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Oramed Pharmaceutical, Inc.

Buy

Volatility: 5

(NASDAQ: ORMP)

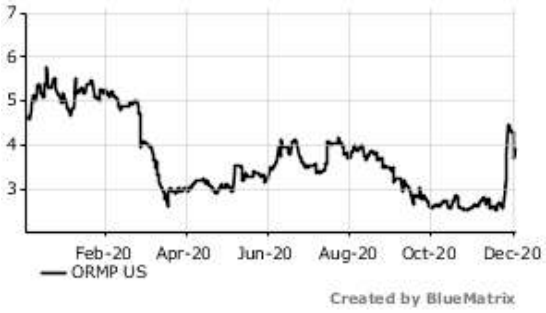
Price	$3.90
52 Week Range	($2.40 - $6.05)
Price Target	**$11.00**
Market Cap (mil)	$100.86
Shares out (mil)	23.68
3-Mo Avg Vol	418,362
Cash per share	$2.13
Total Debt (mil)	NA
Debt/Equity	NA

EPS $

Yr Aug	2020A	2021E	2022E
	Actual	Curr	Curr
Nov	(0.15)A	(0.13)E	(0.17)E
Feb	(0.21)A	(0.16)E	(0.19)E
May	(0.10)A	(0.17)E	(0.19)E
Aug	(0.13)A	(0.19)E	(0.19)E
YEAR	(0.56)A	(0.65)E	(0.75)E

Revenues (millions) $

Yr Aug	2020A	2021E	2022E
	Actual	Curr	Curr
Nov	1A	1E	1E
Feb	1A	1E	1E
May	1A	1E	1E
Aug	1A	1E	1E
YEAR	3A	3E	3E



Developing a potential game-changing oral insulin for type 2 diabetes - Initiate with a Buy, $11 PT

We are initiating coverage of Oramed Pharmaceuticals (ORMP) with a Buy rating and an $11 price target. The company has just initiated the first of 2 Phase 3 trials for ORMD-0801, a novel oral insulin capsule that could revolutionize the treatment paradigm for type 2 diabetes. Diabetes is a huge world health problem with 463M people (34M in the US alone) estimated to have the disease as of 2019, growing ~9% annually. While there are multiple options available to treat Type 2 Diabetes (T2DM), there is no option beside injectable insulin for when needed in that treatment option. We believe an effective oral insulin option like ORMD-0801 would rapidly gain significant acceptance in the T2DM population over injecting insulin. We estimate that - if approved - ORMD-0801 could reach $850M in sales by 2030, the 6th year of launch. By comparison, Eli Lilly's (LLY, NR) injectable GLP-1 agonist Trulicity (dulaglutide) is projected to hit $4.9B in WW sales in 2020, it's 6th year of launch. The 1st of 2 Phase 3 trials is already underway and we could see top line efficacy data for ORMD-0801 as soon as mid-2022, with a potential BLA filing in late 2023/early 2024. ORMP is also developing ORMD-0801 for T2DM with nonalcoholic steatohepatitis (NASH) that just started Phase 2 trials with data potentially by 1H22. Beyond ORMD-0801 the company is in early development of an ORMD-0901, an oral GLP-1 analog for T2DM, and an oral Leptin for weight loss. So with a near term potential blockbuster oral insulin, and a deep pipeline of additional oral proteins behind it, we are initiating coverage on ORMP with a Buy rating and an $11 price target based on a sum-of-the-parts based [primarily on our expectations for ORMD-0801 for T2DM. We value ORMD-0801 for T2DM at $9/share, ORMD-0801 for NASH at $1/share, and the remaining programs (ORMP-0901, oral leptin) plus cash (end-'22) at $1/share for our $11 price target.

ORMD-0801 could revolutionize treatment of T2DM. ORMD-0801 utilizes ORMP's Protein Oral Delivery (POD) technology, which is designed to protect orally delivered proteins through the stomach to be released in the lower intestine. We believe that an effective oral version of injectable insulin would grab significant market share, and could potentially replace injected insulin altogether.

Diabetes a significant and growing worldwide health crisis. Once considered a "first-world" problem due to rising obesity rates, diabetes has seen dramatic growth in formerly "third-world" countries as they advance and are better able to feed their populations. The International Diabetes Foundation (IDF) estimates that diabetes will grow 143% in Africa and 96% in the Middle East & North Africa by 2045.

ORMD-0801 for T2DM already started the 1st Phase 3 trial. ORMP started screening patients in the 1st of 2 ORMD-0801 confirmatory trials in November. The clinical trials are modeled closely on their successful Phase 2 trials, which we believe sets them up for the best chance of success. The 26 week efficacy endpoint for the 1st trial could be as soon as 1H22, with the 2nd Phase 3 trial expected to run ~6 months behind the 1st.

ORMD-0801 for NASH targets another significant market. NASH is the most severe form of Nonalcoholic Fatty Liver Disease (NAFLD), which is the most common chronic liver condition in the US that affects approximately 25% of Americans. According to the American Liver Foundation, about 20% of those with NAFLD develop NASH, representing ~20M Americans.

Emisphere $1.8B acquisition shows big pharma paying attention. Novo Nordisk (NOVO.B-DK, NR) recently acquired Emisphere for $1.8B (all in) which brings into stark relief the interest level at larger pharma for novel biologic delivery platforms such as ORMD-0801. Novo Nordisk also uses Emisphere's Eligen SNAC technology in their oral GLP-1 inhibitor Rybelsus (semaglutide).

Initiating with a Buy rating, $11 price target. Our price target is based on a sum-of-the-parts based [primarily] on our expectations for ORMD-0801 for T2DM. We value ORMD-0801 for T2DM at $9/share, ORMD-0801 for NASH at $1/share, and the remaining programs (ORMP-0901, oral leptin) plus cash (end-'22) at $1/share for our $11 price target.

Company Description and Overview

Oramed (ORMP) is a pharmaceutical company developing an oral insulin capsule for the treatment of diabetes mellitus as well as the use of orally ingestible capsules or pills for delivery of other polypeptides. The company has developed their novel Protein Oral Delivery (POD) technology, which is designed to protect orally delivered proteins from the acidic gut environment and from detrimental enzymatic activity within the gastrointestinal tract while enhancing their absorption across the intestinal wall by utilizing specialized protease inhibitors. Based on data from successful Phase 2 trials, ORMP recently initiated the first of two Phase 3 clinical trials for ORMD-0801 to treat type 2 diabetes mellitus (T2DM) patients. The company also recently initiated a pilot study utilizing ORMD-0801 to treat nonalcoholic steatohepatitis (NASH). Additionally, the company is exploring an oral capsule form of Glucagon-like peptide-1 (GLP-1) that is in early Phase 1/2a bioavailability trials.

