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Biotechnology
Initiating Coverage
September 11, 2019
BUY

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ORAMED PHARMACEUTICALS, INC.

ORMP: Initiating Coverage with a Buy Rating and Price Target of $7.00

ORMP (NASDAQ)

Company & Market Data	
Closing Price (as of 09/10/2019):	$2.97
Rating:	BUY
Price Target:	$7.00
52 Week Range:	$2.78 - $5.05
Shares Outstanding (MM):	17.4
Market Capitalization (MM):	$52
Cash (MM):	$37.0
Fiscal Year End:	Aug

Estimates			
EPS	**2018A**	**2019E**	**2020E**
1Q	$(0.18)	$(0.25)A	$(0.23)
2Q	$(0.20)	$(0.21)A	$(0.21)
3Q	$(0.30)	$(0.23)A	$(0.17)
4Q	$(0.20)	$(0.26)	$(0.03)
Full Year	$(0.86)	$(0.88)	$(0.61)
Revenue (MM)	**2018A**	**2019E**	**2020E**
1Q	$0.6	$0.7A	$0.6
2Q	$0.6	$0.7A	$0.6
3Q	$0.7	$0.7	$0.6
4Q	$0.6	$0.7	$3.7
Full Year	$2.6	$2.6	$5.6

Ratios			
P/E	NA	NA	NA

Oramed Pharmaceuticals is developing products based on its Protein Oral Delivery technology (POD). Its lead product is an oral insulin capsule, currently in Phase 2b trials. Additional indications and products are in clinical development.

We are initiating coverage of Oramed Pharmaceuticals, Inc. (ORMP) with a Buy rating and $7.00 price target. The lead product, ORMD-0801, is an oral insulin capsule in Phase 2b development for Type 1 and Type 2 diabetes. This is the first application of its proprietary drug delivery technology that enables large proteins to be given orally.

Clinical Trials: Oramed Pharmaceuticals is in Phase 2b clinical trials with ORMD-0801, its proprietary formulation of oral insulin. The study began in April 2018 and completed enrollment in May 2019. The first cohort is expected to report data in fall 2019, followed by data from the second cohort in 1Q2020. The study was designed to generate data for both efficacy and safety endpoints, with a primary efficacy endpoint of change in HbA1c at 90 days.

Previous Trial Data Was Promising: Results from the previous Phase 2 clinical trial showed that the drug lowered overnight bloodstream glucose and had statistically significant changes in HbA1c after 28 days of treatment.

The current Phase 2b study has a 90-day treatment period to meet FDA approval requirements. We estimate that if the current study succeeds in reaching its primary endpoint, a Phase 3 study could begin in 2021, followed by data announcement around early 2023.

Additional Indications and Products: Additional trials testing ORMD-0801 in other diabetes-related indications are in early-stage testing, with data expected in 2H19. These include a trial in NASH and with an oral form of leptin, the adipose regulatory hormone. ORMD-0901, its oral glucagon-like peptide-1 (GLP-1) analog of exenatide, is also in development for diabetes. Data from exploratory trials in these indications is expected to be released in 3Q19 and 4Q19.

Conclusion and Valuation: ORMD-0801 could become the first oral insulin for the treatment of diabetes, in our view. This could reduce or replace the self-injections needed by insulin-dependent patients, improving compliance and making it easier for patients to start insulin earlier. It could also enable patients with Type 2 diabetes that have limited benefits from current medication to begin insulin therapy.

We believe both populations would benefit from the slowing of disease progression, reducing late-stage complications and associated hospitalizations. Oral insulin could change the way diabetes is treated for millions of patients and save the healthcare system billions of dollars in related costs.

ORMP currently trades at $2.97, with a market valuation of about $51.8 million and cash on hand of about $37.0 million. This leaves a technology valuation of only around $14.8 million for a company that could have a therapeutic breakthrough for delivery of large molecules. We believe this valuation reflects an assumption of failure based on earlier attempts by other companies to make oral insulin. Successful completion of the clinical trial could be a significant inflection point for the stock.

We value the company based on our 2026 discounted EPS estimate of $2.26, applying a discount rate of 30% with a multiple of 15X to derive our price target of $7 per share.

Investment Summary

Oramed is conducting a Phase 2b clinical trial of ORMD-0801, its orally delivered insulin. Data from a previous Phase 2 trial showed improvements in glucose control with an improvement in HbA1c levels at only 28 days, providing proof-of-concept that it could deliver effective levels of insulin through the digestive tract. The current trial is designed to provide dosing and pharmacokinetic data to meet regulatory requirements for design of Phase 3 trials.

Patient enrollment of its Phase 2b trial of ORMD-0801 in type 2 diabetes (T2D) was completed in May 2019, with top-line results from the first cohort expected around 4Q19. The second cohort began treatment with a lower dose in June 2019, and is expected to report results in 1H20. Both cohorts have three treatment arms administering different total amounts of the drug during the day. The primary endpoint in both cohorts is the change in HbA1c at 90 days. If successful, a Phase 3 trial could begin in 2021.

Pipeline Products Are Based on its Proprietary Technology Platform: The company's proprietary technology is called Protein Oral Delivery (POD). The POD technology protects large proteins from digestive enzymes in the stomach, then facilitates their absorption through the intestines. Oramed has applied this technology to formulate oral versions of several categories of large molecule drugs that are currently given by injection. The lead applications are in diabetes.

Diabetes Programs: ORMD-0801 is Oramed's most advanced product. It is in development to improve glucose control in Type 2 diabetes (T2D, insulin resistant) and in Type 1 diabetes (T1D, insulin dependent). Findings from clinical studies in diabetes have shown a reduction in fat accumulation in the liver as well as effects on weight control. These data have led to preliminary trials in NASH (non-alcoholic steatohepatitis) and obesity.

ORMD-0801 is a recombinant human insulin that is absorbed by the intestine and travels directly to the liver, avoiding systemic insulin exposure. A Phase 2 study in which the drug was administered before bedtime showed a reduction in glucose levels during the overnight hours. The patients had lower glucose levels upon wakening the next morning and better control during the next day. The data showed several important measures of improvement, including a reduction in HbA1c at 28 days.

After an End-Of-Phase 2 meeting with the FDA, the company designed the current Phase 2b trial with a primary endpoint of change in HbA1c after 90 days. This trial has several endpoints that will characterize the pharmacokinetics and dosing requirements for a Phase 3 registration trial. If the Phase 2b trial is successful, the Phase 3 could use the same treatment protocol and endpoints with a larger number of patients. The Phase 3 would be designed to confirm the findings from Phase 2b with few protocol changes, reducing the new variables and lowering clinical risk.

