

INTERNAL REPORT

Reata Pharmaceuticals

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(RETA-Nasdaq)
Initial Report

Current Price	\$14-16
52-week High	NM
52-week Low	NM
Price Target	\$50.00

Rating	Buy
Shares Out	20M
Market Cap	300M
Avg. Daily Vol	NM

FY15 EPS	NM
EPS Growth Rate	NM
FY15 PE	NM
FY15 PEG	NM

Book Value/Share	\$5.00
Cash/Share	\$5.00
Insider Ownership	85%
Institution Ownership	15%

Business Description

Update: The IPO priced at \$11/share. It was upside from 4M shares to 5.5M to still raise \$55M gross. Insiders took 40% (\$22M) after indicating they would take up to \$45M.

Reata Pharmaceuticals has two drugs in clinical development. Bardoxolone methyl (BARD) is an oral small molecule that activates NRF2. BARD was initially studied in a 2200 patient chronic kidney disease study that was terminated for safety reasons when 8% of patients on drug had fluid overload vs 5% of patients on placebo. The cause of the fluid overload was unknown at the time so the study was halted. The mechanism has since been elucidated and is unlikely to be problematic going forward. The company noticed similarities in between ERA medications (used to treat pulmonary arterial hypertension) and BARD. Armed with significant preclinical data on the anti-fibrotic properties of BARD, the company pivoted to the pulmonary hypertension therapeutic space.

The company also has Omaveloxolone (Omap) in phase 2 development for Friedrich's Ataxia (FA), mitochondrial myopathies (MM), and metastatic melanoma. Omaveloxolone hits the same target as BARD, but is optimized to cross the blood brain barrier, and for this reason is being tested in neurological conditions.

Reata was founded in 2002 and is headquartered in Irving, TX. They are offering 4M class A shares in an IPO through Citi, Cowen, and Piper. After the deal, there will be 5M A shares and 15M B shares. B shares have 3x the voting rights of A shares. The expected range is \$14-16 and the post money market cap will be \$300M. Insiders have indicated interest in up to \$45M and there are 200k shares set aside for essentially "friends and family". Their last venture round was 2009.

Competitive Advantages

- **BARD phase 3 program in CTD-PAH**—Patients with connective tissue disease (CTD) and PAH are eligible for this study. The market is estimated to be about 6,000 in the United States, or 1/3 of the total PAH market. Most will have had Lupus or Scleroderma which led to the development of PAH. The traditional classes of PAH drugs do not work well in these patients. Enrollment will begin soon at >100 centers internationally, as the company is looking to enroll 120 patients. Based on patient characteristics at entry, the trial is designed to have the option to increase enrollment up to 220 without changing the protocol. The study is 24 weeks in duration and is expected to read out H1-18.
 - The CTD market opportunity is based on a recent meta-analysis conducted by UPenn. The study showed that based on eleven Phase 3 and Phase 4 studies, CTD-PAH patients have poorer responses to the tune of 1/3 the benefit that non-CTD PAH patients receive from approved PAH treatments.
 - FDA has confirmed that 6 minute walk test (6mwt) is an approvable endpoint for CTD-PAH
 - The LARIAT phase 2 had six CTD patients on drug and two on placebo. CTD patients improved 30m on average compared to a 14m decline in CTD patients on placebo.
- **BARD phase 2 for pulmonary hypertension due to interstitial lung disease**—It is estimated that there are 20k patients in the US with PH-ILD and 75k patients worldwide.
- **BARD phase 2 LARIAT study in PH (with ILD) and in PAH**—LARIAT is designed to study BARD in PAH and in Pulmonary Hypertension with Interstitial Lung Disease (PH-ILD). The PH-ILD market is >20k in the US. Cohorts 1-3 deal with various groups of PAH patients, while cohort 4 is four different types of PH-ILD patients.