The recent acquisition by Novo Nordisk (NOVO.B-DK, NR) of Emisphere for $1.8B brings into stark relief the interest level at larger pharma for novel biologic delivery platforms such as ORMD-0801. Emisphere's Eligen SNAC technology is used in Novo Nordisk's oral GLP-1 inhibitor Rybelsus (semaglutide), the first FDA approved oral GLP-1. We believe that ORMP's platform represents a next-generation improvement over the Eligen SNAC delivery technology.

Figure 1: Upcoming Potential Catalysts

Event	Expected Timing
ORMD-0801 Phase 3 #1 (ORA-D-13-1) started	Now
ORMD-0801 oral insulin for NASH Phase 2 trial start	Now
ORMD-0801 Phase 3 #2 (ORA-D-13-2) start	early CY21
ORMP-0901 oral GLP-1 analog Phase1/2a data	mid-CY21
ORMD-0801 Phase 3 #1 (ORA-D-13-1) efficacy data	1H CY22

Source: Company reports; AGP estimates

Valuation

We value ORMP at $11/share based on a sum-of-the-parts primarily due to our expectations for ORMP-0801 for Type 2 Diabetes (T2DM). We anticipate ORMP receives FDA/EMA approval for ORMP-0801 for T2DM in 2HFY24 (August FY), with a launch in 1HFY25 with WW sales reaching $850M by FY30. We place a 4x multiple on WW sales, discounted back 8 years at 35% for our $9/share value. We anticipate ORMD launches ORMD-0801 for NASH in FY27 with US sales reaching $300M by FY30. We place a 4x multiple on US sales, discounted back 8 years at 50% for our $1.00/share value. We value the remaining technology at ORMP (ORMP-0901 oral GLP-1 analog, Oral leptin for weight loss) and cash (end FY22E) at $1.00/share for our $11/share valuation.

Figure 2: Sum-of-the-Parts Analysis

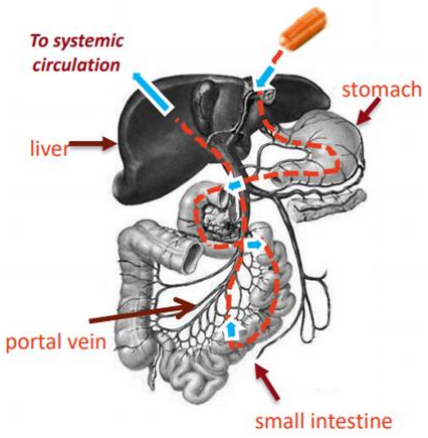
Sum-of-the-parts valuation		
Segment	Valuation (000's)	Per share value
ORMD-0801 for T2D	$395,497	$9.00
ORMD-0801 for NASH	$46,822	$1.00
Cash (end-'22E) & other	$47,176	$1.00
SUM	$489,495	**$11.00**
Fully diluted shares out '22E (000)		43,372

Source: AGP estimates

ORMD-0801

ORMD-0801 is the company's lead product candidate, which is an orally ingestible insulin capsule that allows for insulin to travel from the gastrointestinal tract via the portal vein to the bloodstream. ORMP has completed a successful Phase 2b clinical study to demonstrate the efficacy of ORMD-0801 in 298 patients with T2DM and has initiated one of two Phase 3 clinical trial protocols for T2DM and we expect the company to begin the second, confirmatory Phase 3 trial in 1H21. The company also began a clinical study for ORMD-0801 in patients with T2DM and expects to release the 26 week efficacy data in 1H22 (final data late 2022). ORMD-0801 is delivered through the company's Protein Oral Delivery (POD) technology, which is designed to protect orally delivered proteins from the acidic gut environment and from detrimental enzymatic activity within the gastrointestinal tract and enhance their absorption across the intestinal wall by utilizing specialized protease inhibitors. Oral delivery is expected to offer significant benefits over injection, including being delivered first to the liver resulting in better blood glucose control, reduced hypoglycemia, reduced hyperglycemia, and no weight gain.

Figure 3: Oral insulin an improved delivery method over injection



Source: company reports

Upcoming Clinical Trials

ORMD met with the FDA and received feedback in October about their two Phase 3 study protocols and have since initiated one of their two Phase 3 trials. The protocols will be separated into ORA-D-013-1 and ORA-D-013-2. The ORA-D-013-1 study began screening patients in November for T2DM patients with inadequate glycemic control who are currently on 1, 2 or 3 oral glucose-lowering agents.

ORA-D-013-1 (Phase 3 #1)

This US-based study will recruit 675 patients with inadequate glycemic control who are currently on 1, 2 or 3 oral glucose-lowering agents (Metformin, DPP-4 inhibitor, SGLT-2 inhibitor, thiazolidinedione, or sulfonylurea for 3 months prior to screening) at 75 US sites. Patients will be randomized 1:1:1 in this double-dummy study into cohorts of: 8 mg ORMD-0801 once-daily at night and placebo 45 mins before breakfast; 8 mg ORMD-0801 twice-daily, at night and 45 mins before breakfast; and placebo twice-daily, at night and 45 mins before breakfast. The primary endpoint of the study is to evaluate the efficacy of ORMD-0801 compared to placebo in improving glycemic control as assessed by A1c, with a secondary efficacy endpoint of assessing the change from baseline in fasting plasma glucose at 26 weeks.

Figure 4: ORA-D-013-01 trial design

Phase 3 #1: ORA-D-013-01; ORMD-801 vs Placebo in T2D	
Aim	Interventional trial, safety & efficacy of 801 vs pbo in T2D
Design	3-arm design; 75 US sites; 21 day screen-in; QD; BD; Pbo arms: 26 wk treatment followed by 26 wk safety extension (pbo subjects get QD or BD active dose in ext)
Dosing	QD arm: 1 x 8mg at night before bedtime; BD arm: 1 x 8mg pre-breakfast, 1 x 8mg before bed; Placebo: same as BD arm
Endpoints	1': mean change in A1C baseline to 26 wks (visit 6) 2': mean change from baseline in fasting plasma glucose at 26 weeks (Visit 6); Analyzed using a linear mixed model (similar to the primary)
Patients	N = 675 M/F adults; T2D (type 2 diabetes) & inadequate control on up to 3 oral agents (Metformin, DPP-4 inhibitor, SGLT-2 inhibitor, thiazolidinedione, or sulfonylurea for 3 mo prior to screening)
Clinicaltrials.org	https://clinicaltrials.gov/ct2/show/NCT04606576?term=oramed&phase=2&draw=2&rank=1
Results	26 wk efficacy results mid-22, final data 4Q22/1Q23

Source: clinicaltrials.gov, company reports

ORA-D-013-2 (Phase 3 #2)

This international study will include T2DM patients with inadequate glycemic control who are managing their condition with either diet alone or with diet and metformin monotherapy. A total of 450 patients will be recruited through 36 sites in the U.S. and 25 sites in Western Europe and Israel. Patients will be randomized 1:1 into two cohorts dosed with: 8 mg ORMD-0801 at night; and placebo at night. The primary endpoint is to evaluate the efficacy of ORMD-0801 compared to placebo in improving glycemic control as assessed by A1c over a 26-week treatment period, with a secondary efficacy endpoint of assessing the change from baseline in fasting plasma glucose at 26 weeks.