We see several important potential benefits for ORMD-0801. The Phase 2b trial is enrolling patients with Type 2 Diabetes with inadequate glucose control but not yet taking injectable medications. These patients have high levels of bloodstream glucose that cause long-term diabetic complications throughout the body, including cardiovascular disease, nephropathy, diabetic retinopathy, and neuropathy. If successful, we believe ORMD-0801 would enable insulin therapy to slow progression of disease and reduce secondary morbidities in these patients. Delaying or avoiding these secondary morbidities would slow the patients' deterioration and reduce the additional treatments that cost billions each year. This population is estimated to include about 40% of the 20 million Type 2 diabetes patients in the US alone.

The second product, ORMD-0901, is an oral version of GLP-1 (exenatide). Exenatide is a hormone normally secreted by the small intestine during digestion. It increases insulin secretion and decreases glucagon release, providing a second mechanism to regulate glucose in the bloodstream. A Phase I trial is in progress and is expected to report data in 3Q19/4Q19.

Collaborations and Partnerships

Oramed has a partnership covering China and Japan with Hefei Tianhui Incubator Technologies Co. Ltd (HTIT), a division of Sinopharm Group Co. Ltd (private). Fees and milestones received have totaled $33 million, with an additional $17 million in milestones remaining for the next three years. To date, the HTIT partnership has provided dilution-free capital and technology validation while advancing ORMD-0801 in China. It has built a manufacturing plant and has received approval to begin clinical testing. The testing and approval process for China is expected to take about three years, with first sales around 2022-23.

In anticipation of product launch, HTIT plans to expand its manufacturing capacity to make enough ORMD-0801 to supply 1 million patients. Considering that an estimated 8% to 9% of the Chinese population has Type 2 diabetes, estimated at over 114 million patients, this large quantity of drug would still only serve a small percentage of the patient population. Upon approval, HTIT will pay a 10% royalty on its sales to Oramed. We expect this to become an important revenue stream once it reaches the market.

Oramed has stated its intention to partner the drug in North America and Europe. We expect the company to wait until the Phase 2b data is available before negotiating potential partnership terms. An agreement could include research support for Phase 3 trials, regulatory support through approval, and marketing rights. We have not included any fees or milestones in our estimates at this time.

Valuation and Conclusion

We expect ORMP to be driven by top line data from the Phase 2b data announcements currently expected in 4Q19 and 1H20. ORMP currently trades at $2.97, with a market valuation of about $51.8 million and cash estimated at $37.0 million. This leaves a technology valuation of just $14.8 million for a company that could have a therapeutic breakthrough for delivery of large molecules. We believe the valuation reflects many failed attempts by other companies in the field of oral protein delivery and the perception of risk in the current trial.

We value ORMP based on potential sales of ORMD-0801 in the diabetes indications. Based on our 2026 estimate of $2.26 per share, we discount at 30% and apply a 15X multiple for a price target of $7 per share.

Exhibit 1: Oramed Milestones and Events

Product	Indication	Event	Timeline
ORMD-0801	Type 2 diabetes	Phase IIb enrollment completion	2Q19
ORMD-0801	NASH	Exploratory study data announcement	4Q19
ORMD-Leptin	Leptin	Exploratory study data announcement	4Q19
ORMD-0801	Type 2 diabetes	Phase IIb trial results announcement	4Q19
ORMD-0801	Type 2 diabetes	Phase 2b second cohort data announcement	1H20
ORMD-0801	Type 2 diabetes	Glucose clamp studies completion	1H20
ORMD-0901	Type 2 diabetes	Food effect studies completion	1H20
ORMD-0901	Type 2 diabetes	End-of-Phase 2 meeting with FDA	2Q20
ORMD-0801	Type 2 diabetes	Initiate Phase 3 studies	2021

Source: Company reports and Ladenburg Thalmann estimates

Company Background

Oramed was established in 2006 to develop products based on protein delivery technologies discovered by its founder, a scientist at Jerusalem's Hadassah Medical Center. The proprietary technology, known as Protein Oral Delivery or "POD", protects proteins from digestive enzymes and enhances their absorption in the intestines. This has been applied to several large therapeutic molecules to make them orally available. ORMD-0801 is an oral insulin capsule in clinical testing for both Type 1 and Type 2 diabetes.

Type 1 diabetes is an autoimmune disease in which the insulin-producing cells of the pancreas are destroyed. This is often associated with juvenile-onset in which patients quickly become insulin dependent. Type 2 diabetes is the insulin resistant form in which the body does not respond properly to insulin. This is common with advanced age or obesity, in which patients have high blood glucose and insufficient transport of glucose into cells. It has a gradual onset, beginning with insulin resistance.

In the early stages with high glucose levels, patients with T2D can change their diet and increase exercise to reduce blood glucose levels. As the disease progresses, the oral drug metformin may be added to decrease hepatic insulin production and increase peripheral insulin sensitivity. Patients who no longer respond to metformin may start using other oral or injectable drugs. Due to the costs and side effects, many patients discontinue therapy or are not treated. These patients could benefit from insulin but do not use it due to the requirement of daily injections. Over time, their high glucose levels affect the circulatory system, nerves, and other systems. These lead to a variety of associated conditions ranging vision loss/blindness to heart attacks, kidney disease, stroke, as well as nerve and circulatory problems.

The current Phase 2b trial is testing ORMD-0801 in Type 2 diabetes patients with poor glucose control. ORMD-0801's oral administration could make insulin a viable therapy for these populations, slowing the progression of diabetes and avoiding its many secondary morbidities. Additional studies are planned for Type 1 diabetes, where ORMD-0801 could reduce or replace the daily insulin injections. Many diabetic patients are hospitalized each year due to poor glucose control, often attributed to difficulty complying with insulin regimens. An oral insulin that reduces the number of daily insulin injections would likely increase patient compliance and help maintain target glucose levels.

In 2017, the Centers for Disease Control and Prevention (CDC) reported that an estimated 30.3 million people in the US, or 9.4% of the population, has diabetes. Another 84.1

million have prediabetes, defined as a condition that left untreated often leads to diabetes within five years. This is consistent with estimates from the International Diabetes Federation, which estimates that 390 million to 450 million people worldwide have diabetes currently.

ORMD-0801 Could Become the First Oral Insulin

Insulin is a large protein with a complex structure that is easily denatured, inactivated, or destroyed by the enzymes of the digestive tract. Many attempts have been made to develop products that would avoid the insulin injections and pumps that diabetic patients use to control their blood glucose levels. Numerous oral insulin products have failed clinical development, while inhaled versions of insulin have reached the market. None have achieved both clinical and commercial success.