- Cohort 1 had 38 patients. It enrolled PAH patients who could walk >150m but <450m in six minutes. It was randomized 3:1. It started enrolling May 2014. All patients have left the study or are still on drug. Patients were dosed at 2.5mg, 5mg, 10mg, or 20mg.
- Cohort 2 began enrolling January 2015 and was PAH patients who can walk >450m. There were 16 patients in this cohort. Patients were dosed at 5mg or 20mg. Cohort 1 and 2 form the basis of the clinical evidence for BART in the phase 3 CATALYST study.
- Cohort 3 started in September 2015. It is open to all PAH patients who can walk >150m. Cohort 3a will enroll up to 24 patients with PAH-CTD and cohort 3b will enroll up to 24 non-CTD. Patients are randomized 2:1 and data is expected H1-17 and will be important to help handicap the CATALYST study. Patients are titrated from 5mg to 10mg based on tolerability.
- Cohort 4 is the PH-ILD cohort and it started in September 2015. It is broken into four parts. All are randomized 2:1 and dosed at 5mg up to 10mg if tolerated. There are at least 20,000 PH-ILD patients in the US. Data is expected in these four cohorts 2H-17
 - 4a is up to 24 CTD-ILD patients
 - 4b is up to 24 IPF patients with PH-ILD.
 - 4c is up to 24 NSIP patients with PH-ILD
 - 4d is up to 24 Sarcoidosis patients with PH-ILD.
- **Omap phase 2 MOTOR study**–This study in mitochondrial myopathies began in August 2014 and is expected to provide initial data H1-17. There are fewer than 100k patients globally with MM, and an estimated 20-40k in the US (we estimate a multi-billion dollar TAM). The study is being conducted in the US and EU. Eight patients have been enrolled in the 2.5mg, 5mg, 10mg, 20mg, and 40mg cohorts and two patients have been enrolled in the 80mg cohort. Few AE’s have been observed to date.
- **Omap phase 2 MOXIe study**–This study in Friedrich’s Ataxia began in August 2014 and is expected H1-17. The FA market is 6-7k people in the US and 23k globally. This double blind placebo controlled study will enroll up to 100 patients with FA. The study is being conducted in the US, EU, and Australia. The first part of the study is dose ranging from 2.5mg to 160mg. Eight patients have been enrolled in the 2.5mg, 5mg, 10mg, 20mg, 40mg and 80mg cohorts, and three patients have been enrolled in the 160mg cohort. Few AE’s have been observed to date. Data from the first part of this study is expected in H1-17. The company will start part 2 which is the pivotal study at a single dose upon receipt of the data.
- **Omap phase 2 REVEAL study**- This study in metastatic melanoma on top of existing immunotherapies is expected to read out 2H-17. We view this study as more of a long shot with a longer development path. The hurdle to invest further funds in this clinical path should be quite high.

Assessment of Management

Founder and CEO J. Warren Huff leads the company as CEO, President, and Chairman. Colin Meyers is CMO and VP Product Development and has also been with the company since 2003. The management team and the board have been together for many years. Should there be further snags in the clinical progress of either drug, shareholder may press for some fresh perspective from the board/management team but it is unclear if shareholders have the voice to do with the two classes of shares.

Corporate governance is in line with peers. Post the deal there will be 5M class A shares and 15M class B shares. Insiders may take up to \$45M of the \$60M deal. After the deal, CPMG (Dallas) will own 27% of the company, Cardinal Investment Company (Dallas) will own 36%, Novo will own 15%, and Abbvie will own 10%. CPMG and CIC are VC’s we do not often see in the biotech space. The company has not raised money since 2009.

Growth Drivers

- **LARIAT PAH data in 2H-16 (cohort 3b) late 2016** – We expect cohort 3b (non-CTD-PAH) in 24 patients in late 2016. This would be 24 patients (16 drug/8 placebo) in the general PAH population. BART would represent a new mechanism of action for PAH. There are three classes of drugs approved for PAH and each class does about \$1.5B in annual revenue. Results would need to be replicated in a larger phase 3, but this would both increase the probability of success for CATALYST and our probability of success in general PAH would increase. We model \$750M in CTD-PAH sales and have a 65% probability of success (\$22/share). If it

is successfully developed for the entire PAH population, we model \$1.5B in sales and ascribe a 50% probability of success in this indication (an incremental \$11/share over the CTD-PAH population).