Figure 5: ORA-D-013-02 trial design

Phase 3 #2: ORA-D-013-02; ORMD-801 vs Placebo in T2D	
Aim	Interventional trial, safety & efficacy of 801 vs pbo in T2D
Design	2-arm design; QD vs pbo arm; 36 US & 25 ex-US sites
Dosing	1 x 8mg before bedtime vs. placebo
Endpoints	1': mean change in A1C baseline to 26 wks (visit 6) 2': maintain glycemic control over 52 wk full treatment period
Patients	N = 450 M/F adults; T2D (type 2 diabetes) & inadequate control on diet control alone or diet control & metformin monotherapy
Results	26 wk efficacy 1H22; final extension data mid-23

Source: company reports

Completed Clinical Trials

Phase 2b – Type 2 Diabetes Mellitus (T2DM)

The company's Phase 2b study was a 12-week (90-day), double-blind, randomized, multi-center trial designed to evaluate the safety and efficacy of ORMD-0801 as a treatment for patients with T2DM. The primary efficacy endpoint was a reduction in Hemoglobin A1c (A1c, also known as HbA1c, a key clinical measure of blood sugar control) at Week 12.

Cohort A included 269 patients who were treated with a dose-increasing approach: 16 mg initial dose, titrated to 24 mg per dose, and then titrated to 32 mg per dose. Patients were randomized into three groups to assess dosing frequency: once-daily (32mg per day), twice-daily (64mg per day), thrice-daily (96mg per day). There was a corresponding placebo for each treatment arm. 209 patients completed treatment to the 12-week endpoint and were included in the data analysis (24 subjects did not complete the full 12 weeks of treatment). In addition, due to the evidence of treatment-by-center interaction, two sites, 36 patients (13.4% of enrolled subjects) were excluded from the statistical analysis.

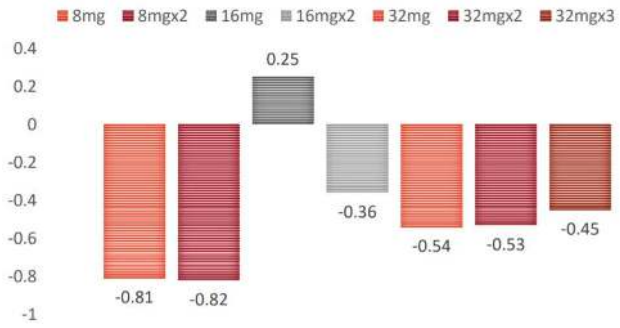
Figure 6: Phase 2 T2DM 12-week trial design

Phase 2b: ORMP-0801 12-week (90-day) HbA1c Study	
Aim	Efficacy & safety in lowering HbA1c over 12 weeks
Design	90 day, 2x blind, random, 2 cohorts (A & B)
Dosing	Cohort A: dose escalation 16mg to 24mg to 32mg, then into 1 of 3 groups: 1x/day (32mg TDD). 2x/day (64mg TDD), 3x/day (96mg TDD) vs placebo Cohort B: 8mg, 16mg, 32mg dose vs. placebo
Endpoints	Both Cohorts 1': Change in HbA1c at 12 weeks (90 days) Both Cohorts 2': Fasting glucose plasma (FPG); Post-prandial glucose during mixed meal tolerance test (MMTT); weight, etc
Patients	N = 269 T2DM pts enrolled, 209 completed to 12 week endpoint, 36 excluded from final analysis due to anomalies
Safety	No SAE's in either Cohort
Results 11/2019 & 2/2020	Cohort A 1': 1x/day reduced HbA1c 0.54% (p=0.036) & 2x/day reduced HbA1c 0.53% (p=0.042) were stat sig (3x/day was not) Cohort B 1': 8mg 1x/day reduced HbA1c 0.81%

Source: company reports

Once-daily ORMD-0801 achieved a reduction in mean A1c of 0.60% from baseline, or a reduction 0.54% adjusted for placebo (p value = 0.036). Twice-daily ORMD-0801 achieved a reduction in mean A1c of 0.59% or 0.53% adjusted for placebo (p=0.042). Thrice-daily dosing did not result in a statistically different reduction in mean A1c.

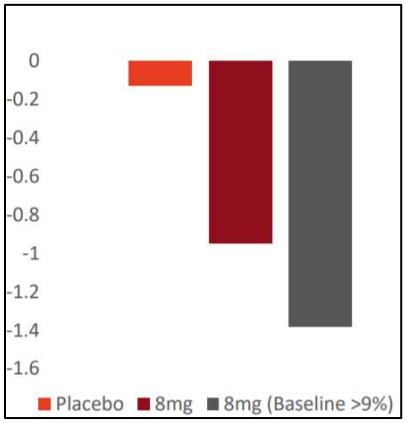
Figure 7: HbA1c (%) Change From Baseline in Cohort A Patients



Source: Company reports

Cohort B patients in the trial treated with 8 mg of ORMD-0801 once-daily achieved an observed mean reduction of 1.29% from baseline and a least square mean reduction of 0.95% from baseline, or 0.81% adjusted for placebo (p=0.028). Patients who had HbA1c readings above 9% at baseline and received 8 mg of oral insulin once-daily, experienced a 1.26% reduction in HbA1c by week 12. Patients dosed once-daily at 16 mg and twice-daily at 16 mg did not show statistically significant reductions in A1c. Treatment with ORMD-0801 at all doses demonstrated a positive safety profile, with no serious drug-related adverse events and with no increased frequency of hypoglycemic episodes or weight gain compared to placebo. The primary efficacy endpoint was a reduction in HbA1c at week 12. Data for both cohorts is shown below and non-placebo adjusted data for patients treated with ORMD-0801 at 8 mg/day is shown below.

