Marinus Pharmaceuticals, Inc. (MRNS)

Initiating Coverage at Market Outperform; Novel Treatment for Seizure Disorders

MARKET DATA

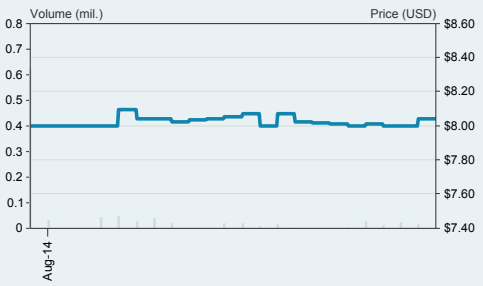
Price	$8.02
52-Week Range:	$8.00 - $8.16
Shares Out. (M):	13.8
Market Cap ($M):	$110.7
Average Daily Vol. (000):	70.0
Cash (M):	$9
Cash/Share:	$0.64
Enterprise Value (M):	$102
LT Debt (M):	$0

Source: Thomson Reuters and JMP Securities LLC

FY DEC		2013A	2014E	2015E
Revenue ($M)	1Q	--	$0.0A	--
	2Q	--	$0.0	--
	3Q	--	$0.0	--
	4Q	--	$0.0	--
	FY	**$0.0**	**$0.0**	**$0.0**
EPS	1Q	--	($7.40)A	--
	2Q	--	($8.47)	--
	3Q	--	($0.36)	--
	4Q	--	($0.36)	--
	FY	**($19.60)**	**($2.39)**	**($1.99)**

Source: Company reports and JMP Securities LLC

STOCK PRICE PERFORMANCE



MARKET OUTPERFORM | Price: $8.02 | Target Price: $14.00

INVESTMENT HIGHLIGHTS

We are initiating coverage on Marinus Pharmaceuticals with a Market Outperform rating and $14 price target. Marinus is focused on the development of ganaxolone, an oral drug candidate with a novel mechanism of action being developed for the treatment of epilepsy. The company has completed a ~150 patient Phase 2 trial in adults with partial onset seizures, demonstrating a statistically significant reduction in seizure frequency vs. placebo. Based on the differentiated mechanism of action and preclinical data, we believe the safety profile of the candidate may be favorable vs. current anti-epileptic drugs. A Phase 2b trial is ongoing, and results are expected in 2H15. Marinus completed its IPO in July, and we believe the funds raised are sufficient to support clinical development of ganaxolone in multiple indications through key value-inflecting milestones in 2015 and 2016. Our $14 price target is derived through an NPV analysis of U.S. ganaxolone sales in the adult partial onset seizure indication.

Demonstrated efficacy with increasing evidence to support differentiated safety profile. Ganaxolone is a novel drug candidate that modulates the neurotransmitter gamma-aminobutyric acid (GABA) in a manner different to current anti-epileptic drugs. Results from a Phase 2 trial in adults with refractory partial onset seizures demonstrated a significant reduction in seizure frequency vs. placebo (20%; p=0.014). We view efficacy as compelling in this refractory patient population. Marinus is now enrolling patients in a Phase 2b trial, and leveraging the proceeds from its IPO; the company has expanded the size of the trial to increase statistical power, enabling its use as one of two pivotal trials to support U.S./EU approval. Additionally, in our view, ganaxolone's safety and tolerability profile may prove to be a primary differentiating attribute, with no signals observed for CV risk, urinary retention, behavioral side effects, weight gain, or fetal toxicity, all of which are limiting side effects of current anti-epileptic drugs.

Attractive commercial opportunity in patient populations with the greatest unmet medical needs. Approximately 50MM people suffer symptoms of epilepsy globally, and 5 million are treated for seizure disorders in key global markets, representing ~$14B worldwide market opportunity. While current therapies are effective, more than one million patients remain refractory to therapy, presenting an opportunity for ganaxolone. We project that ganaxolone will be launched in the U.S. in early 2019, and achieve sales of ~$430MM in 2024, when we project that peak market share will be reached.

Further opportunities in orphan neuropsychiatric indications. Marinus is also developing ganaxolone in pediatric epilepsy patients with the PCDH19 genetic mutation and has reported encouraging initial clinical results in this patient population. Additional proof-of-concept results are anticipated in 1H15 that we believe could support advancement into late-stage development in this indication. It is also conducting a Phase 2 trial in patients with Fragile X syndrome, with results expected in mid-2015.

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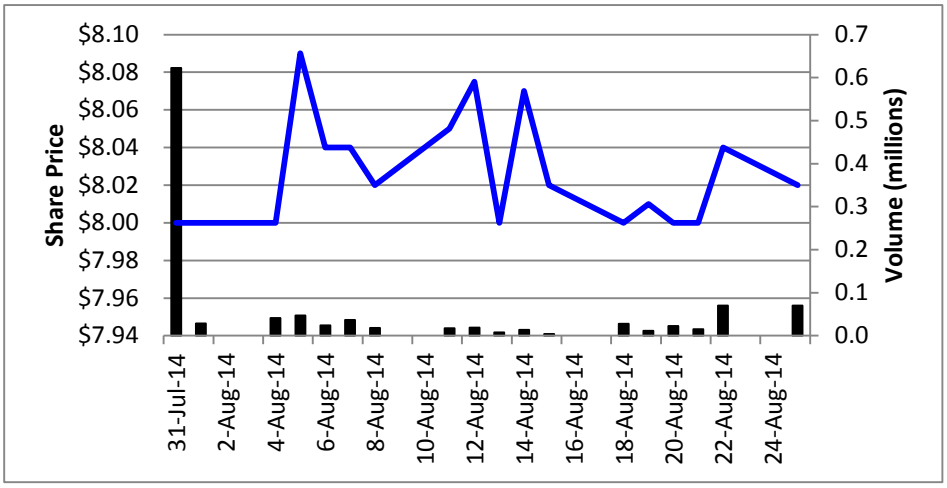
COMPANY DESCRIPTION

Marinus Pharmaceuticals is a clinical-stage biopharmaceutical company focused on developing and commercializing innovative neuropsychiatric therapeutics. The company's lead drug candidate is ganaxolone, an oral, small molecule synthetic analog of the neurosteroid allopregnanolone. The lead development indication for ganaxolone is as an adjunctive therapy for the treatment of partial, (focal) onset seizures in adults with epilepsy. The company has completed a Phase 2 trial in the refractory treatment setting, and is currently conducting a Phase 2b trial. We believe positive Phase 2b results, together with a confirmatory Phase 3 trial, could support regulatory approvals in the U.S. and Europe. Marinus is also developing ganaxolone for additional indications, including an orphan pediatric epilepsy population and Fragile X syndrome.

FIGURE 1. Marinus Stock Chart



Source: Thomson Reuters

KEY UPCOMING MILESTONES

1H15	Ganaxolone	Top-line results in PCDH19 female pediatric epilepsy
2H15	Ganaxolone	Phase 2 results read-out in Fragile X Syndrome (FXS)
2H15	Ganaxolone	Phase 2b results read-out in Focal Onset Seizures
2016	Ganaxolone	Initiation of Phase 3 trial in epilepsy

INVESTMENT THESIS

Marinus' lead product candidate is ganaxolone, for refractory focal onset seizures in epilepsy. Ganaxolone is being developed as an adjunct therapy for epilepsy patients who experience refractory, partial (focal) onset seizures. The drug demonstrated statistically significant reductions in seizure frequency in a previous Phase 2 trial in this tough-to-treat patient population, and the company is now enrolling patients in a Phase 2b trial in the same patient population. We anticipate results in 2H15, which we view as the most important catalyst for the stock in the coming 12-18 months. In addition to demonstrating benefit in this treatment refractory population, we view the opportunity for ganaxolone as compelling based on the potential for a more favorable safety profile than current epilepsy drugs. In our view, this potential is supported by the drug's novel mechanism of action, and preclinical and clinical data generated to date.