Oramed has developed ORMD-0801 using its POD technology to protect insulin from digestive enzymes. The drug carries the insulin through the stomach and improves absorption through the intestine. It is then carried through the portal vein to be stored in the liver for release as needed. This is closer to the natural action of insulin than injected insulin, which circulates through the tissues before reaching the liver. ORMD-0801 is also based on recombinant human insulin, a notable difference from products that were based on insulin analogues.

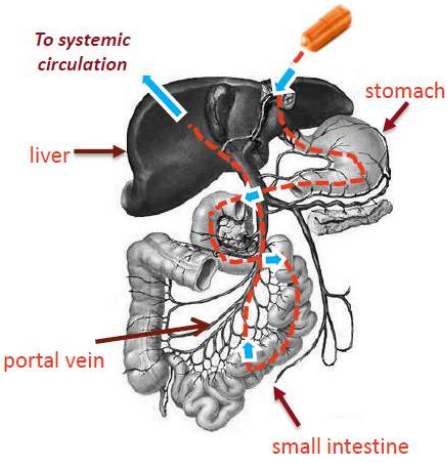
Exhibit 2: ORMD-0801 Travels Directly to the Liver for Release

ENDOGENOUS INSULIN produced by the pancreas and delivered to the body via the liver

INJECTED INSULIN introduced directly to the bloodstream with only a fraction of it reaching the liver. This can cause excess sugar to be stored in fat and muscle which often results in weight gain. This may also cause hypoglycemia

ORAL INSULIN like natural insulin is delivered first to the liver. This should lead to:

- Better blood glucose control
- Reduced hypoglycemia: liver metabolizes 80%
- Reduced hyperglycemia: insulin closes down glucose overproduction/secretion
- Reduced weight gain (neutral): vs. SC insulin focus on glucose disposal leads to substantial weight gain



Source: Oramed Pharmaceuticals

Phase 2b Began in April 2018

Preliminary Phase 2 Trial Results Were Promising: In May 2016, the company announced data from its first Phase 2 trial. These data showed a statistically significant decrease in mean night-time glucose levels, its primary endpoint (p=0.0268). There was also a significant improvement it HbA1c at the 28-day endpoint. We believe this demonstrated that the drug could pass through the stomach, be absorbed by the intestines, and have its intended effect.

The company designed the current Phase 2b trial following an End-Of-Phase 2 meeting with the FDA. This new trial was designed to provide additional data to more fully characterize the effects at different doses and administration intervals before Phase 3 trials. It also has 90-day endpoints to meet FDA requirements for Phase 3 studies.

Patient enrollment began in April 2018 and was completed in May 2019. Top-line results are expected to be announced during 4Q19. The trial has two cohorts with patients receiving either high dose or low doses of ORMD-0801. Following the announcement of the first cohort results, Oramed plans to request an End-Of-Phase 2 meeting with the FDA to discuss design of the Phase 3 trial. If the Phase 2b trial shows efficacy and meets its endpoints, the Phase 3 could repeat the study with larger patient numbers for approval. This would effectively be confirming the Phase 2b trial data. By reducing trial design changes and the introduction of new variables from the Phase 2 trial, there would be less risk of trial failure.

Phase 2b Design: The study is designed to identify the optimal dose and administration schedule for Phase 3 studies. The primary endpoint is a change in HbA1c, the accepted measure of glucose control in diabetes. Secondary end points include measures of fasting plasma glucose (FPG), post-prandial glucose (PPG levels) during a mixed-meal tolerance test (MMTT) and weight. Additional safety endpoints include evaluation of adverse and hypoglycemic events.

- The first cohort has a target enrollment of about 300 patients divided into three different dosing arms and a placebo comparator. The treatment begins with a two-week dose escalation period, using a starting dose of 16 mg, increased to 24 mg, and then 32 mg. Patients in the three arms receive the full 32 mg dose either once, twice, or three times daily for the next 10 weeks. Each arm has about 80 patients and a randomization of about 2:1, with about two-thirds receiving active drug and one-third receiving placebo.

- A second cohort with 75 patients receives a lower dose. The dosing protocol is the same, but patients receive a starting dose of 8mg, then increase to 16mg during the first 2 weeks. Dosing continues at 16mg for the next 10 weeks. This trial began enrolling patients in June 2019, with results expected in 1Q 2020.

Additional Studies - Glucose Clamp Study and Food Effects: In June 2018, Oramed began two additional studies to provide supporting data for ORMD-0801. The glucose clamp is an accepted method to measure insulin absorption, the patient's sensitivity to insulin, and glucose metabolism. A food-effect study is also in progress to determine the best timing for dosing ORMD-0801 before or after meals. This study is a single blind, five period, randomized, placebo-controlled crossover study enrolling up to 24 healthy volunteers and 24 patients. ORMD-0801 will be given at different times in relation to meals. The study should provide additional pharmacokinetic and pharmacodynamic data to determine best dosing schedules.

The ORMD-0801 Phase 2b Program Builds on Findings from Phase 2a

The previous Phase 2 trial for ORMD-0801 tested its effect on controlling glucose levels in Type 2 diabetes patients. The primary objective was to evaluate the nighttime glucose lowering effect and safety of ORMD-0801 compared with placebo.

ORMD-0801 was administered before bedtime, then tested fasting blood sugar 8 hours later. The study was a randomized, double-blind trial conducted in 33 sites across the United States. It enrolled 188 adults with Type 2 diabetes that was not adequately managed through diet and medication (metformin) alone.

ORMD-0801 was safe and well tolerated, with no drug-related serious or severe adverse events and no statistically significant differences in laboratory values or vital signs. Secondary and exploratory objectives of the study included evaluating the effect of ORMD-0801 on mean 24-hour glucose, fasting glucose, and daytime glucose:

- The primary endpoint of mean nighttime glucose showed a significant difference in mean change from run-in (13.70 mg/dL for placebo vs. 1.66 mg/dL for the pooled ORMD-0801 arms with a p=0.0117).
- The mean 24-hour glucose showed a highly significant difference in mean change from run-in (13.26 mg/dL for placebo vs. -0.32 mg/dL for ORMD-0801, p <0.0001).
- The mean fasting glucose showed a highly significant difference in mean change from run-in (15.95 mg/dL for placebo vs. -0.41 mg/dL for ORMD-0801, p <0.0001).
- The mean daytime glucose monitored by CGM (continuous glucose monitoring) systems show a highly significant difference in mean change from run-in (11.88 for placebo vs. 0.88 for ORMD-0801, p=0.0010).
- There was a statistically significant difference in change in HbA1c at Day 29 (0.20% for placebo vs. -0.01% for ORMD-0801, p=0.0149). While this was a promising finding, the changing levels of HbA1c over time require a study longer than four-weeks.
- ORMD-0801 did not show a significant difference in change in morning fasting serum insulin, C-Peptide, or triglycerides.