Figure 8: HbA1c Change from Baseline at Week 12 (8 mg/day)



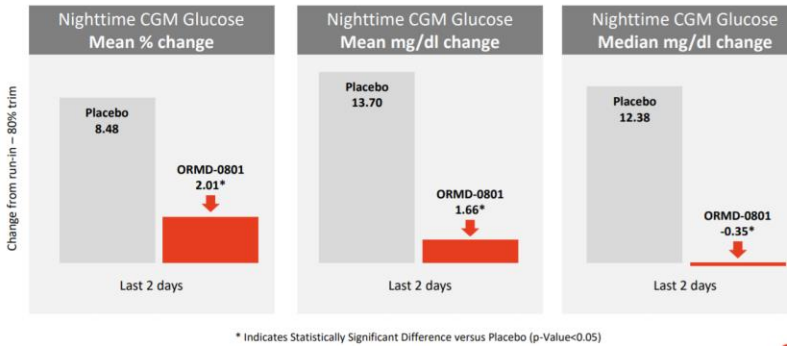
Source: Company reports

Phase 2 – T2DM

In 2016, the company completed its Phase 2 study using ORMD-0801 to treat patients with T2DM. The Phase 2 trial enrolled 180 patients whose diabetes was not adequately managed through proper diet and medication in a double blind, 28-day randomized study. The primary objective of the study was to evaluate the nighttime glucose lowering effect and safety of ORMD-0801 compared to a placebo. Other secondary and exploratory objectives of the study included evaluating the effect of ORMD-0801 on mean 24-hour glucose, fasting glucose, and daytime glucose.

In the study, the mean nighttime glucose showed a significant difference in mean change from run-in, with a 13.70 mg/dL change for the placebo vs. a 1.66 mg/dL change for the pooled ORMD-0801 arms (p=0.0117). The mean 24-hour glucose also showed a significant difference with a mean change of 13.26 mg/dL for the placebo vs. a mean change of -0.32 mg/dL for ORMD-0801 (p<0.0001). The mean fasting glucose showed a significant difference in mean change from run-in with a 15.95 mg/dL change for the placebo vs. a mean change of -0.41 mg/dL for ORMD-0801 (p<0.0001). The mean daytime CGM glucose showed a significant difference in mean change from run-in with a 11.88 change for the placebo vs. 0.88 for ORMD-0801 (p=0.0010).

Figure 9: ORMD-0801 Reached Every Primary Endpoint in Phase 2 Study

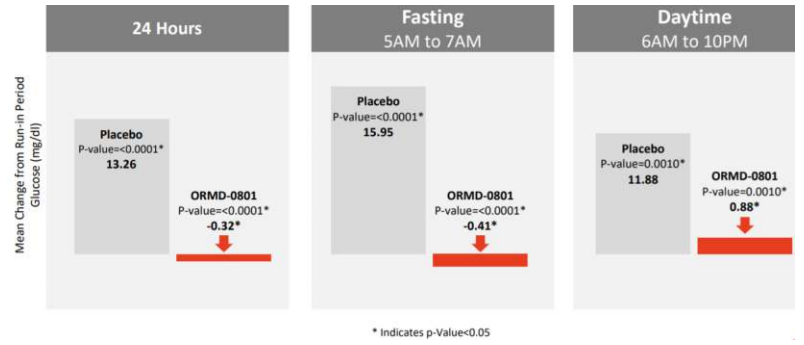


Source: Company reports

There was also a statistically significant difference in change in HbA1c at Day 29 with a 0.20% change for the placebo vs. a -0.01% change for ORMD-0801 (p= 0.0149). Due to the kinetics of change of HbA1c, a four week study is insufficient to fully appreciate the potential positive impact of ORMD-0801 on HbA1c, according to management.

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. ORMD-0801 did not show a significant difference in change in morning fasting serum insulin, C-Peptide, or triglycerides.

Figure 10: ORMD-0801 Reached Secondary Endpoints from CGM Parameters in Phase 2 Study

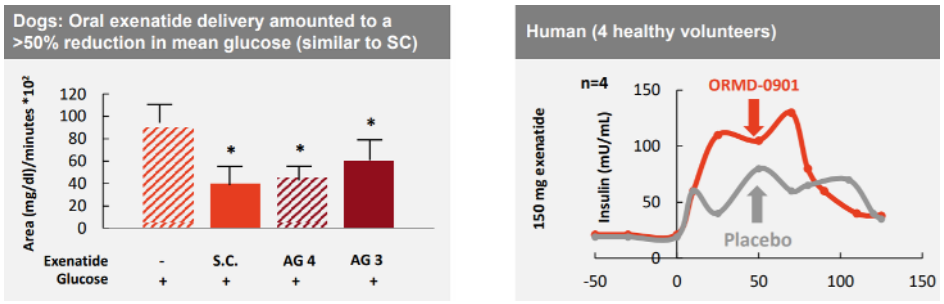


Source: Company reports

ORMD-0901 - Oral GLP-1 for T2DM

ORMD-0901 is the company's oral glucagon-like peptide-1 (GLP-1) capsule which is currently marketed in an injectable form. GLP-1 is an incretin hormone, which stimulates the secretion of insulin from the pancreas. The company completed their Phase 1 pharmacokinetics trial in February 2019 and expects to release data in 3Q20. ORMP is also planning to submit an IND to the FDA to begin further clinical studies.

Figure 11: ORMD-0901 human Insulin Levels & dogs mean glucose levels



Source: Company reports

ORMD-0801 Phase 2 trial in nonalcoholic steatohepatitis (NASH)

ORMP recently initiated a Phase 2 trial of ORMD-0801 oral insulin to reduce liver fat content in Type 2 diabetes patients with nonalcoholic steatohepatitis (NASH). ORMP has screened the first patients in this global trial at a US site. The study is being conducted in 3 US, 3 EU, and 2 Israeli clinical sites. The trial will measure liver fat content MRI-Proton Density Fat Fraction from baseline to week 12, percent change in liver fibrosis as measured by FibroScan Elasticity in units of kilo Pascals (kPa), and percent change in liver steatosis as measured by FibroScan Controlled Attenuation Parameter (CAP) in units of dB/meter.