Ganaxolone's mechanism may offer better safety and efficacy versus other anti-epileptic drugs. As discussed in more detail on page 6, ganaxolone is thought to reduce the frequency of seizures by impacting the neurotransmitter GABA in a different manner than current anti-epileptic drugs. This novel mechanism of action acts on the extrasynaptic part of the GABA-A receptor to provide stabilizing and anti-convulsive effects in epileptic seizures. In contrast, current anti-epileptic drugs act primarily as sodium channel blockers or as GABA agonists. While standard of care anti-epileptic drugs (e.g., benzodiazepines, carboximides, valporates, lamotrigines) are modestly effective, they are limited by safety concerns, including liver, heart, or blood toxicity, as well as the risk of birth defects when taken by women who are pregnant. In clinical trials thus far, ganaxolone has not shown these risks, and preclinical studies provide compelling evidence for the absence of fetal toxicity. We believe ganaxolone may represent a novel treatment option with a differentiated competitive profile. In our opinion, it is also important to note that ganaxolone is not limited by the same steroidal effects as allopregnanolone, enabling chronic treatment in a broad outpatient setting.

Unmet need in refractory epilepsy, a large market potential. It is estimated that approximately 50 million people worldwide have epilepsy, and more than five million people are treated in the U.S., Europe, and Japan. According to data from IMS Health, global sales for anti-epileptic drugs reached $14 billion in 2011, and are continuing to grow. Approximately 30-35% of patients are not adequately controlled, despite treatment with three or more current therapies. We believe this represents an attractive commercial opportunity for ganaxolone.

Additional pipeline assets are expected to provide catalysts within a 12-18 month time frame. Beyond the opportunity in refractory partial onset seizures, Marinus is also developing ganaxolone in an orphan subset of epilepsy of pediatric females with the PCDH19 mutation, a patient population of ~40-50k in the U.S. These patients are characterized by decreased levels of allopregnanolone, and data from a pilot pediatric trial supports the efficacy of ganaxolone in children with multiple seizure types, including those with this genetic mutation. An open-label trial in epileptic children with the PCDH19 mutation is about to be initiated, and results are expected in 1H15. We believe the initial clinical data and clear mechanistic rationale support the potential for success in this patient population. The company is also conducting a Phase 2 trial of ganaxolone in Fragile X syndrome, and results are expected in 2H15. Preclinical studies, using a well-established animal model of Fragile X syndrome, have implicated a deficit in GABA signaling pathways in this condition, and provide rationale for the development of ganaxolone in this patient population, in our view.

VALUATION

We value Marinus through an NPV analysis of ganaxolone sales in refractory partial onset seizures. As detailed on page 17 and in Figure 15, we assume the product is launched in the U.S. in 2019, and project sales in 2024 of ~$430 million. Our NPV calculation assumes a 65% probability of success (taking into consideration clinical, regulatory, and commercial risks), and an operating margin of 35%. We use a 15% discount rate. As shown in Figure 2, we derive an NPV for ganaxolone of ~$210 million, or $14 per share. Our NPV analysis assumes generic entry in 2031, following patent expiration (assuming five years of patent term extension).

FIGURE 2. Marinus NPV Valuation

	Revenue	Revenue year	Economics	Probability of success	Discount rate	NPV	NPV per share	Contribution
Gannaxolone U.S. sales	429.4	2024	100%	65%	15%	210.1	$14.37	100%
Price target							**$14.37**	100%

Source: JMP Securities LLC

Our NPV analysis includes ganaxolone sales in the U.S., with Europe and other worldwide geographies representing upside potential. Importantly, we believe that the planned Phase 2b/3 program for ganaxolone in refractory partial onset seizures could be sufficient to satisfy U.S. and European regulatory requirements, which, in turn, would likely support approvals in most global markets.

We see further upside potential to our current valuation assumptions in the opportunities for ganaxolone in additional indications, including PCDH19 pediatric epilepsy, and Fragile X syndrome.

Capital structure

Following the completion of the IPO, Marinus had ~13.8 million shares outstanding, not including the overallotment option. Marinus completed its IPO in July 2014, issuing 5.6 million shares of common stock at $8.00 per share. It granted underwriters a 30-day option to purchase up to an additional 843,750 shares of common stock at the same price to cover overallotments. Current shares outstanding exclude 1.1 million stock options with a weighted average exercise price of $1.04 per share, and 0.7 million shares that could be made available under the 2014 Equity Incentive Plan.

Our price target is based on ~14.6 million shares outstanding, which assumes full exercise of the overallotment option.

Balance sheet

As of March 31, 2014, Marinus had ~$9 million in cash and cash equivalents. Proceeds from its IPO were ~$42 million, and exercise of the overallotment option would provide up to an additional ~$6 million. We believe Marinus should have enough cash and cash equivalents to fund operations into mid-2016, including through completion of the ongoing Phase 2b trial in partial onset seizures, and the Phase 2 trial in Fragile X syndrome, and the trial in the orphan PCDH19 female pediatric epilepsy population. IPO proceeds will also be used to fund advances in ganaxolone manufacturing processes, with an aim of entering the Phase 3 trial with a commercial-ready formulation.

INVESTMENT RISKS

Clinical risk. We note that results from early trials cannot always be replicated, and the drug may fail to produce positive data in later trials. There may be dosing, efficacy, or safety issues related to product candidates undergoing clinical trials that could preclude continued development. In addition, there may be manufacturing issues, including challenges with the scale-up to commercial quantities. Any of these issues could pose a risk to clinical development success.

Regulatory risk. The company's potential regulatory filing for its NDA may not receive approval from the FDA or ex-U.S. agencies. The FDA may request further studies, in which case the approval pathway will likely take longer, and cost significantly more.

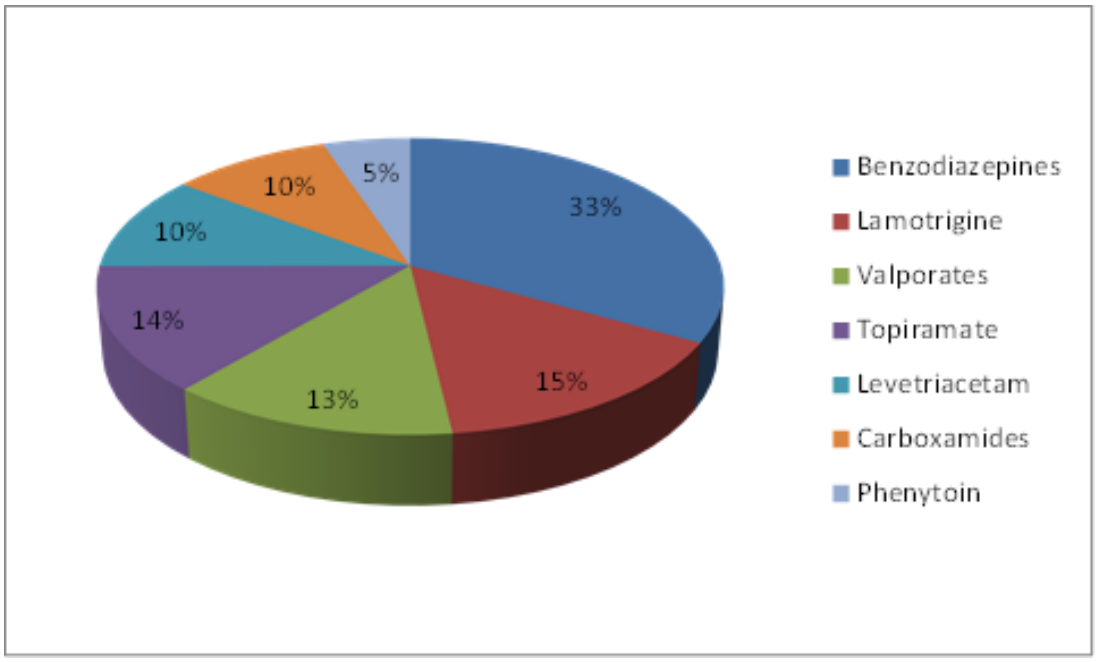
Market risk. Market estimates of patients, or patients eligible for ganaxolone treatment, may be overestimated. Furthermore, new drugs entering the market could provide greater competition for the product candidate. This would impact the ability to reach revenue and profitability projections. In addition, the company must retain its intellectual property rights. Other companies may file patent applications or may receive patents that claim the same methods or formulations. Generic competition would affect operations and potential business prospects.