We believe these data show that ORMD-0801 successfully passed through the GI tract to reach the liver and had its intended effect on glucose levels. Patients receiving ORMP-0801 had a reduction in nighttime glucose levels and several important clinical measures of diabetes. Patients also had a stabilization or small decline in HbA1C compared with increases in the placebo group. This effect on HbA1C was statistically significant after only 28 days, although the nature of the HbA1c measurement requires a longer treatment period to evaluate the clinical benefit.

Hemoglobin A1c is formed when hemoglobin in red blood cells (RBCs) binds irreversibly with bloodstream glucose to form a glycated hemoglobin molecule. HbA1c forms in proportion to bloodstream glucose, making it a standard measurement of glucose levels. The red blood cells have an average life of approximately 120 days, with old blood cells removed and replaced by new ones every day. The HbA1c diagnostic test analyzes blood samples that include both new and old RBCs and is considered a 90-day moving average of bloodstream glucose levels.

We see the effect shown by ORMD-0801 in lowering HbA1C after 28 days of treatment as a promising signal of activity. The HbA1c level is a mean value based on RBCs formed over a 90-day period, yet the study only treated patients for 28 days. The blood samples in the study would have included RBCs that had been formed during the 28 days of treatment as well as those in circulation for up to 62 days before treatment began.

To show a statistical difference from placebo, the HbA1c levels in the one-third of the RBCs formed after the treatment began would need have been lower than the RBCs they replaced. In addition, the magnitude of the decline would need to be large enough to offset higher levels expected in the older two-thirds of RBCs that remained in circulation and were included in the test samples.

If our interpretation is correct, blood samples drawn after the full 90-day treatment in the Phase 2b study would contain only RBCs that have been formed after the drug has begun to lower blood glucose. Without including RBCs from the period before treatment, the average level should be as low or lower than the levels seen in the Phase 2a trial. We await the 90-day treatment data from Phase 2b for better comparisons.

ORMD-0801 Partnerships and Marketing Agreements

In December 2015, Oramed formed a partnership covering China with Hefei Tianhui Incubator of Technologies Co. Ltd., known as HTIT. The agreement gave HTIT marketing rights for ORMD-0801 throughout China, Hong Kong and Macau in exchange for $38 million in milestone payments and 10% royalties on sales. Oramed received a $15 million payment on signing, with a $3 million fee and an equity investment of $12 million for 1,155,367 shares at $10.39 per share. HTIT currently owns about 6.6**%** of the estimated 17.4 million shares outstanding. The Chairman of HTIT became a member of the Oramed Board of Directors in July 2019.

Since the signing, milestones have led to payments of an estimated $18 million for a total of $33 million received through 2019. Remaining and additional milestones could lead to payments of $17 million over the next 2 to 3 years. HTIT has built the manufacturing infrastructure to make oral insulin for the Chinese market and has completed construction of a pilot manufacturing facility. In March 2019, HTIT received clearance to begin clinical testing for regulatory approval in China. This approval is expected to take about three years. During this time, it plans to expand its manufacturing capacity to make enough ORMD-0801 supplies for 1 million diabetic patients. HITT will pay 10% royalties on sales, which we believe can lead to substantial revenue.

We see HTIT as a good partner for these countries. HTIT is partially owned by Sinopharm Group Co. Ltd., a private equity firm that develops early-stage technologies for the Chinese health care market. China has the largest population in the world, and the Chinese people have an inherently high rate of diabetes. An estimated 8% to 9% of its 1.4 billion people are diagnosed with diabetes, implying a patient population of over 110 million patients.

We Expect an Agreement for Late Stage Testing and Marketing for the US and ROW

Oramed has stated that it plans to seek a commercial partnership for the US and Europe that could include clinical development support and marketing rights. We see this as a good strategy, since the Phase 3 program could benefit from additional clinical development expertise, resources, and funding.

A partnership with another company could also provide an experienced marketing organization. A salesforce with existing relationships could reach the large number of generalists and specialists that treat diabetes to promote ORMD-0801. Given the size of

the patient population and potential sales, we believe a partnership would be a good strategy for achieving market share quickly. We would expect negotiations after the Phase 2b results, with a potential announcement in 2020. Our models do not include any fees or royalties, but could have significant potential upside.

Additional Findings from the Phase 2a Trial Have Led to New Indications

The ORMD-0801 Phase 2a study had several findings that have led to exploration of new indications. Since insulin has a role in glucose uptake by the body tissues, injected insulin typically causes weight gain as it circulates through the body. However, patients in the ORMD-0801 clinical studies showed less weight gain and body fat than would have been expected from injected insulin use. This may be due to bypassing the bloodstream and reduced absorption as it travels through the portal vein to the liver.

NASH Exploratory Clinical Study Enrolling Patients: NASH is a severe form of nonalcoholic fatty liver disease (NAFLD) caused by fat buildup that leads to damage to the liver. This can lead to inflammation, fibrosis, cirrhosis, liver failure, and hepatocellular carcinoma. Prevalence of NASH has been increasing and has been correlated with the rising incidence of Type 2 diabetes. According to the Journal of Hepatology, incidence of NASH is expected to increase from 16 million patients in 2015 to 27 million patients in 2030.

ORMD-0801 patients also showed a decrease in fat accumulation in the liver, an early symptom of NAFLD. In October 2018, the company began an exploratory trial to test ORMD-0801 reduction in liver fat, inflammation, and fibrosis in NASH and Type 2 diabetes over a 3-month period. Liver fat content will be evaluated by MRI PDFF (MRI-Proton Density Fat Fraction) images, the FibroMax Test and Fibroscan. Based on the results, an additional 20 patients may be added. The study is expected to report data from its first cohort of 10 patients in 4Q19. Since these are early research studies, we have excluded them from our valuation but see them as proof-of-concept for the technology platform.

Leptin Exploratory Trial: Leptin is a hormone produced in fat cells that has a role in regulating metabolism by maintaining stable energy levels and body weight. Obesity is an established risk factor for diabetes, with leptin resistance correlated with obesity.

Oramed is conducting an exploratory trial with an oral leptin capsule in patients with Type 1 diabetes. A single-dose trial in 10 patients has been designed to evaluate pharmacokinetics, pharmacodynamics, and safety. The trial began in 3Q19, with data expected by year-end 2019. If the safety goals are met, additional studies could be designed to show effects on fat accumulation and body weight in Type 1 diabetes patients.