Figure 12: ORMD-0801 in NASH Phase 2 study

Phase 2: open label trial of ORMP-0801 in diabetics with NASH	
Aim	Safety & potential of oral insulin to reduce liver fat content in T2DM patients with Nonalcoholic Steatohepatitis (NASH)
Design	2-arm, Open label, non-random, single group
Dosing	ORMD-0801 8mg 1x/day and ORMD-0801 8mg 2x/day (morning & evening) for 12 wks
Endpoints	1': Treatment related AE's at week 12; 2': % change liver fat, liver fibrosis & liver steatosis at week 12
Patients	N = 40 T2DM M&F patients with NASH
Clinicaltrials.org	https://clinicaltrials.gov/ct2/show/NCT04616014?term=oramed&draw=2&rank=4
Results	Anticipated mid-2022

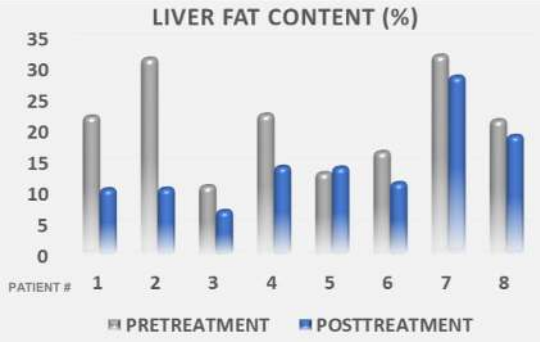
Source: clinicaltrials.gov, company reports

Pilot Study – T2DM Patients with NASH

ORMP is conducting a 40-patient study to determine the safety and early effects of oral insulin in T2DM patients with NASH, the most severe form of non-alcoholic fatty liver disease (NAFLD). The study has already enrolled and treated eight patients. Patients were treated with a 2-week placebo run-in phase followed by 12 weeks of once-daily 16mg ORMD-0801.

The treatment demonstrated no serious adverse events and induced an observed mean reduction of 6.9±6.8% in liver fat content (p=0.035), and the relative reduction was 30% as measured by MRI-PDFF.

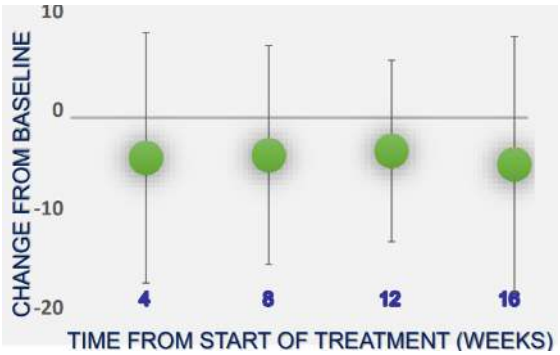
Figure 13: Mean Reduction of Liver Fat Content was Statistically Significant



Source: Company Poster

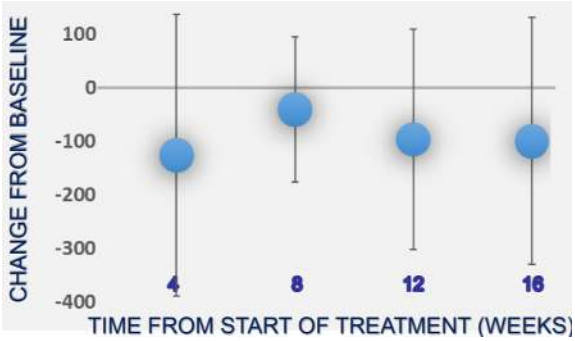
In parallel, concentrations of gamma-glutamyltransferase (GGT), a key marker of chronic hepatitis, were significantly lower after 12 weeks of treatment as compared to baseline: -14.6±13.1 U/L (p=0.008), as were fasting insulin levels: -96.5±206.0 pmol/L (p=0.035).

Figure 14: GGT (U/L) Significantly Lower After 12 Weeks of Treatment



Source: Company Poster

Figure 15: Fasting Insulin (pmol/L) Significantly Lower After 12 Weeks of Treatment

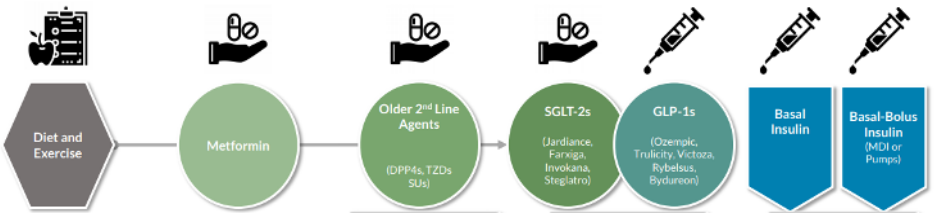


Source: Company Poster

Market Opportunity in Diabetes and Benefits of Oral Insulin

According to the American Diabetes Association (ADA), about 34.2M Americans had diabetes in 2018 with 7.3M of those being undiagnosed. Approximately 1.5M people are diagnosed with diabetes in the US every year. Additionally, the International Diabetes Foundation (IDF) estimates that as of 2019 463M adults suffer from diabetes around the world. Those over the age 65 make up the majority of diabetes cases in the US, in fact over 21% of Americans over the age of 65% have been diagnosed with diabetes, according the Center for Disease Control and Prevention (CDC). T2DM also accounts for approximately 90% of all diabetes cases. Diabetes is also associated with numerous comorbidities, which can complicate treatment and lead to worsening outcomes for patients. In fact, according to the Medical Expenditure Panel Survey, most adult diabetes patients have at least one comorbidity and as many as 40% of patients have as many as three comorbidities. The most common comorbidities among diabetes patients include hypertension, obesity, hyperlipidemia, chronic kidney disease and NAFLD among others.

Figure 16: Diabetes treatment algorithm



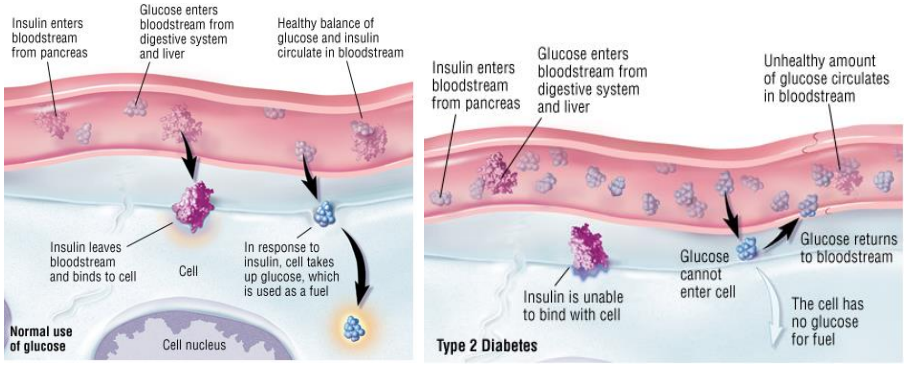
Source: Seagrove partners

The standard of care treatment for diabetes remains metformin and insulin injections. Insulin injections cause cells to absorb more glucose from the bloodstream and as a result injecting excess insulin or injecting at the wrong time can lead to a drop in blood sugar, which can cause seizures and loss of consciousness in severe cases. Additionally, over time the dose and number of injections typically increases, which can cause more complications as patients forget to inject themselves or inject themselves too frequently. Therefore, we believe that ORMD-0801 and ORMD-0901 represent a potentially efficacious and easier to administer option for Diabetes patients. ORMD-0801 may also provide mechanistic advantages described below.