Financial risk. Marinus has incurred losses each year since inception due to research and development expenses for the ganaxolone preclinical and clinical programs. These expenses and losses are expected to continue to incur in the near future. It has not generated revenue to date from sales, and if there are any issues preventing the successful commercialization of products, the company may not reach profitability. We believe the company's cash runway will last ~24 months, into mid-2016. We anticipate that Marinus will likely need to raise additional funds, to continue future operations. Raising additional funds may cause dilution to Marinus shares or require that it give up rights to product candidates. Any of the aforementioned scenarios may jeopardize the business. Additionally, as usual, the share price is subject to market volatility risk.

GANAXOLONE – NOVEL MECHANISM PRESENTS POTENTIAL FOR DIFFERENTIATION

The most commonly prescribed anti-epileptic drugs (anti-convulsants) include GABA analogs (gabapentin, pregablin), benzodiazepines (clobazam, clonazepam), carboxamides (carbamazepine, oxcarbazepine, eslicarbazepine acetate), lamotrigine, levetriacetam, phenytoin, topiramate, and valproates (valproic acid, sodium valproate, divalproex sodium). These drugs act primarily as GABA agonists (activators).

FIGURE 3. Prescription Share of Most Commonly Used Anti-Epileptic Drugs



Source: IMS Health

N.B. Excludes GABA analogs as these drugs are used extensively for other indications, such as neuropathic pain.

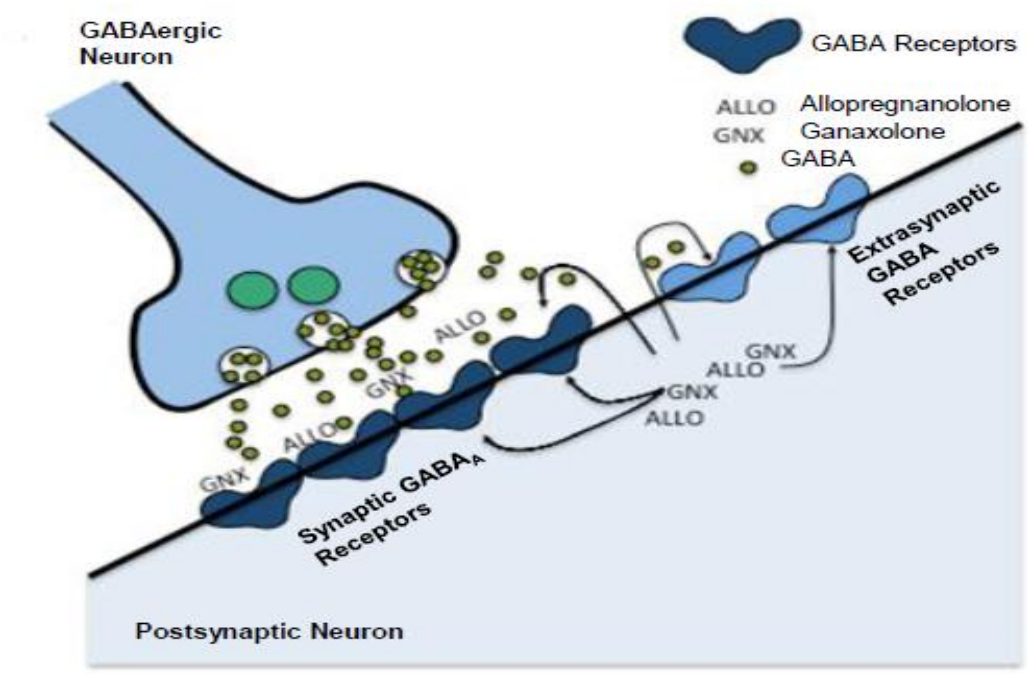
The primary limitations of current anti-epileptic drugs include increased cardiovascular and/or psychiatric risk in patients, and contraindications in patients with hepatic or renal disease. In addition, commonly used anti-epileptic drugs have been associated with fetal toxicities in animals, humans, or both. As such, these drugs carry a Pregnancy Category C.

Ganaxolone

Ganaxolone is a synthetic analog of allopregnanolone being developed by Marinus for the adjunct treatment of refractory partial onset epilepsy. The drug works by a novel mechanism of action compared to currently available epilepsy drugs, and as a result, we believe it may have a differentiated clinical profile, with respect to both efficacy and safety.

Allopregnanolone is an endogenous neurosteroid that modulates GABA-A, and is produced as a byproduct of the metabolism of progesterone. Ganaxolone is chemically similar to allopregnanolone with the addition of a methyl group which, importantly, prevents its conversion back to an active steroid, thus avoiding unwanted hormonal effects and enabling chronic treatment. Ganaxolone modulates overexcited neurons via the GABA-A receptors, both synaptically and extra-synaptically (Figure 4). Its activation of the extra-synaptic receptor produces the sought after neuronal stabilization without hormonal side effects, and is unique among other anti-seizure drugs that are GABA receptor agonists. In our view, this mechanism is the differentiating factor for ganaxolone as an epilepsy therapy.

