eye, male aged ≥18 years, diagnosed with choroideraemia | Diagnosed with ligneous conjunctivitis associated with Type I plasminogen deficiency | |
| Status | Ongoing | Ongoing | |
| NCT | NCT02077361 | NCT01554956 | |

Source: Company data, Wedbush Securities, Inc.

Choroideremia is an X-linked disease caused by mutations in the *CHM* gene leading to progressive vision loss. Vision problems are due to an ongoing loss of cells in the retina and nearby network of blood vessels leading to complete blindness in late adulthood. Ataluren normalized eye morphology in a zebrafish model.

Figure 7: Ataluren Normalized Eye Morphology in Nonsense Mutation Choroideremia



Source: Company data, Wedbush Securities, Inc.

Financial Model



Christopher N. Marai Ph.D.

3/7/2014

PTC Therapeutics, Inc.

Annual Financial Results & Projections

(\$ in thousands except per share data)

Ticker: PTCT (Nasdaq)

| | FY:13A | Q1:14E | Q2:14E | Q3:14E | Q4:14E | FY:14E | FY:15E | FY:16E | FY:17E | FY:18E | FY:19E |
|-----------------------------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|------------------|--------------------|--------------------|
| Revenue: | | | | | | | | | | | |
| Ataluren Sales US - DMD | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 49,618 | 216,553 | 313,599 | 335,577 |
| Ataluren Sales EU - DMD | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 35,543 | 185,637 | 310,494 | 345,451 |
| Ataluren Sales ROW - DMD | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 715 | 10,692 | 47,266 | 93,713 |
| Ataluren Sales US - CF | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 94,984 | 267,911 | 344,683 |
| Ataluren Sales EU - CF | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 37,354 | 185,142 | 367,238 |
| Ataluren Sales ROW - CF | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1,010 | 12,187 |
| Grant and other revenues | 3,370 | 1,000 | 1,000 | 1,000 | 1,000 | 4,000 | 4,000 | 0 | 0 | 0 | 0 |
| Collaboration revenue | 31,326 | 7,500 | 0 | 0 | 0 | 7,500 | 0 | 1,000 | 1,000 | 1,000 | 1,000 |
| Total Revenues | \$34,696 | \$8,500 | \$1,000 | \$1,000 | \$1,000 | \$11,500 | \$4,000 | \$86,876 | \$546,221 | \$1,126,423 | \$1,499,849 |
| Cost and Expenses: | | | | | | | | | | | |
| Costs of goods sold | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 8,588 | 54,522 | 112,542 | 149,885 |
| Research and Development | 54,875 | 15,000 | 15,250 | 15,500 | 16,000 | 61,750 | 59,500 | 62,305 | 66,497 | 67,837 | 69,204 |
| Sales, General and Administrative | 25,219 | 7,500 | 7,500 | 7,500 | 7,500 | 30,000 | 31,500 | 43,000 | 52,000 | 53,313 | 55,478 |
| Other | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Total Costs and Expenses | \$80,094 | \$22,500 | \$22,750 | \$23,000 | \$23,500 | \$91,750 | \$91,000 | \$113,893 | \$173,019 | \$233,692 | \$274,566 |
| Operating Income (loss) | (45,398) | (14,000) | (21,750) | (22,000) | (22,500) | (80,250) | (87,000) | (27,017) | 373,202 | 892,731 | 1,225,283 |
| Net Interest Income (Expense) | (6,083) | 427 | 740 | 677 | 613 | 2,458 | 2,061 | 2,610 | 3,867 | 9,802 | 19,221 |
| Other income / (Expense) | (92) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Income Before Income Taxes | (51,574) | (13,573) | (21,010) | (21,323) | (21,887) | (77,792) | (84,939) | (24,407) | 377,069 | 902,533 | 1,244,504 |
| Net Income | (\$51,574) | (\$13,573) | (\$21,010) | (\$21,323) | (\$21,887) | (\$77,792) | (\$84,939) | (\$24,407) | \$351,408 | \$708,114 | \$933,378 |
| GAAP Net Income | (\$66,432) | (\$13,573) | (\$21,010) | (\$21,323) | (\$21,887) | (\$77,792) | (\$84,939) | (\$24,407) | \$341,408 | \$698,114 | \$923,378 |
| GAAP Basic EPS with sFAS123 | (5.18) | (0.49) | (0.70) | (0.71) | (0.73) | (2.64) | (2.72) | (0.75) | 10.83 | 21.76 | 28.60 |
| GAAP Diluted EPS with sFAS123 | (5.29) | (0.49) | (0.70) | (0.71) | (0.73) | (2.64) | (2.72) | (0.75) | 10.83 | 21.76 | 28.60 |
| Weighted shares outstanding | 12,829 | 27,521 | 30,127 | 30,152 | 30,177 | 27,521 | 31,240 | 32,340 | 32,440 | 32,540 | 32,640 |
| Fully diluted shares outstanding | 12,565 | 27,521 | 30,127 | 30,152 | 30,177 | 29,494 | 31,240 | 32,340 | 32,440 | 32,540 | 32,640 |
| Cash Burn | (51,574) | (13,573) | (21,010) | (21,323) | (21,887) | (77,792) | (84,939) | (24,407) | - | - | - |
| Cash Balance | 142,468 | 246,784 | 225,775 | 204,452 | 182,565 | 182,565 | 181,326 | 241,358 | 576,890 | 1,270,218 | 2,196,308 |