Mechanism of Action of Insulin

Insulin secreted from pancreatic β-cells promotes glucose disposal through stimulation of glucose uptake and subsequent intracellular oxidative and nonoxidative metabolism in insulin-sensitive tissues and organs. Ingestion of a meal containing carbohydrates, elicits a prompt rise in insulin and a decrease in glucagon concentrations, both potentiated by intestinal L cell-secreted GLP-1. In parallel, intestinal K cell-secreted gastric inhibitory polypeptide (GIP) stimulates glucagon release.

Figure 17: Insulin in T2DM



Source: Harvard health

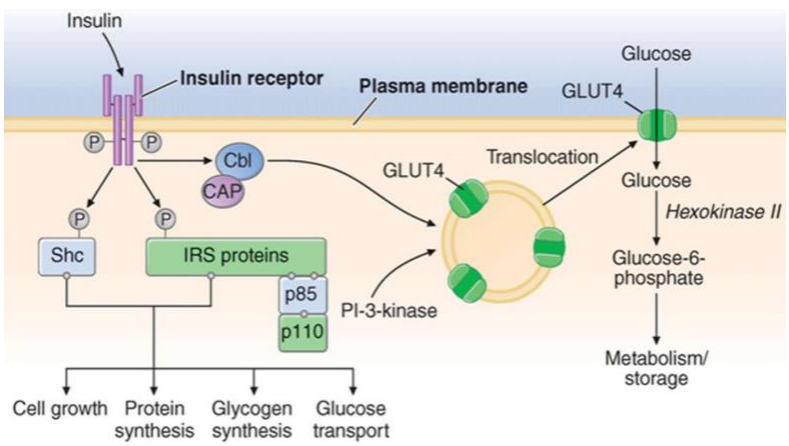
From the portal vein, insulin passes through the liver, where up to 80% is extracted on first-pass, giving rise to a significantly (2.5- to 3-fold) higher insulin concentration in the portal vein as compared to the systemic circulation. This portal–peripheral gradient is maintained both in the fasting state (basal) and postprandial state, leaving the liver constantly exposed to significantly higher insulin concentrations as compared with other organs/tissues. The fraction of insulin extracted by the liver is dynamic, varying in accordance with metabolic demands to maintain optimal peripheral insulinization, while also securing sufficient insulinization of the liver.

Oral Delivery Could Increase Uptake of Insulin

This process is further reinforced by insulin's short half-life of 4-6 min in the circulation, which simplifies fine-tuning of insulin release into the systemic circulation, avoiding peaks and troughs in insulin concentrations and in glycemic excursions. The liver maintains plasma glucose concentrations within a narrow range, by sequestering ingested glucose

after a meal (postprandial) and releasing glucose in response to low glucose levels (e.g., fasting state). Fasting hyperglycemia is the sequela of increased or unconstrained hepatic glucose release resulting from insufficient insulin secretion in T1DM or in the context of relative hepatic insulin resistance in T2DM, whereas postprandial hyperglycemia is mainly due to disproportionately high endogenous glucose production resulting from its reduced suppression and/or decreased glucose clearance in tissues. Thus, sufficient hepatic insulinization is indispensably needed to suppress hepatic glucose production and to reduce both fasting and postprandial hyperglycemia. Hepatic glucose production is discerningly sensitive to changes in insulin levels and thus can be controlled by a minute increase in hepatic insulinization.

Figure 18: Insulin Mechanism of Action



Source: Ingle, Pravinkumar. Current Trends in Pharmacological Treatment of Type II Diabetes Mellitus. International Journal of Pharma Research & Review..(2018); 7(1): 1-15.

Oral insulin could have therapeutic advantages in the management of hepatic glucose production, via its potential to mimic the natural route of endogenous insulin secreted by the pancreas. After reaching the portal vein, the oral insulin is directly delivered to the liver and then to the peripheral circulation, thereby reestablishing the physiologic portal–peripheral insulin gradient and providing for adequate hepatic insulinization.

In contrast, parenteral or inhaled insulin is absorbed directly into the peripheral circulation without initial hepatic extraction and fails to restore the portal-peripheral insulin gradient and physiologic hepatic insulinization. In addition, these routes expose peripheral targets to greater insulin concentrations relative to the liver, predisposing patients to a high risk of hypoglycemia, and the deleterious effects of hyperinsulinemia.

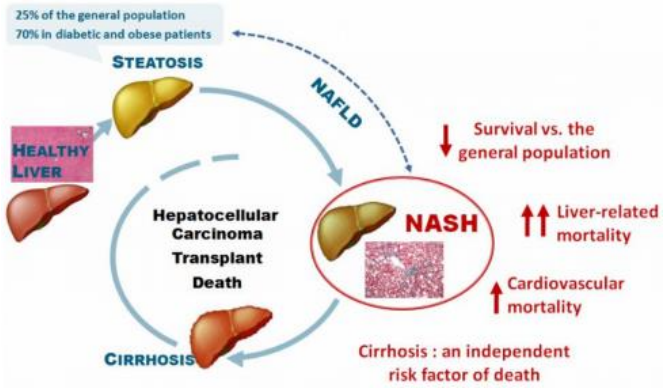
GLP-1 Mechanism of Action

GLP-1 stimulates insulin secretion after an oral glucose load via the incretin effect. Incretins are a group of metabolic hormones that stimulate a decrease in blood glucose levels. The incretin effect is the increased stimulation of insulin secretion elicited by oral as compared with intravenous administration of glucose under similar plasma glucose levels. Patients with type 2 diabetes have been demonstrated to exhibit an almost total loss of incretin effect. Therefore, it is believed that a deficient incretin effect could be due to impaired secretion of the incretin hormones as well as impaired effects of the islet function.

Market Opportunity in Nonalcoholic steatohepatitis (NASH)

NASH is the most severe form of Nonalcoholic Fatty Liver Disease (NAFLD), which is the most common chronic liver condition in the US that affects approximately 25% of Americans. According to the American Liver Foundation, about 20% of those with NAFLD develop NASH. NAFLD is characterized by excess fat storage in liver cells, which impedes proper function. NASH is when the liver experiences inflammation, which can lead to fibrosis, or scarring and possibly progress to cirrhosis.