FIGURE 4. Ganaxolone Mechanism of Action

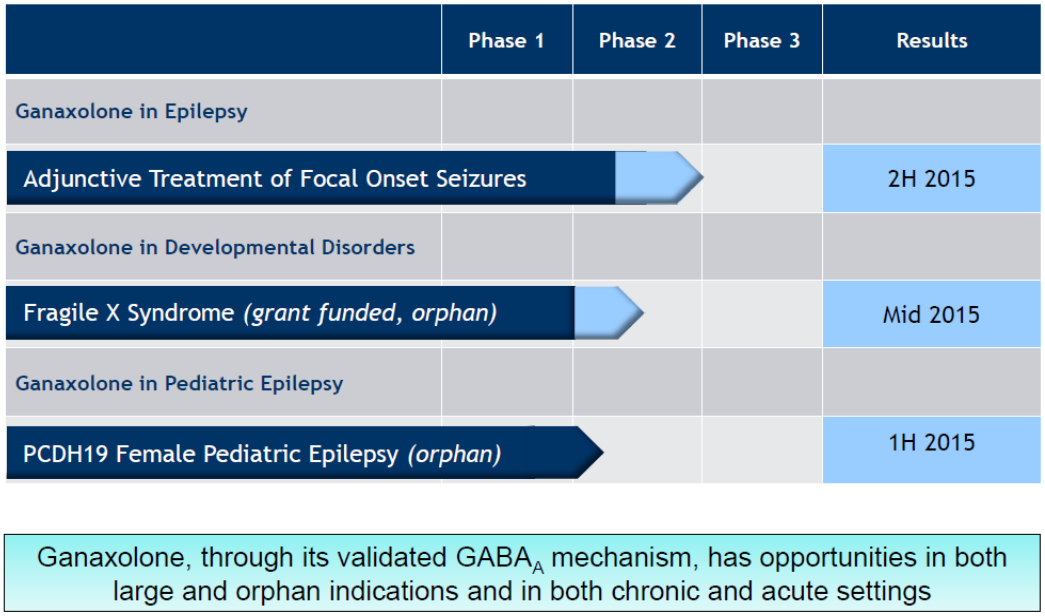


Source: Company reports

Unlike anti-epileptic drugs currently in the market, which are all Pregnancy Category C, in preclinical toxicology studies, ganaxolone did not cause malformations of the embryo or fetus or other birth defects. Based on these findings, Marinus will seek FDA Pregnancy Category B labeling for ganaxolone. As a result, we believe ganaxolone may have a differentiated clinical profile with respect to both efficacy and safety, especially for women of childbearing age.

Ganaxolone's unique mechanism of action may also have applicability in other neuropsychiatric disorders, including Fragile X syndrome, anxiety, sleep, mood or developmental disorders, as well as addictions, such as alcoholism and smoking.

FIGURE 5. Marinus Pipeline



Source: Company reports

GANAXOLONE DEVELOPMENT FOR PARTIAL ONSET SEIZURES IN ADULTS

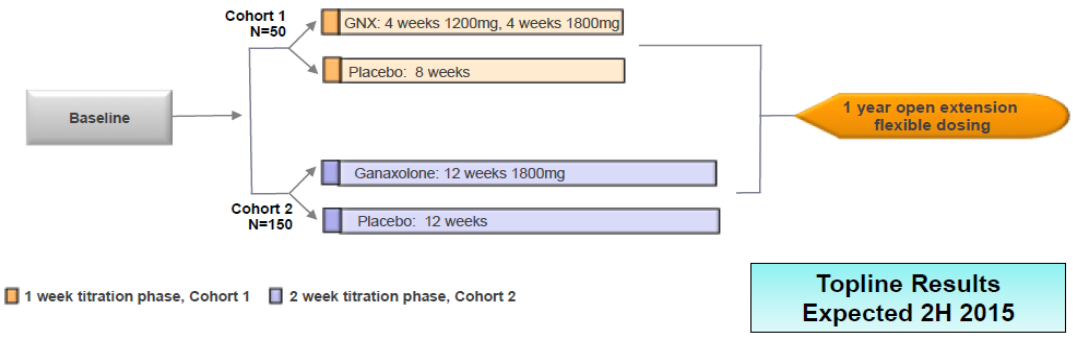
The lead indication for ganaxolone is as an adjunct treatment for focal onset seizures in adult epilepsy. A ~150 patient Phase 2 trial in this indication demonstrated a statistically significant reduction in mean seizure frequency compared to placebo. Marinus has initiated a Phase 2b trial in this patient population, which may serve as one of two pivotal trials to support approval. Results from this trial are expected in 2H15, and assuming positive results, we anticipate the company would conduct a single confirmatory Phase 3 trial. We believe that based on ganaxolone's novel mechanism of action and results from completed preclinical and clinical studies, the drug candidate has the potential to provide a differentiated treatment option to anti-epileptic drugs currently available on the market.

Phase 2b trial ongoing with results expected in 2H15

Marinus is currently enrolling patients in a Phase 2b trial (Study 603; NCT01963208) evaluating ganaxolone in adults as an adjunctive treatment of partial onset seizures. The trial was originally designed to enroll 150 patients; however, leveraging the proceeds of its IPO, the company is increasing the size of the trial. This is intended to increase the statistical power of the trial, as well as the safety database, and could enable it to serve as one of two pivotal trials for registration.

The trial is randomized (1:1), and placebo-controlled with two cohorts. In Cohort 1, patients are being randomized to either placebo or ganaxolone for a total treatment period of eight weeks, including a titration after four weeks from 1,200mg to 1,800mg of drug. Blood levels of ganaxolone are being measured at each dose level to provide information on optimal dosing schedule. In Cohort 2, patients are being randomized to receive either placebo or 1,800 mg/day of ganaxolone for 12 weeks. Marinus plans to use IPO proceeds to expand Cohort 2 to enroll ~300 patients. The Phase 2b trial design is summarized in Figure 5, and top-line results are expected in 2H15.

FIGURE 6. Ganaxolone Phase 2b Trial Design



Source: Company reports

The primary endpoint of the trial is the change in seizure frequency from baseline. Secondary endpoints include the proportion of responders, defined as those who had a 50% improvement over baseline, seizure-free status, and changes in seizure subtypes. The company will also monitor adverse events.

Following completion of the ongoing Phase 2b trial, Marinus plans to conduct a Phase 3, double-blind, randomized, fixed-dose study to confirm the efficacy, tolerability, and safety of ganaxolone as an adjunctive treatment in adults with focal onset seizures. Consistent with the Phase 2b trial, this study would enroll adults with drug-resistant partial onset seizures, currently on anti-epileptic drugs who require add-on therapy. As currently envisaged, the Phase 3 trial would consist of three fixed dose arms of ganaxolone treatment and a placebo arm, with a treatment period of 12 weeks. The primary endpoint would again be the change in seizure frequency from baseline.

Phase 2 results provide compelling proof-of-concept in this patient population

Marinus completed a Phase 2 trial (Study 600; NCT00465517) evaluating ganaxolone (oral suspension formulation) as an adjunctive treatment in adults with uncontrolled partial onset seizures. This was a 10-week, placebo-controlled, randomized trial conducted in the U.S. Patients were randomized (2:1) to receive ganaxolone (200-500mg three times per day) or placebo. The primary endpoint was the weekly seizure frequency during weeks 3-10 of treatment.

Patients continued to receive standard of care therapies, a maximum of three anti-epileptic medications. Of the enrolled patients, ~75% were taking two or three anti-epileptic drugs to control seizures. Mean baseline weekly seizure frequency was 6.5 and 9.2 in the ganaxolone and placebo groups, respectively.

The results showed that the addition of ganaxolone demonstrated a 20% reduction in seizure frequency vs. placebo that was statistically significant (p=0.014). Weekly seizure frequency in patients treated with ganaxolone decreased 17.6% from baseline to week 10, compared to an increase of 2% in the placebo arm (Figure 7). Additionally, more subjects who received ganaxolone were classified as responders than placebo, although this endpoint did not achieve statistical significance (p=.057). A responder was defined as a patient achieving a reduction in seizure frequency of greater than or equal to 50% improvement from baseline. The percent of responders in the ganaxolone group was 26.3%, compared to 13.0% for placebo.

FIGURE 7. Phase 2 (Study 600) Results

	Ganaxolone	Placebo	P value
Patient numbers	98	49	
Seizure reduction from baseline			
Mean	-17.6%	2.0%	
Treatment difference	19.6%		0.014
Responders	26.3%	13.0%	0.057

Source: Company reports

The safety and tolerability profile for ganaxolone was favorable in Study 600, with the most frequently reported adverse events greater than placebo being dizziness, fatigue, and somnolence (Figure 8).