GLP-1 Analogue Could Be a Large Opportunity: Exenatide, also known as glucagon-like peptide-1 or GLP-1, is a hormone produced in the intestine that has several actions in regulating glucose. In the pancreas, GLP-1 stimulates the beta cells to secrete insulin to lower blood glucose. It also suppresses alpha cells to decrease glucagon release, reducing glucose output by the liver. Other actions include slowing gastric emptying to extend the time for the digestive process, thus slowing the entry of glucose to the bloodstream after meals.

The first GLP-1 analog, Byetta, was introduced in 2005. Byetta had an important impact on diabetes treatment, and was followed by an extended release version, Bydureon, in 2012. Byetta is injected with meals, while Bydureon is injected once a week. Several other GLP-1 receptor agonists have been developed, with sales in the category estimated at $6.5 billion in 2018.

ORMD-0901 is an oral version of exenatide in development for Type 2 diabetes. A Phase 1 study to evaluate the safety and pharmacokinetics in 16 healthy patients began in 1Q19. The study is a randomized, single-blind, placebo-controlled, crossover study that compares ORMD-0901 to placebo and to open-label subcutaneous exenatide (Byetta). Data is expected in 3Q19.

A combination study with both ORMD-0801 and ORMD-0901 is also planned if justified by results of the Phase IIb studies. Due to the early stage of the program, we have not included any revenues from ORMD-0901 in our earnings estimates.

Revenue Forecasts: Following the Phase 2b trial, we have allowed for a Phase 3 trial starting in early 2021 and running for two years. This allows about 12 months for design of the Phase 3 trial and for a partnership agreement that includes funding for the trial. The Phase 3 trial could include a treatment arm with Type 1 diabetes that could provide data for approval in both types. We have not included Type 1 diabetes in our revenue models since this trial has not started, however, it could give substantial potential upside to our estimates.

Phase 3 data could be announced in early 2023, followed by an NDA submission in early 2024. Although the application could receive priority review, we assume a standard review of 10 months with FDA approval in 2025. Our models allow for launch preparations with first US sales in 2026.

Our target market is based on the entry criteria for the Phase 2b trial, consisting of Type 2 diabetes patients who have inadequate glucose control. We estimate this to be about 40% of the 20 million patients. Our price estimate of $10 per day compares with injectable GLP-1 analogues and insulin which currently cost about $15 per day. Although an oral medication used before an injectable could justify premium pricing, we allow for generic drugs and price cutting to lower the cost of alternative diabetic medications. In view of the reduction in secondary morbidities that would justify premium pricing, we believe our models are conservative.

Our estimates include the remaining milestones from the HTIT agreement based on Phase 3 trials, approval, and sales levels. Forecasts for HTIT royalties are based sales reaching only an estimated one-third of its expected capacity. We have included expense levels for Oramed as a self-funded company, without milestones or cost sharing for Phase 3 trials that could be part of a collaboration for US or European marketing rights.

We have included a risk adjustment of 75% to our revenue estimates due to the nature of oral insulin and the perception of risk in the geographies and the indication. This risk adjustment would decrease based on positive developments, potentially raising the valuation.

Conclusion and Valuation

We expect the stock to be driven in the near term by data from the Phase 2b trial in Type 2 diabetes. The trial is expected to announce top-line data from the first cohort in 4Q19, followed by the second low-dose cohort in 1H20. Data from studies with ORMD-0901, in NASH, and leptin could provide proof-of-concept, then become additional indications in the longer term. We view these trial results and development milestones to be important milestones for the stock in the coming year.

We value the company based on our 2026 discounted EPS of $2.26, applying a discount rate of 30% with a multiple of 15X to derive our price target of $7 per share. With cash reported for the quarter ended May 31,2019 to be about $37 million ($2.11 per share), this leaves a technology value of roughly $13.1 million for products that could generate billions

in sales. We believe the valuation for a breakthrough technology platform for oral protein delivery that serves the diabetes market would have substantial upside potential if successful.

Exhibit 3: ORMD-0801 Product Revenue Model

ORMD-8001 Oral Insulin			
T2 Diabetes population - China	100,000,000	100,000,000	100,000,000
Target market	1%	1%	1%
Target market	1,000,000	1,000,000	1,000,000
Market penetration	16%	27%	33%
Patients treated per quarter, avg during year	160,000	267,500	325,000
Cost per treatment per quarter	900	900	900
Revenues (thousands)	576,000	963,000	1,170,000
Risk adjustment factor	75%	75%	75%
Adjusted revenues	144,000	240,750	292,500
Royalty to ORMD	10%	10%	10%
Revenues (in thousands)	14,400	96,300	117,000

ORMD-8001 Oral Insulin	
T2 Diabetes population	20,000,000
Target market	40%
Target market	8,000,000
Market penetration	16%
Patients treated	1,300,000
Treatments per quarter/year	90
Cost per treatment	10
Revenues (in thousands)	1,310,400
Risk adjustement factor	75%
Adjusted revenues	327,600
Royalty to ORMD	10%
Revenues (in thousands)	32,760

Source: Ladenburg Thalmann estimates

Risk Factors

Risks to our rating and price target include but are not limited to:

Drug development risk: Oramed is a development stage company conducting clinical trials for its lead product. The company faces the risks of the drug development industry, including scientific, technical, clinical, regulatory failures. As novel therapies, the drugs also face risks with reimbursement and product adoption.

Company risks: The company has a limited operating history and has incurred significant losses and negative cash flow operations since inception and they expect to incur losses and negative cash flows for at least the next 12 months. Their independent registered public accounting firm has expressed doubt about their ability to continue as a going concern. Because certain of their stockholders control a significant number of shares of their common stock, they may have effective control over actions requiring stockholder approval.

Emerging growth company: The company is considered an emerging growth company and due to the reduced operating requirements applicable to emerging growth companies, certain investors may find investing in their securities less attractive.

International risks: The international aspects of their business expose the company to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the US.

Foreign Company Risk. The company is affected by the political, economic, and military risks of having operations in Israel, as well as fluctuations in currency exchange rates. It may be difficult to enforce a U.S. judgment against the company or its officers and directors and to assert U.S. securities laws claims in Israel. The company received grants from the Israel Innovation Authority of the Israeli Ministry of Economy & Industry and may be subject to ongoing restrictions.

Intellectual property risk: The field of patents and intellectual property involves complex scientific and legal issues that are subject to change by legislation or judicial action. Other companies with greater resources may challenge the company through the legal system or in the marketplace.