Figure 19: Nonalcoholic Fatty Liver Disease (NAFLD) cycle



Source: Company Poster

A meta-analysis in the journal Medicine by Dr. Wenjie Dai, et al. demonstrated that approximately 60% of T2DM patients suffer from NAFLD, therefore we believe that over 20M Americans with T2DM could also have NASH, and over 250M worldwide.

Hefei Tianhui Incubator of Technologies (HTIT) License

ORMP entered into a license agreement with Hefei Tianhui Incubator of Technologies (HTIT) in 2015, granting HTIT an exclusive commercialization license in China, Macau and Hong Kong, for ORMD-0801. According to the license agreement, HTIT must pay royalties of 10% of net sales in China, Macau and Hong Kong, and an aggregate of $37.5M to ORMP. $3M of the $37.5M was payable immediately, $8M will be paid subject to ORMP entering into certain agreements with certain third parties, and $26.5M will be paid once the company reaches certain milestones and conditions. Additionally, the company issued 1.2M shares for $12M in 2015 to HTIT. If ORMP does not meet certain conditions, the royalty rate may be reduced to a minimum of 8%. Following the final expiration of ORMP's patents covering ORMD-0801 in China, Macau and Hong Kong in 2033, the Royalties rate may be reduced, under certain circumstances, to 5%.

The royalty payment obligation will last from the first commercial sale of ORMD-0801 until either, the later of the expiration of the last-to-expire licensed patents in China, Macau and Hong Kong; or 15 years after the first commercial sale. As of May 31, 2020, ORMP has received $20.5M in milestone payments.

Novo Nordisk acquisition of Emisphere for $1.8B sets the bar

Novo Nordisk (NVO, NC) recently acquired Emisphere Technologies for their oral delivery technology, Eligen SNAC, for $1.8B (all in). Novo Nordisk has been using Eligen for their GLP-1 receptor agonist Rybelsus (semaglutide) and paying royalties associated with product sales. Eligen can improve bio-availability through an increase in the rate of absorption of peptides, proteins, oligosaccharides and oligonucleotides as well as small molecules such as GLP-1, insulin, calcitonin, B12, ibandronate, heparin as well as others. Eligen achieves this through passive transcellular transport; once the drug and paired carrier leave the gastrointestinal lumen and reach the intracellular space, they disassociate, leaving the drug free to pass directly to the circulation and exercise its intended pharmacological action and the carrier is then eliminated through normal secretion pathways, according to Emisphere.

ORMP's Protein Oral Delivery (POD)has been designed to protect orally delivered proteins from detrimental enzymatic activity within the gastrointestinal (GI) tract and to enhance their absorption across the intestinal wall. The active protein is encapsulated in a capsule with a protective coating that remains intact in the most acidic segments of the gut, as well as enzymatic support provided by specialized protease inhibitors which protect the insulin in the protease-rich small intestine. Drug availability to the small intestine is boosted by an absorption enhancer that facilitates protein passing across the intestinal barrier. POD works through the combination of preventing protein-drug breakdown in the GI tract and promoting drug crossing the small intestine,

.

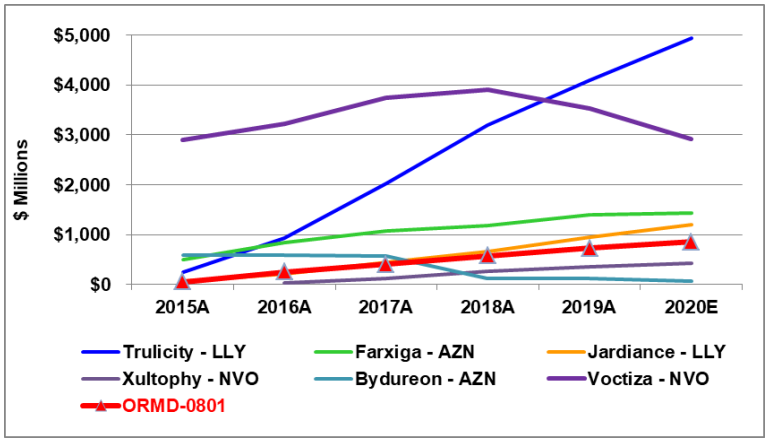
Because Eligen enhances absorption without a capsule, it requires patients to take the treatment 30 minutes prior to eating a meal. ORMP's technology does not have the same constraint and operates through a separate mechanism of action that we believe will be more effective.

When Novo Nordisk first attempted a Phase 2 study of oral basal insulin compared to subcutaneous injection, there was found to be no difference in glycemic control. However, given their pipeline of insulin products and acquisition of Emisphere, we believe that Novo Nordisk may use Eligen for the development of their own oral insulin delivery product.

Launch Expectations

We anticipate that ORMD-0801 for T2DM gets US & EMA approval in 2H24 with an early 2025 launch starting at $50M in its first year, which we conservatively project growing to $850M in 2030. We have compared our launch expectations for ORMD-0801 for T2DM with 6 other diabetes treatments, including SGLT2 & GLP-1 compounds. See our comparator launch trajectories below.

Figure 20: Launch Projections



Source: Company reports, AGP estimates

Select Company Officers

Nadav Kidron, Esq, CEO. Mr. Kidron co-founded ORMP in 2006 and has served as CEO throughout his tenure. Prior to ORMP, Mr. Kidron co-founded Entera Bio as a joint venture formed by Oramed and DNA Biomedical Solutions. Mr. Kidron holds a bachelor's degree in law and an international master's in business administration, both from Bar-Ilan University in Israel. Mr. Kidron is a fellow of the Merage Business Executive Leadership Program and a member of the Israeli Bar Association.

Avi Gabay, CFO. Mr. Gabay joined ORMP in 2019 as CFO. From 2015 until joining ORMP, Mr. Gabay served as a corporate controller at Orcam Technologies Ltd. Previously, Mr. Gabay provided economic services in the advisory department of KPMG Israel, and worked in the tax department of the law firm, Gornitzky & Co. Mr. Gabay holds a bachelor's degree in law and accounting from Tel-Aviv University and is a certified public accountant in Israel and a member of the Israeli Bar Association.

Miriam Kidron, PhD, CSO. Dr. Kidron serves as Chief Scientific Officer ORMP, which she co-founded in 2006. Dr. Kidron is a pharmacologist and biochemist, who earned her PhD in biochemistry from the Hebrew University of Jerusalem. For about 20 years, Dr. Kidron was a senior researcher in the Diabetes Unit at Hadassah-Hebrew University Medical Center in Jerusalem, Israel, earning the Bern Schlanger Award for her work on diabetes research. Dr. Kidron was formerly a visiting professor at the Medical School at the University of Toronto and is a member of the American, European and Israeli Diabetes Associations.