- **LARIAT PAH-CTD data (cohort 3a) H1-17** – Cohort 3a enrolls CTD-PAH patients and is essentially a preview of the planned phase 3 CATALYST study. There are currently 10-11 patients enrolled and the target is 24 patients (with 16 on drug/8 on placebo). Once CATALYST is up and running they will stop enrolling this cohort.
- **MOXIe study data in H1-17** – The company is enrolling the seventh cohort of eight patients in FA treated with Omap. There are two placebo patients per cohort. The goal of this study is to show a signal of efficacy and to help select a dose for a pivotal phase 2b. We model \$750M in sales to FA patients if the drug is successfully developed here. We presently ascribe a 20% probability of success. This program is worth \$6/share.
- **MOTOR study data in H1-17** – The company is enrolling the sixth cohort of eight patients in MM treated with Omap. There are two placebo patients per cohort and all the placebo patients will be combined. There is wiggle room in interpreting these data, particularly at low doses where efficacy may not be seen. The goal of the company is to present data that are convincing enough to go to a pivotal phase 2b. We project \$1.5B in sales if the drug is successfully developed for MM. We currently model 20% probability of success. This program is worth \$12/share.
- **BARD in various PH-ILD cohorts** – These four cohorts will read out 2H-17. There are four separate proof of concept studies that are independent. The market in aggregate is large (>20k in the US which translates to a \$2B TAM). We ascribe no value to these at this point in time, but the company could easily see a signal that is worth moving into a pivotal study in one or multiple indications.
- **CATALYST data in H1-18** – This is a pivotal study in PAH-CTD, a 6,000 patient market. We would project \$750M in peak sales for this indication if approved, but see upside to this number if there is evidence of efficacy in non-CTD-PAH. As described previously, we assume a 65% probability of success in this study and, if successful, model \$750M in peak sales for this indication.
- **Path forward on topical Omap** – Before the mechanism of fluid overload in BARD was elucidated; the company began working on a topical formulation of Omap for ophthalmic conditions. The path forward will be made public in the future; there are current contractual issues with Abbvie. We ascribe no value to this program.

Issues / Risks

Despite a significant amount of animal work predicting broad utility for BARD and Omap, there has been limited human success. The recent PAH data is the first successful human study for BARD. It was working in the CKD study before that study was stopped early for a safety signal. BARD has been tried in a number of oncology settings, the data from which has largely been unreported.

A topical formulation of Omap has had mixed results. The company has done a series of signal finding studies and to date has only moved drugs forward in two indications (CKD and CTD-PAH).

Flexibility of FDA would be very good for Omap. The review of Omap will be done by the neurology division. The neurology division has been the division reviewing the drugs in the Duchenne Muscular Dystrophy space. The company has said that FDA has been very flexible and encouraged the company to design a pivotal phase 2 study that contains a placebo arm so it could be used for a quick approval if a strong signal is seen in the data.

Summary and Recommendation

For all indications, we use a 3x peak sales multiple, discount it back 7 years at 12%, and adjust for the probability of success. Post the deal there are 20M shares out, we assume an addition 10M shares to reach profitability and use 30M shares for all calculations. We believe BARD in CTD-PAH is worth \$22/share with a 65% probability of success. BARD in overall PAH is worth an incremental \$11/share with a 50% probability of success; in total BARD in PAH is worth \$33/share. We give no value to BARD in any of the phase 2 PH-ILD's. For Omap, we value FA at \$6/share and MM at \$12/share—both have a 20% probability of success in our current model.

In total, BARD is worth \$33 for PAH and OMAV is worth \$18/share in FA and MM. We have a \$50 price target.