Clinical supplies and manufacturing risk: Oramed leases its operating facilities and depends on clinical trial managers and third party suppliers for its clinical trial grade materials, including the active pharmaceutical ingredients. We believe the supply of clinical materials is sufficient to conduct the trials, but third party manufacturing still carries a risk of problems or disagreements that could cause delays.

Regulatory risk: The company has conducted Phase 2 trials, and although we believe the pre-clinical and early clinical data indicate efficacy, further testing is needed before market approval. The findings from clinical trials must be reviewed by the FDA before the company receives approval to continue clinical testing. Analysis by the FDA may not agree with the analysis presented by the company. Approval of the application cannot be assumed.

Exchange and market risk: ORMP shares trade on the NASDAQ exchange with relatively small daily volume. The company is expected to raise additional capital to fund operations before its products reach the market, which is subject to market conditions.

Legislation and policy changes: Laws for drug approval are established by Congress and administered by the FDA. Reimbursement by third-party payors often follows policies established by the Center for Medicaid/Medicare. Both agencies are divisions of the

Department of Health and Human Services, run by Commissioners appointed by the President and confirmed by the Senate. Changes in policies or political agendas could have broad effects on the environment for drug development and reimbursement.

Oramed: Income Statement (in thousands)														
Fiscal Year Ended August 31	**2017A**	**2018A**	**1Q19A**	**2Q19A**	**3Q19A**	**4Q19E**	**2019E**	**2020E**	**2021E**	**2022E**	**2023E**	**2024E**	**2025E**	**2026E**
License and Milestone Payments	2,456	2,535	674	666	682	650	2,672	5,600	5,950	6,950	6,950		-	-
Royalites														
ORMD-0801 Type 2 diabetes - China												15,525	80,775	117,000
ORMD-0801 Type 2 diabetes - US only														32,760
Total Product Revenues	**2,456**	**2,535**	**674**	**666**	**682**	**650**	**2,672**	**5,600**	**5,950**	**6,950**	**6,950**	**15,525**	**80,775**	**149,760**
Expenses														
Cost of Goods Sold	187	-	35	55			90		-			2,329	10,247	14,976
%COGS												*15%*	*13%*	*10%*
Research and Development	10,281	11,979	4,347	3,114	3,861	4,100	15,422	14,300	19,000	23,000	28,000	31,000	35,000	37,750
General and Administrative	2,759	4,083	932	1,065	899	950	3,846	4,334	5,200	7,500	11,000	14,500	16,000	17,000
Total expenses	**13,227**	**16,062**	**5,314**	**4,234**	**4,760**	**5,050**	**19,358**	**18,634**	**24,200**	**30,500**	**39,000**	**47,829**	**61,247**	**69,726**
Operating Income (Loss)	(10,771)	(13,527)	(4,640)	(3,568)	(4,078)	(4,400)	(16,686)	(13,034)	(18,250)	(23,550)	(32,050)	(32,304)	19,529	80,034
Financial income	792	903	286	273	263	250	1,072	815	805	730	820	910	915	950
Other financial expenses	(101)	(103)	(8)	(19)	(14)	(15)	(56)	(69)	(69)	(71)	(85)	(122)	(130)	(140)
Income from changes in fair value of investments			60	(87)	(243)		(270)							
Total other income	691	800	338	167	6	235	746	746	736	659	735	788	785	810
Pretax Income	**(10,080)**	**(12,727)**	**(4,302)**	**(3,401)**	**(4,072)**	**(4,165)**	**(15,940)**	**(12,288)**	**(17,514)**	**(22,891)**	**(31,315)**	**(31,516)**	**20,314**	**80,844**
Income Tax Provision (benefit)	400			300		350	650							8,084
Tax Rate														10%
Net income (loss)	(10,480)	(12,727)												
Unrealized gain (loss) on available for sale securities	295	301												
Net Income (loss)	**(10,185)**	**(12,426)**	**(4,302)**	**(3,701)**	**(4,072)**	**(4,515)**	**(15,290)**	**(12,288)**	**(17,514)**	**(22,891)**	**(31,315)**	**(31,516)**	**20,314**	**72,760**
EPS (basic)	**($0.79)**	**($0.86)**	**($0.25)**	**($0.21)**	**($0.23)**	**($0.26)**	**($0.88)**	**($0.49)**	**($0.58)**	**($0.83)**	**($1.06)**	**($0.99)**	**$0.63**	**$2.26**
EPS (diluted)	**($0.79)**	**($0.86)**	**($0.25)**	**($0.21)**	**($0.23)**	**($0.26)**	**($0.88)**	**($0.61)**	**($0.70)**	**($0.83)**	**($1.05)**	**($0.99)**	**$0.63**	**$2.26**
Weighted Avg Shrs (Basic) - (thousands)	13,309	14,882	17,449	17,454	17,457	17,474	17,458	20,019	25,107	27,714	29,826	31,950	32,078	32,207
Weighted Avg Shrs (Diluted) - (thousands)	13,309	14,882	17,449	17,454	17,457	17,474	17,458	20,019	25,107	27,714	29,826	31,950	32,078	32,207