Source: Wedbush Securities and PacGrow Life Sciences

Covered Companies Mentioned

| | | | | |
|---------|------|------------|------|---------|
| Epizyme | EPZM | OUTPERFORM | \$52 | \$26.54 |
|---------|------|------------|------|---------|

Analyst Biography

Chris Marai is an Analyst covering the Biotechnology/Biopharmaceuticals/BioDefense sector. Prior to Wedbush PacGrow Life Sciences, Dr. Marai was at Morgan Stanley where he specialized in quantitative modeling; he has also consulted for structure-based drug design companies and biotechnology startups.

Dr. Marai holds a B.S. in Chemistry from Trinity College, University of Toronto and a Ph.D. in Biochemistry and Structural Biology from Stony Brook University, New York.

Christopher's Edge: Dr. Marai has a strong quantitative background and has covered a wide range of disease areas including gastrointestinal, CNS, oncology and rare diseases. His quantitative background has translated into an exceptional track record predicting binary events and assessing risk as a sell-side analyst.

Analyst Certification

I, Christopher N. Marai, Ph.D., Gregory R. Wade, Ph.D., David M. Nierengarten, Ph.D., certify that the views expressed in this report accurately reflect my personal opinion and that I have not and will not, directly or indirectly, receive compensation or other payments in connection with my specific recommendations or views contained in this report.

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Neutral: Expect the total return of the stock to perform in-line with the median total return of the analyst's (or the analyst's team) coverage universe over the next 6-12 months.

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The Investment Ratings are based on the expected performance of a stock (based on anticipated total return to price target) relative to the other stocks in the analyst's coverage universe (or the analyst's team coverage).*

| Rating Distribution (as of December 31, 2013) | Investment Banking Relationships (as of December 31, 2013) |
|--|---|
| Outperform: 54% | Outperform: 18% |
| Neutral: 43% | Neutral: 2% |
| Underperform: 3% | Underperform: 0% |

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| Company | Disclosure |
|------------------|------------|
| PTC Therapeutics | 1,3,4,5,7 |

Research Disclosure Legend

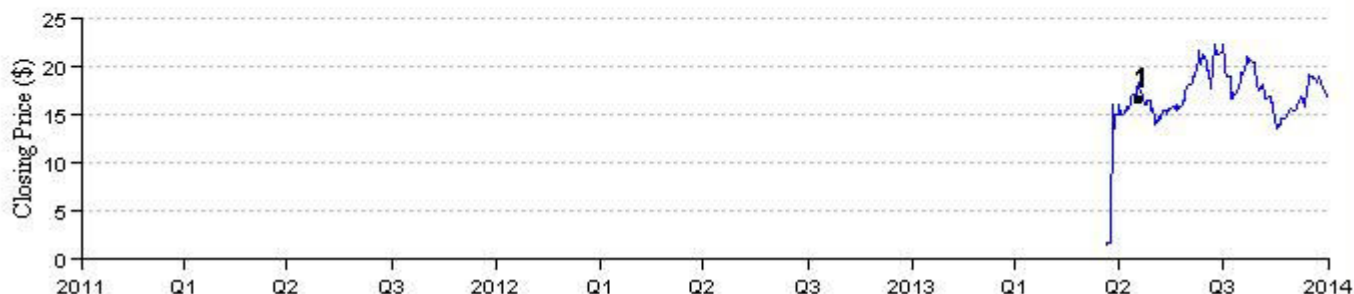
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PTCT

1) 07/16/13
OUTPERFORM \$55



* WS changed its rating system from (Strong Buy/Buy/Hold/Sell) to (Outperform/ Neutral/Underperform) on July 14, 2009.

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