FIGURE 8. Phase 2 Study 600 Ganaxolone Safety Profile

Summary of Most Frequently Reported (≥ 5% of Subjects) TEAEs by System Organ Class and Preferred Term (ITT Population)

Preferred Term	Ganaxolone (n=98) %	Placebo (n=49) %
Dizziness	16.3	8.2
Fatigue	16.3	8.2
Somnolence	13.3	2.0
Injury, poisoning and procedural complications	17.3	22.4
Headache	8.2	12.2
Coordination abnormal	6.1	6.1
Convulsion	5.1	8.2
Nasopharyngitis	5.1	10.2
Fall	5.1	12.2

Source: Company reports

Study 601 was an open-label extension study of Study 600, in which 95% of eligible subjects continued to receive treatment for ~39 weeks. Results from this trial were in line with results from the double-blind portion of the study, and importantly, patients who received placebo in the double-blind portion that were switched to ganaxolone in the open-label study showed reductions in seizure frequency comparable to patients randomized to ganaxolone in the double-blind study.

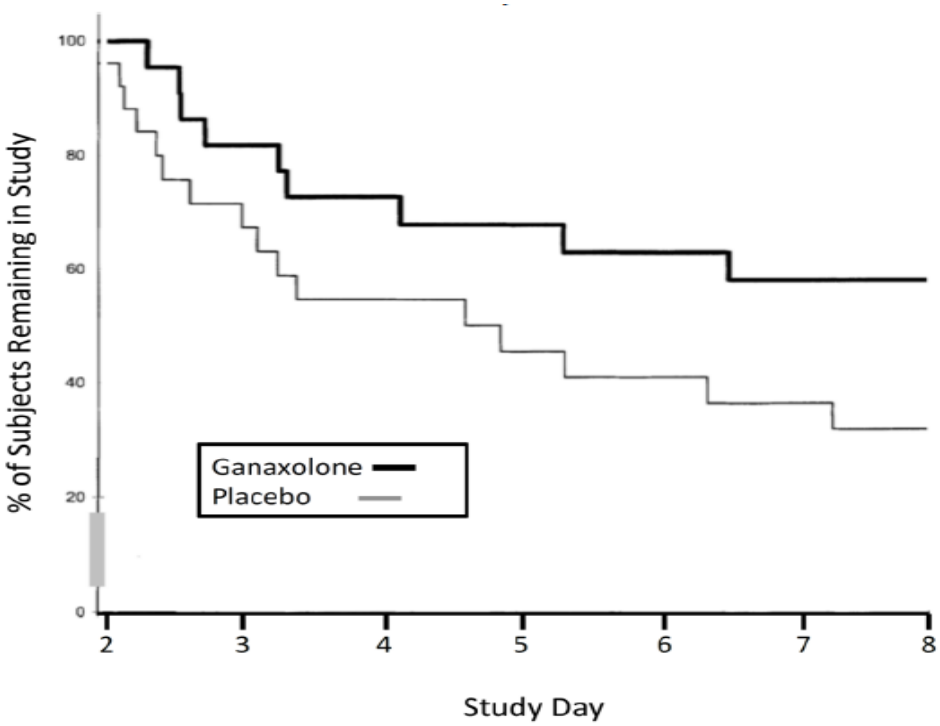
The mean and median reductions in weekly seizure frequency were 14.2% and 23.2% from baseline to the end of treatment. Furthermore, 70% of subjects had a reduction in seizure frequency during the study. During the open-label extension, 24% of patients met the responder criteria, and 43% of those who remained in the study for 52 weeks or more met responder criteria. Patients also reported a 17.4% increase in the number of seizure-free days per week.

Monotherapy trial also supportive of anti-seizure benefit

The Phase 2 Study 104 was a double-blind, randomized, placebo-controlled trial that evaluated ganaxolone as monotherapy in patients with resistant focal onset seizures. The trial enrolled 52 patients who stopped taking anti-epileptic medications prior to evaluation for surgical treatment of seizures. Patients were treated with ganaxolone monotherapy (625mg three times per day) for eight days. The primary endpoint was the duration of treatment prior to study withdrawal as measured from day 2 of the study.

The results showed that 62% of patients treated with ganaxolone remained in the trial at day 8 vs. 39% of placebo subjects (p=0.08) (Figure 9). The safety and tolerability profile of ganaxolone was also favorable in this trial. The most commonly reported adverse event between the two groups was dizziness. There was one severe adverse event in arch arm. One ganaxolone subject presented with severe agitation and depression, while a subject receiving placebo had an episode of postictal psychosis.

FIGURE 9. Phase 2 Study 104: Ganaxolone as Monotherapy



Source: Company reports

GANAXOLONE POTENTIAL IN OTHER EPILEPSY SETTINGS, AND FRAGILE X

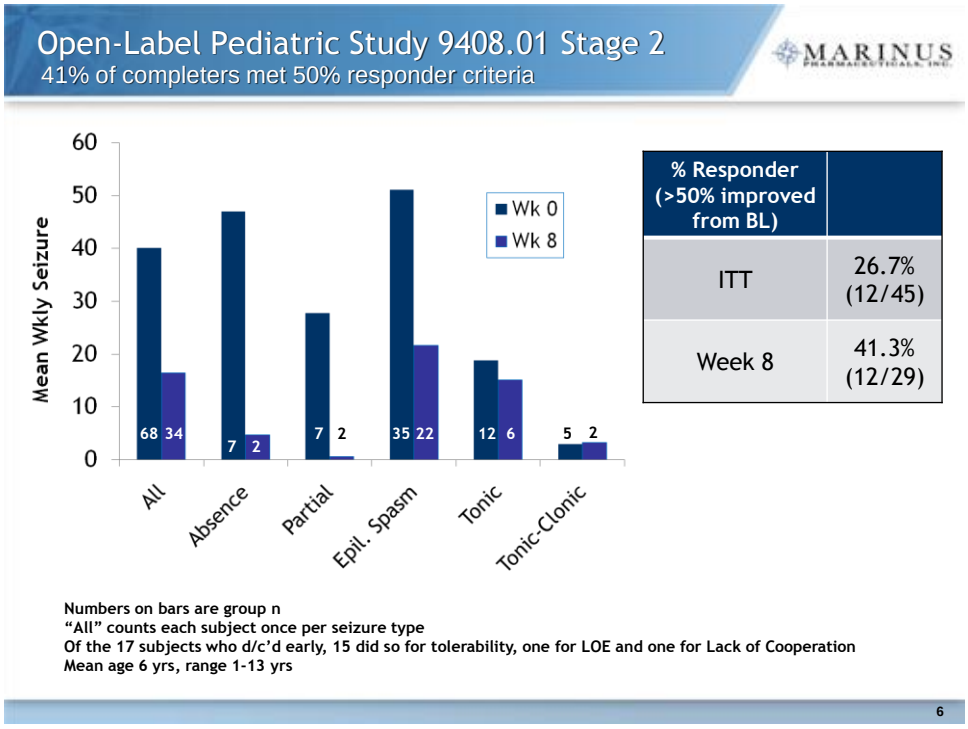
PCDH19 mutation in epilepsy

Marinus is also developing ganaxolone in a subset of epilepsy of pediatric females with the x-linked PCDH19 mutation. The mutation results in a deficit in 3a-HSD, an enzyme that converts 5a-dihydroprogesterone (5a–DHP) to allopregnanolone. It has been shown that these females have decreased allopregnanolone, and decreased mRNA for the enzyme that converts progesterone to allopregnanolone. Patients experience focal, absence, generalized, and clusters seizures. At times, patients can be at Status epilepticus or a state of persistent seizure.