Source: Company reports and Ladenburg Thalmann estimates

Oramed: Balance Sheet (in thousands)														
Assets	**2017A**	**2018A**	**1Q19A**	**2Q19A**	**3Q19A**	**4Q19E**	**2019E**	**2020E**	**2021E**	**2022E**	**2023E**	**2024E**	**2025E**	**2026E**
Cash and Cash Equivilents	3,969	4,996	3,861	3,429	3,946	29	29	14,261	42,881	22,408	46,048	17,691	41,373	117,658
Short tem deposits	13,293	20,875	19,920	19,748	18,025	17,725	17,725	17,725	17,725	17,725	17,725	17,725	17,725	17,725
Marketable securities	2,860	4,592	5,143	5,474	4,223	4,223	4,223	4,223	4,223	4,223	4,223	4,223	4,223	4,223
Restricted cash	16													
Prepaid expenses and other current assets	159	574	727	950	394	394	394	394	394	394	394	394	394	394
Total current assets	**$20,297**	**$31,037**	**$29,651**	**$29,601**	**$26,588**	**$22,371**	**$22,371**	**$36,603**	**$65,223**	**$44,750**	**$68,390**	**$40,033**	**$63,715**	**$140,000**
Long term deposits and investment	16,232	13,542	11,613	11,120	9,400	9,400	9,400	9,400	9,400	9,400	9,400	9,400	9,400	9,400
Marketable securities	2,151	2,785	2,290	1,051	1,400	1,400	1,400	1,400	1,400	1,400	1,400	1,400	1,400	1,400
Amounts funded in respect of employee rights	14	16	16	17	17	17	17	17	17	17	17	17	17	17
Property and equipment	18	17	23	21	27	27	27	27	27	27	27	27	27	27
Total assets	**$38,712**	**$47,397**	**$43,593**	**$41,810**	**$37,432**	**$33,215**	**$33,215**	**$47,447**	**$76,067**	**$55,594**	**$79,234**	**$50,877**	**$74,559**	**$150,844**
Liabilities:														
Accounts payable and accured liablities	2,716	2,058	2,982	2,346	2,474	2,474	2,474	2,474	2,474	2,474	2,474	2,474	2,474	2,474
Deferred revenues	2,449	2,449	1,131	2,703	2,703	2,703	2,703	2,703	2,703	2,703	2,703	2,703	2,703	2,703
Advance on account of license agreement														
Related parties		46	51	55	39	39	39	39	39	39	39	39	39	39
Total current liabilities	**$5,165**	**$4,553**	**$4,164**	**$5,104**	**$5,216**	**$5,216**	**$5,216**	**$5,216**	**$5,216**	**$5,216**	**$5,216**	**$5,216**	**$5,216**	**$5,216**
Deferred revenues/Contract liabilities	13,837	11,388	10,259	11,020	10,339	10,339	10,339	10,339	10,339	10,339	10,339	10,339	10,339	10,339
Employee rights upon retirement	18	20	20	21	21	21	21	21	21	21	21	21	21	21
Provision for uncertain tax position	11	11	11	11	11	11	11	11	11	11	11	11	11	11
Other liabilities	443	313	281	306	288	288	288	288	288	288	288	288	288	288
Total liabilities	**$19,474**	**$16,285**	**$14,735**	**$16,462**	**$15,875**	**$15,875**	**$15,875**	**$15,875**	**$15,875**	**$15,875**	**$15,875**	**$15,875**	**$15,875**	**$15,875**
								26,534						
Stockholders' equity:														
Common stock	163	207	207	207	207	207	207	207	207	207	207	207	207	207
Accumulated and other comprehensive income	401	702												
Addtitional paid-in capital	75,170	99,426	99,701	99,892	100,173	100,471	100,471	126,991	173,125	175,543	230,498	233,657	237,025	240,551
Accumulated deficit	(56,496)	(69,223)	(71,050)	(74,751)	(78,823)	(83,338)	(83,338)	(95,626)	(113,140)	(136,031)	(167,346)	(198,862)	(178,548)	(105,789)
Total Equity	19,238	31,112	28,858	25,348	21,557	17,340	17,340	31,572	60,192	39,719	63,359	35,002	58,684	134,969
Total Liab & Equity	**$38,712**	**$47,397**	**$43,593**	**$41,810**	**$37,432**	**$33,215**	**$33,215**	**$47,447**	**$76,067**	**$55,594**	**$79,234**	**$50,877**	**$74,559**	**$150,844**
Shares Issued (in thousands)	13,309	14,882	17,449	17,454	17,457	17,474	17,458	20,019	25,107	27,714	29,826	31,950	32,078	32,207
Shares Out (in thousands)	13,309	14,882	17,449	17,454	17,457	17,474	17,458	20,019	25,107	27,714	29,826	31,950	32,078	32,207

Source: Company reports and Ladenburg Thalmann estimates

Oramed: Cash Flow Statement (in thousands)														
Cash flows from operating activities:	**2017A**	**2018A**	**1Q19A**	**2Q19A**	**3Q19A**	**4Q19E**	**2019E**	**2020E**	**2021E**	**2022E**	**2023E**	**2024E**	**2025E**	**2026E**
Net income (loss)	(10,480)	(12,727)	(4,302)	(8,003)	(12,075)	(16,590)	(16,590)	(12,288)	(17,514)	(22,891)	(31,315)	(31,516)	20,314	72,760
Depreciation and amortization	5	6	2	4	4	9	9	8	9	8	9	12	14	15
Exchange differences and interest on deposits	124	22	(116)	(83)	(161)	(161)	(161)							
Stock based compensation	1,575	1,547	239	422	693	925	925	1,100	1,200	1,250	1,350	1,400	1,600	1,750
Common stock issued for services	72	99	36	44	54	54	54							
Changes in assets and liabilities:														
Prepaid expenses and other current assets	39	(415)	(153)	(376)	180	180	180							
Accounts payable and accrued expenses	1,257	(612)	929	297	409	409	409							
Deferred revenue	1,520	(2,449)	(674)	1,659	978	978	978							
Liabilitiy for employee rights upon retirement	4	2		1	1	1	1							
Provision for uncertain tax position														
Other liabilities	53	(130)	(32)	(7)	(25)	(25)	(25)							
Net Cash Used in Operating Activities	**(5,831)**	**(14,657)**	**(4,131)**	**(6,015)**	**(9,672)**	**(13,950)**	**(13,950)**	**(11,180)**	**(16,305)**	**(21,633)**	**(29,956)**	**(30,104)**	**21,928**	**74,525**
Cash flows from investing activities:														
Purchase of property and equipment	(7)	(5)	(8)	(8)	(14)	(14)	(14)							
Purchase of short term deposits	(3,557)	(7,101)		(2,650)	(2,900)	(2,900)	(2,900)							
Purchase of long term deposits	(17,230)	(15,040)		(2,750)	(4,237)	(3,937)	(3,937)							
Purchase of held to maturity securities	(3,869)	(4,429)	(397)	(397)	(747)	(747)	(747)							
Proceeds from the sale of short term deposits	26,551	17,316	3,000	9,051	14,321	14,321	14,321							
Proceeds of held to maturity securities	2,417	2,257	400	1,200	2,200	2,200	2,200							
Proceeds from sale fo marketable securities	(3)	(2)												
Funds in respect of employee rights upon retirement				(1)	(1)	(1)	(1)							
Other														
Net cash provided by investing activities	**4,302**	**(7,004)**	**2,995**	**4,445**	**8,622**	**8,922**	**8,922**							
Cash flows from financing activities:														
Proceeds from issuance of common shares and warrants, n	25	21,657				61	61	25,412	44,925	1,160	53,596	1,747	1,754	1,761
Proceeds from exercise of warrants and options	1,561	997												
Net cash provided by financing activities	1,586	22,654	0	0	0	61	61	25,412	44,925	1,160	53,596	1,747	1,754	1,761
Effect of exchange rate on cash and cash equivalents	5		1	3										
Net Increase (decrease) in cash and cash equivilents	62	993	(1,135)	(1,567)	(1,050)	(4,967)	(4,967)	14,232	28,620	(20,473)	23,640	(28,357)	23,681	76,286
Cash and equivalents, beginning of period	3,969	4,996	4,996	4,996	4,996	4,996	29	14,261	42,881	22,408	46,048	17,691	41,373	117,658
Cash and equivalents, end of period	3,969	4,996	3,861	3,429	3,946	29	29	14,261	42,881	22,408	46,048	17,691	41,373	117,658