The mutation affects ~40-50k pediatric females in the U.S., most of whom experience seizure onset in infancy. A genetic test exists for diagnosis. Seizures resolve in adolescence, but patients continue to experience developmental delay, intellectual disability, and behavioral issues.

Data from the Ganaxolone Pediatric study 9408.01/2 support ganaxolone efficacy in children with multiple seizure types (Figure 10).

FIGURE 10. Open-Label Study 9408.01 Stage 2 in PCDH19 Mutation



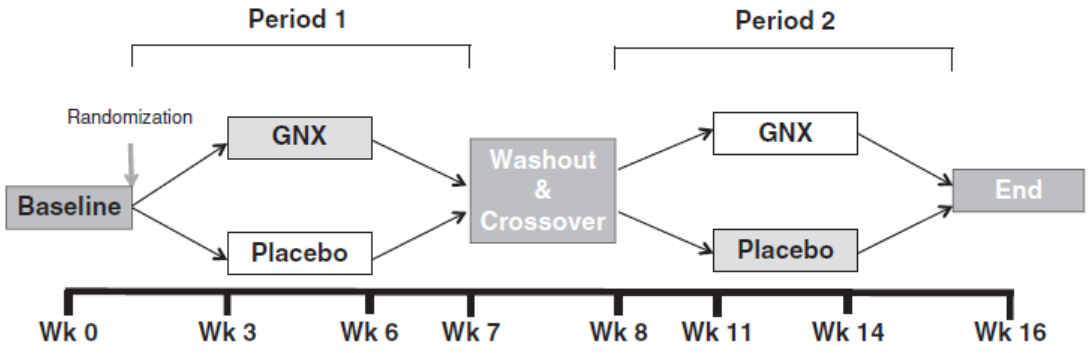
Source: Company reports

The company is now initiating an open-label expanded access, and we anticipate top-line results in 1H15.

Fragile X syndrome (FXS)

Fragile X syndrome (FXS) is a genetic mutation in the fmr1 gene that causes mental disability and autism. FXS is an orphan indication as there are no known cures or approved therapies. Approximately 100,000 people have FXS in the U.S., and ~7% of women and ~18% of men experience seizures. Ganaxolone may have utility in FXS through its potential to lessen seizures and symptoms, such as anxiety and mood disorders. Marinus, in collaboration with the MIND Institute at the University of California, Davis is conducting a Phase 2 (Study 800), proof-of-concept study in FXS. The primary endpoint is improvement of symptom severity as measured by the Clinical Global Impression Rating Scale for Improvement. Secondary endpoints include measures in the Aberrant Behaviors Checklist, and ratings scales for specific behaviors associated with childhood FXS. The n=60 trial is a randomized, placebo-controlled study where subjects are titrated up to a maximum dose of 1,500 mg/day of ganaxolone or placebo over a two-week period, followed by four weeks of treatment. At the end of the first treatment period and following a washout period, subjects are crossed over to the other treatment for a similar two-week titration period, followed by four weeks of treatment (Figure 11). Results for Study 800 are scheduled to read-out in 2H15.

FIGURE 11. Phase 2 (Study 800) Trial Design of Ganaxolone in FXS



Source: Company reports

COMMERCIAL OPPORTUNITY FOR GANAXOLONE

According to IMS Health, ~ 50 million people worldwide suffer from epilepsy, including five million in the U.S., EU, and Japan. The global market for anti-epileptic drugs stands at $14 million, as of 2011. Epilepsy is characterized by seizures that stem from neural oscillation (abnormal electrical activity) in the brain. The underlying cause of epilepsy remains unknown; however, seizures can be caused by heredity or injury to the brain.

Epileptic seizures are grouped into primary generalized seizures and focal onset seizures. Primary generalized seizures begin at both sides of the brain at once. Focal onset seizures start in one limited area of the brain. Seizures can range from convulsions known as a tonic-clonic seizure to a momentary loss of awareness known as an absence seizure. During a seizure, the patient can experience involuntary movement, sensations, or altered consciousness. Epileptic patients are typically treated with a daily AED.

American Academy of Neurology guidelines

In 2004, the American Academy of Neurology published treatment guidelines for epilepsy, addressing patients with new onset seizures and those with refractory disease. The table below (Figure 12) summarizes these guidelines and their recommendations for the use of standard anti-epileptic drugs. According to the AAN, patients with newly diagnosed epilepsy can be initiated on common anti-epileptic drugs such as carbamazepine, phenytoin, valproic acid, phenobarbital, or on lamotrigine, gabapentin, oxcarbazepine, or topiramate. Lamotrigine can be included in the options for children with newly diagnosed absence seizures.

FIGURE 12. AAN Treatment Guidelines for New Onset Epilepsy

Drug	Newly diagnosed monotherapy partial/mixed	Newly diagnosed absence
Gabapentin	Yes*	No
Lamotrigine	Yes*	Yes*
Topiramate	Yes*	No
Tiagabine	No	No
Oxcarbazepine	Yes	No
Levetiracetam	No	No
Zonisamide	No	No

* Not Food and Drug Administration–approved for this indication.

Source: American Academy of Neurology

According to AAN, the choice of AED depends upon seizure type, patient age, concomitant medications, AED tolerability, safety, and efficacy. The AAN recommends use gabapentin, lamotrigine, tiagabine, topiramate, oxcarbazepine, levetiracetam, and zonisamide as add-on therapy in patients with refractory epilepsy. Additional recommendations include the following: 1) oxcarbazepine and topiramate can be used as monotherapy in patients with refractory partial epilepsy; 2) lamotrigine can

be used as monotherapy in patients with refractory partial epilepsy; and 3) there is insufficient evidence to recommend use of gabapentin, levetiracetam, tiagabine, or zonisamide in monotherapy for refractory partial epilepsy. Below is a table showing guidelines from the AAN for treatment of refractory epileptic seizures (Figure 13).

FIGURE 13. AAN Treatment Guidelines for Refractory Epilepsy

Drug	Partial adjunctive adult	Partial monotherapy	Primary generalized	Symptomatic generalized	Pediatric partial
Gabapentin	Yes	No	No	No	Yes
Lamotrigine	Yes	Yes	No	Yes	Yes
Topiramate	Yes	Yes†	Yes (only generalized tonic-clonic)	Yes	Yes
Tiagabine	Yes	No	No	No	No
Oxcarbazepine	Yes	Yes	No	No	Yes
Levetiracetam	Yes	No	No	No	No
Zonisamide	Yes	No	No	No	No

* NB: In a previous parameter, felbamate was recommended for intractable partial seizures in patients over age 18 and patients over 4 with the Lennox-Gastaut syndrome. Felbamate is associated with significant and specific risks, and risk-benefit ratio must be considered.[3]
† Not Food and Drug Administration approved for this indication.

Source: American Academy of Neurology

Approximately 60% are able to get adequate seizure control from one AED. Other patients must use several drugs (polypharmacy) to control their seizures. Even so, ~30-35% of patients cannot control their seizures to an acceptable level. These patients are known as refractory, and represent the target patient population that Marinus intends to address with ganaxolone. In addition, a subset of focal onset seizure patients must resort to implantable devices or brain surgery. Marinus estimates a ~$4 billion opportunity exists to treat refractory patients in the U.S., EU, and Japan. We view ganaxolone as differentiated in the marketplace from other antiepileptic drugs, due to its unique mechanism of action and more favorable safety profile (Figure 14).

FIGURE 14. Ganaxolone Versus Other Anti-Epileptic Drugs

	Ganaxolone Target Profile[1]	Keppra (2000)	Vimpat (2008)	Fycompa (2012)
Mechanism	PAM of extra-synaptic and synaptic $GABA_A$ receptors	Binds to synaptic vesicle protein SV2A	slow inactivation of VSSC	AMPA (glutamate) receptor antagonist
Reproductive Toxicity, Pregnancy Category	No abnormalities, Category B	Teratogenicity and developmental toxicity, Category C	Developmental toxicity, Category C	Developmental toxicity, Category C
CV Risk	No CV warning	No CV warning	Warning: Pts w/ CV conduction abnormalities or severe CV disease	No CV warning
Psychiatric Side Effects	Low incidence (<2%)	Warning: Psychiatric Reactions	No Psychiatric Warning	Black Box: Serious Psychiatric and Behavioral Reactions
Renal and Hepatic Impairment	Monitor dose in hepatic impairment	Dose adjustment in renal impairment	Dose adjustments in both; not recommended in severe hepatic disease	Adjust dose in hepatic disease; monitor in renal disease; not recommended in severe renal or hepatic disease

Source: Company reports

Ganaxolone revenue model

As discussed above, there are approximately two million adults being treated for epilepsy in the U.S., of which ~370,000 have focal onset disease, and are refractory to current therapies. We view this as the initial target patient population for ganaxolone. We assume that results from the ongoing Phase 2b trial are successful, and the company subsequently conducts a confirmatory Phase 3 trial. We anticipate NDA filing in 2H17 or 1H18, with launch in the U.S. in early 2019.

We currently model and value ganaxolone sales assuming that Marinus commercializes the product through its own specialty sales force, targeting neurologists and epilepsy specialists (which we believe would comprise a field force of several hundred sales reps). As such, our NPV analysis assumes an operating margin of 35%. Ultimately, we view it as possible/likely that the company secures a commercial partner with experience and established infrastructure for marketing CNS drugs. We believe the additional resources brought by a larger partner can enable the product's potential to be maximized by additionally targeting primary care physicians who also treat the disease.

We anticipate that the product will be launched at a price of $20 per day, in line with Keppra XR and Vimpat, and assume a 20% gross-to-net discount. We include 5% annual price increases in the U.S. We project that the product can achieve a peak market share of 15% by 2024, and determine net sales in that year of ~$430 million, as summarized in Figure 15.

FIGURE 15. Ganaxolone Revenue Model – Partial Onset Seizures, 2015E – 2024E

U.S. Epilepsy Opportunity	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024
Epilepsy prevalence (adult)	2,040,301	2,050,503	2,060,755	2,071,059	2,081,414	2,091,821	2,102,280	2,112,792	2,123,356	2,133,972
# Focal onset patients	1,224,181	1,230,302	1,236,453	1,242,635	1,248,848	1,255,093	1,261,368	1,267,675	1,274,013	1,280,383
% of Total	*60.0%*	*60.0%*	*60.0%*	*60.0%*	*60.0%*	*60.0%*	*60.0%*	*60.0%*	*60.0%*	*60.0%*
# Refractory patients	367,254	369,090	370,936	372,791	374,655	376,528	378,410	380,302	382,204	384,115
% of Total	*30.0%*	*30.0%*	*30.0%*	*30.0%*	*30.0%*	*30.0%*	*30.0%*	*30.0%*	*30.0%*	*30.0%*
# Ganaxolone treated patients					5,620	11,296	22,705	45,636	53,509	57,617
% penetration	*Phase 2b*	*Phase 3*	*Phase 3*	*NDA*	*1.5%*	*3.0%*	*6.0%*	*12.0%*	*14.0%*	*15.0%*
Annual cost					7,300	7,665	8,048	8,451	8,873	9,317
Cost per day					$20.00	$21.00	$22.05	$23.15	$24.31	$25.53
Ganaxolone gross sales ($MM)					**41.0**	**86.6**	**182.7**	**385.7**	**474.8**	**536.8**
Gross-to-net adjustment					*20%*	*20%*	*20%*	*20%*	*20%*	*20%*
Ganaxolone net sales ($MM)	**0.0**	**0.0**	**0.0**	**0.0**	**32.8**	**69.3**	**146.2**	**308.5**	**379.8**	**429.4**

Source: JMP Securities LLC

Intellectual property protection

Marinus owns full, worldwide rights to ganaxolone, except in Russia. There are seven issued patents in the U.S. and ex-U.S. covering the novel composition of nanoparticles and complexing agents that deliver consistent exposure and improved stability of ganaxolone. These patents include oral solid and liquid dose formulations. These patents are expected to expire in 2026, excluding an additional five years possible under patent term extension. Corresponding foreign patents have been granted in Australia, Canada, Eurasia, Japan, New Zealand, and Singapore, and patent applications are pending in China, Europe, India, Israel, Japan, Mexico, South Africa, and South Korea.

The company also owns issued patents issued in the U.S. and New Zealand covering its synthesis process for ganaxolone, which are expected to expire in 2030. Corresponding patent applications are pending in Australia, Brazil, Canada, China, Eurasia, Europe, Hong Kong, Israel, India, Japan, Mexico, and South Korea.

MANAGEMENT TEAM

Christopher M. Cashman – Chairman, President and Chief Executive Officer

Mr. Cashman has served as Chairman of the Board of Directors since September 2011, and as President and Chief Executive Officer since October 2012. From August 2010 to May 2011, Mr. Cashman provided consulting services to Quaker Partners, a private venture capital fund. From 2003 to June 2010, Mr. Cashman served as President and Chief Executive Officer of Protez Pharmaceuticals, Inc., a company specializing in the development of antibiotics. Prior to his time with Protez, Mr. Cashman served as President and Chief Executive Officer of Message Pharmaceuticals Inc., and as Vice President for both Pfizer Inc. and SmithKline Beecham plc. Mr. Cashman began his pharmaceutical career at SmithKline Corporation. He currently serves on the board of directors of Rapid Micro Biosystems, Inc., Noble Biomaterials, Inc., and MBF Therapeutics Inc. Mr. Cashman holds an M.S. in Economics from Purdue University, and a B.S. in Business Management from the University of Minnesota.

Edward F. Smith – Chief Financial Officer

Mr. Smith has served as Vice President, Chief Financial Officer, Secretary, and Treasurer since November 2013. From July 2013 to November 2013, Mr. Smith served as an advisor to Tetralogic Pharmaceuticals Corporation in its initial public offering. From January 2006 to April 2013, Mr. Smith served as Chief Financial Officer of PolyMedix, Inc., a company engaged in the development of small-molecule drugs for the treatment of serious acute care conditions. From September 2000 to December 2005, Mr. Smith was Executive Director of Finance at InKine Pharmaceutical Company, Inc., a biopharmaceutical company focused on the diagnosis and treatment of gastrointestinal disorders. Earlier in his career, Mr. Smith held various positions of increasing responsibility in public accounting, most recently as a manager in the audit practice at Deloitte & Touche LLP. Mr. Smith is licensed as a Certified Public Accountant in Pennsylvania, and holds a B.S. in Business Administration from the University of Hartford.