Source: Company reports and Ladenburg Thalmann estimates

APPENDIX A: IMPORTANT RESEARCH DISCLOSURES

ANALYST CERTIFICATION

I, Robert M. LeBoyer, attest that the views expressed in this research report accurately reflect my personal views about the subject security and issuer. Furthermore, no part of my compensation was, is, or will be directly or indirectly related to the specific recommendation or views expressed in this research report, provided, however, that:

The research analyst primarily responsible for the preparation of this research report has or will receive compensation based upon various factors, including the volume of trading at the firm in the subject security, as well as the firm's total revenues, a portion of which is generated by investment banking activities.

Additional information regarding the contents of this publication will be furnished upon request. Please contact Ladenburg Thalmann, Compliance Department, 277 Park Avenue, 26th floor, New York, New York 10172 (or call 212-409-2000) for any information regarding current disclosures, and where applicable, relevant price charts, in regard to companies that are the subject of this research report.

COMPANY BACKGROUND

Oramed Pharmaceuticals is developing products based on its Protein Oral Delivery technology (POD). Its lead product is an oral insulin capsule, currently in Phase 2b trials. Additional indications and products are in clinical development.

VALUATION METHODOLOGY

We value the company based on our 2026 discounted EPS, applying a discount rate of 30% with a multiple of 15X to derive our price target of $7.00 per share.

RISKS

Risks to our rating and price target include, but are not limited to:

Drug development risk. Oramed is a development stage company conducting clinical trials for its lead product. The company faces the risks of the drug development industry, including scientific, technical, clinical, and regulatory failures. As novel therapies, the drugs also face risks with reimbursement and product adoption.

Industry risk. The company faces the risks of the drug development industry, including scientific, technical, clinical, regulatory failures. As novel therapies, its products also face risks with reimbursement and product adoption.

Company risk. The company has a limited operating history and has incurred significant losses and negative cash flow operations since inception and they expect to incur losses and negative cash flows for at least the next 12 months. Their independent registered public accounting firm has expressed doubt about their ability to continue as a going concern.

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Exchange and market risk. ORMD shares trade on the NASDAQ exchange with relatively small daily volume. The company is expected to raise additional capital to fund operations before its products reach the market, which is subject to market conditions.

Legislation and policy changes. Laws for drug approval are established by Congress and administered by the FDA. Reimbursement by third-party payors often follows policies established by the Center for Medicaid/Medicare. Both agencies are divisions of the Department of

Health and Human Services, run by Commissioners appointed by the President and confirmed by the Senate. Changes in policies or political agendas could have broad effects on the environment for drug development and reimbursement.

STOCK RATING DEFINITIONS

Buy: The stock's return is expected to exceed 12.5% over the next twelve months.

Neutral: The stock's return is expected to be plus or minus 12.5% over the next twelve months.

Sell: The stock's return is expected to be negative 12.5% or more over the next twelve months.

Investment Ratings are determined by the ranges described above at the time of initiation of coverage, a change in risk, or a change in target price. At other times, the expected returns may fall outside of these ranges because of price movement and/or volatility. Such interim deviations from specified ranges will be permitted but will become subject to review.

RATINGS DISPERSION AND BANKING RELATIONSHIPS AS OF (September 11, 2019)

Rating	%	IB %
BUY	73.4	56.9
NEUTRAL	26.6	34.0
SELL	0.0	0.0

COMPANIES UNDER ROBERT'S COVERAGE

Oramed Pharmaceuticals, Inc. (ORMP)

Outlook Therapeutics, Inc. (OTLK)

COMPANY SPECIFIC DISCLOSURES

Ladenburg Thalmann & Co. Inc. makes a market in Oramed Pharmaceuticals, Inc..

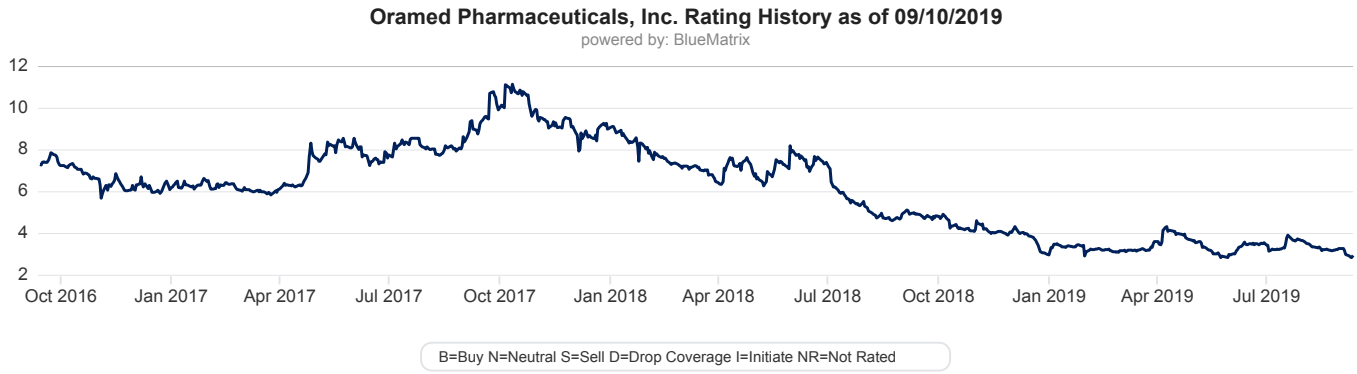
Ladenburg Thalmann & Co. Inc. expects to receive compensation for investment banking and/or advisory services from Oramed Pharmaceuticals, Inc. within the next 3 months.

Ladenburg Thalmann & Co. Inc received compensation for investment banking services from Oramed Pharmaceuticals, Inc. within the past 12 months.

Ladenburg Thalmann & Co. Inc had an investment banking relationship with Oramed Pharmaceuticals, Inc. within the last 12 months.

Ladenburg Thalmann & Co Inc. acted in an advisory capacity for Oramed Pharmaceuticals, Inc. in the last 12 months.

INVESTMENT RATING AND PRICE TARGET HISTORY



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Member: NYSE, NYSE American, NYSE Arca, FINRA, all other principal exchanges and SIPC

Additional Information Available Upon Request

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