Gail M. Farfel, Ph.D. – Chief Clinical and Regulatory Officer

Dr. Farfel has served as Chief Clinical Development and Regulatory Officer since January 2010. In May 2008, she founded G. Meredith Consulting serving as President. From March 2006 through April 2008, Dr. Farfel was employed at Novartis Pharmaceuticals Corp., as U.S. Vice President, Therapeutic Area and Head for Neuroscience Clinical Development and Medical Affairs. From November 1996 to February 2006, Dr. Farfel held a variety of leadership positions in Clinical Development and Global Medical Affairs at Pfizer, Inc. where she directed programs through all stages of clinical development and regulatory submissions, including development of the first product approved globally to treat PTSD. Dr. Farfel currently serves on the board of directors of PrintedArt. Dr. Farfel is the author of over 50 scientific articles in the areas of neuropsychopharmacology and drug treatment. Dr. Farfel holds a Ph.D. in Neuropsychopharmacology from the University of Chicago, where she trained as a behavioral scientist and neurotoxicologist, and received the Ginsburg Prize for Dissertation Excellence. She has a Bachelor's degree in Biochemistry from the University of Virginia.

Virinder Nohira M.D., Ph.D. – Chief Medical Advisor

Dr. Nohria is an experienced biotechnology entrepreneur and drug developer with a track record of success in the pharmaceutical and biotechnology sector. In addition to his work with Marinus, Dr. Nohria serves as President of Vidara Therapeutics, a privately held biopharmaceutical company which he co-founded. In the past, Dr. Nohria was Chief Medical Officer, Chief Compliance Officer, and Executive Vice President of Alaven Pharmaceutical and Alaven Consumer Health LLC. Dr. Nohria worked for Eli Lilly on Zyprexa and at UCB, where he was clinical lead for submission and commercialization of Keppra in the USA. Between 2003 and 2005, he was Vice President and Chief Medical Officer of Xcel Pharmaceuticals where he led development of retigabine (ezogabine) for the treatment of epilepsy. Dr. Nohria is on the board of Promentis Pharmaceuticals Inc., a privately held early stage neuroscience company. Dr. Nohria is a board-certified neurologist with special qualification in child neurology. His medical training was conducted at the University of Cambridge in England. His postgraduate training was completed in the UK and USA at Duke University. He also holds a Ph.D. in Neuropharmacology. He has authored many publications and book chapters.

Julia Tsai, Ph.D. – Senior Director of Clinical Development & Project Management

Dr. Tsai has served as Senior Director of Clinical Development and Project Management since November 2012. From September 2006 to November 2012, Dr. Tsai served as Director, Drug Development, and from 2004 to 2006, she served as Manager, Drug Development. Dr. Tsai is responsible for all facets of the company's drug development operations. Dr. Tsai is an author of several scientific articles and abstracts in the area of neuroscience and neurology. Dr. Tsai holds a Ph.D. in Neuroscience and Physiology from the Sackler Institute of Graduate Biomedical Sciences, New York University School of Medicine, and a B.A. from Cornell University.

Source: Excerpted from company reports

FIGURE 16. Marinus Pharmaceuticals Earnings Model

	2012	2013A	1Q:14	2Q:14	3Q:14E	4Q:14E	2014E	2015E	2016E
Revenue									
Revenue	100	0	0	0	0	0	0	0	0
Total Revenue	**100**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Cost of goods sold	0	0	0	0	0	0	0	0	0
Gross Profit	**100**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Operating expenses									
R&D	846	4,150	2,149	2,192	2,849	3,419	10,608	21,217	24,399
G&A	685	1,229	517	527	2,107	1,686	4,837	7,255	8,706
Total Operating Expenses	**1,531**	**5,379**	**2,665**	**2,719**	**4,957**	**5,105**	**15,445**	**28,472**	**33,106**
Operating income (loss)	**(1,431)**	**(5,379)**	**(2,665)**	**(2,719)**	**(4,957)**	**(5,105)**	**(15,445)**	**(28,472)**	**(33,106)**
Interest income	3	19	4	0	0	0	4	0	0
Interest expense	(321)	(91)	0	0	0	0	0	0	0
Change in fair value of warrants	336	153	428	0	0	0	428	0	0
Net Income Before Taxes	**(1,413)**	**(5,298)**	**(2,233)**	**(2,719)**	**(4,957)**	**(5,105)**	**(15,013)**	**(28,472)**	**(33,106)**
Income tax provision	4	28	(2)	0	0	0	(2)	0	0
Cumulative preferred stock dividends	(2,186)	(3,804)	(1,071)	(1,100)	0	0	(2,171)	0	0
Net income (loss)	**(3,594)**	**(9,074)**	**(3,306)**	**(3,819)**	**(4,957)**	**(5,105)**	**(17,186)**	**(28,472)**	**(33,106)**
EPS									
Basic	**($8.00)**	**($19.60)**	**($7.40)**	**($8.47)**	**($0.36)**	**($0.36)**	**($2.39)**	**($1.99)**	**($1.73)**
Diluted	**($8.00)**	**($19.60)**	**($7.40)**	**($8.47)**	**($0.36)**	**($0.36)**	**($2.39)**	**($1.99)**	**($1.73)**
Weighted shares outstanding									
Basic	450	463	447	451	13,779	14,055	7,183	14,336	19,123
Diluted	450	463	447	451	13,779	14,055	7,183	14,336	19,123
Cash Flow									
GAAP Net Income	(3,594)	(9,074)	(3,306)	(3,819)	(4,957)	(5,105)	(17,186)	(28,472)	(33,106)
Depreciation & amortization	18	10	3	4	4	4	15	20	25
Stock-based compensation	121	236	23	500	1,000	1,000	2,523	4,250	4,500
Other adjustments	2,227	2,200	2,155	1,100	0	0	3,255	0	0
Operating Burn	**(1,228)**	**(6,628)**	**(1,125)**	**(2,215)**	**(3,953)**	**(4,101)**	**(11,393)**	**(24,202)**	**(28,581)**
Cash at start of period	986	8,634	10,037	8,830	6,615	44,513	10,037	40,412	16,210
Cash from operations	(1,228)	(6,628)	(1,125)	(2,215)	(3,953)	(4,101)	(11,393)	(24,202)	(28,581)
Cash from investing	(5)	(17)	0				0	0	0
Cash from financing	8,882	8,048	(82)		41,850		41,768		68,400
Shares issued					5,625				4,500
Price per share					8.00				16.00
Effect of Fx	0								
Cash at end of period	**8,634**	**10,037**	**8,830**	**6,615**	**44,513**	**40,412**	**40,412**	**16,210**	**56,029**

Source: Company reports and JMP Securities LLC

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MARKET PERFORM	Hold	138	*30.73%*	Hold	138	*30.73%*	18	*13.04%*
MARKET UNDERPERFORM	Sell	4	*0.89%*	Sell	4	*0.89%*	0	*0%*
COVERAGE IN TRANSITION		36	*8.02%*		36	*8.02%*	0	*0%*
TOTAL:		449	*100%*		449	*100%*	119	*26.50%*

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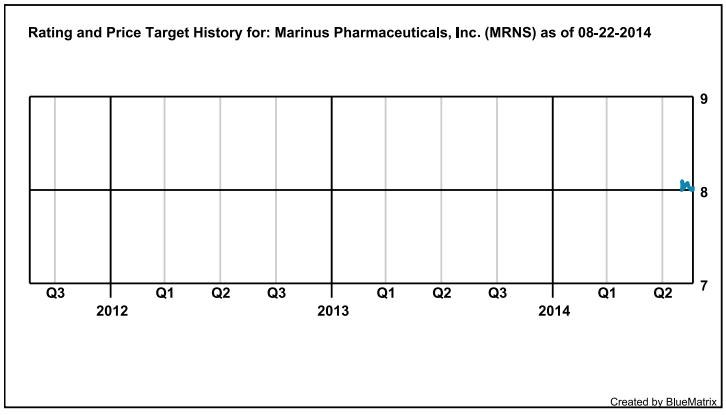

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