Roy Eldor, M.D., Ph.D., Chief Medical Advisor. Dr. Eldor serves as Chief Medical Advisor of Oramed Pharmaceuticals, which he joined in 2016. Dr. Eldor is an endocrinologist, internist and researcher and is currently Director of the Diabetes Unit at the Institute of Endocrinology, Metabolism & Hypertension, Tel-Aviv Sourasky Medical Center. He previously served as Principal Scientist at Merck Research Laboratories, Clinical Research – Diabetes & Endocrinology. Prior to that, he served as a senior physician in internal medicine at the Diabetes Unit in Hadassah Hebrew University Hospital, Jerusalem, Israel and the Diabetes Division at the University of Texas Health Science Center in San Antonio.

Harold Jacob, MD. CMO. Dr. Jacob currently serves as Chief Medical Officer of NanoVibronix. Previously, Dr. Jacob was Director of Medical Affairs at Given Imaging and was instrumental in the development and launch of the Given Imaging Pillcam. Dr. Jacob has patented and licensed a number of medical devices. He is Board Certified in Internal Medicine and Gastroenterology and is Director of Advanced Gastrointestinal Endoscopy at Hadassah Medical Center, Jerusalem.

Major Risks

Exogenous events could impact our outlook. We believe pharmaceutical companies have the least control over competitive, political, and regulatory risks. Although we have incorporated competitive assumptions into our forecasts, there may be other risks beyond the scope of our analysis. Changes in the drug reimbursement system, as well as any political or regulatory amendments, may significantly influence the earnings power of these companies.

Actual clinical results and the FDA's conclusions may deviate from expectations. Many of our assumptions are based on a review of incomplete clinical trial data available in the public domain. Often, our conclusions are drawn from early stage data, which may not be reflected by pivotal studies. Furthermore, the FDA's conclusions may not coincide with our own, materially changing our revenue and earnings assumptions.

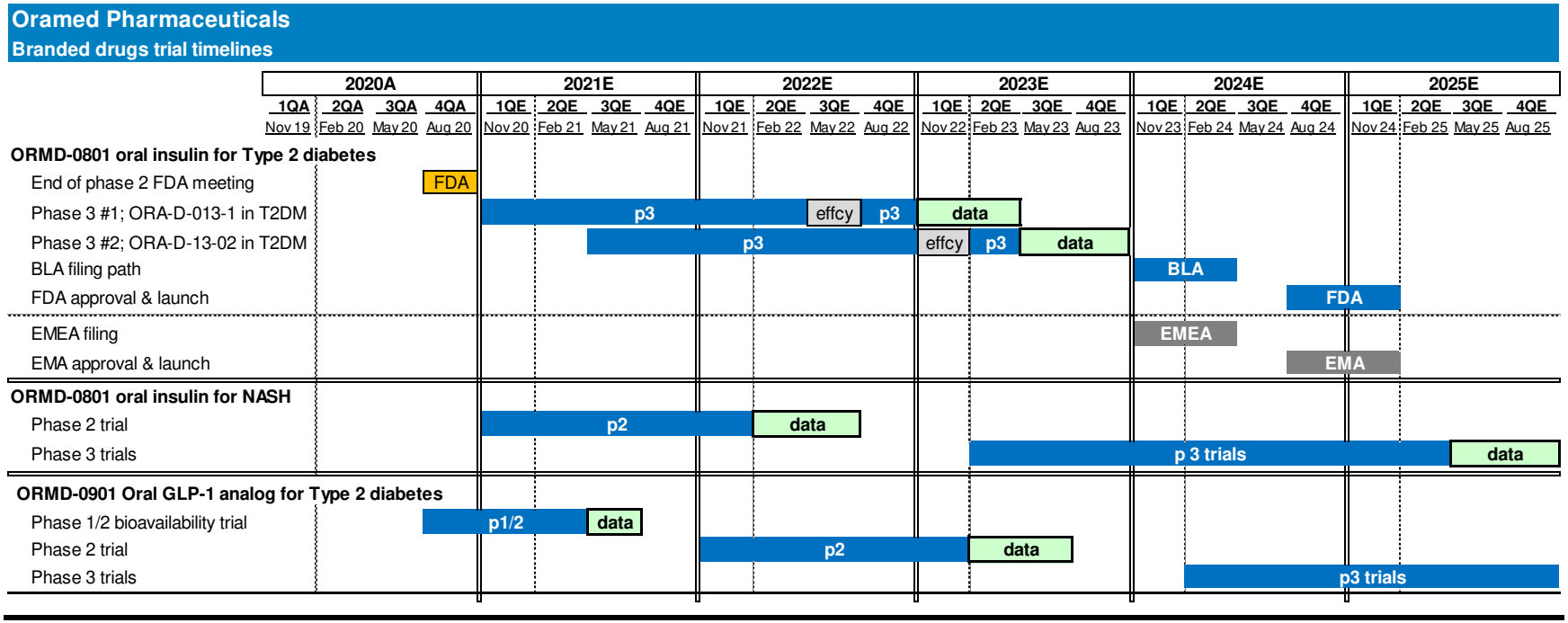
Compliance issues, product recalls, and other mandates by regulatory authorities could materially change our expectations. Regulatory compliance issues, ranging from accounting irregularities to defective manufacturing practices, could materially change our assumptions and earnings outlook. Unanticipated product recalls and labeling changes could also have adverse consequences on our earnings assumptions.

Legal risks could lead to additional liabilities and revenue loss. In addition to the expenses incurred by patent challenges, product liability and other legal suits could occur and lead to additional liabilities and revenue loss, which could substantially change our financial assumptions.

Raising additional capital may cause dilution. If the company requires additional funding through raises in equity offerings, or similar financial instruments shareholders' ownership interests will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect shareholders' rights.

Please see the company's SEC filings for a more comprehensive discussion of potential risks.

Figure 21: Potential clinical trial timelines



Source: Company reports; AGP estimates

Figure 22: Quarterly Income Statement

Oramed Pharmaceuticals
Quarterly income statement

($000 except per share)	2020A 1QA Nov 19	2020A 2QA Feb 20	2020A 3QA May 20	2020A 4QA Aug 20	2020A Year Aug 20	2021E 1QE Nov 20	2021E 2QE Feb 21	2021E 3QE May 21	2021E 4QE Aug 21	2021E Year Aug 21
Revenues	$674	$674	$681	$681	$2,710	$681	$681	$681	$681	$2,724
Total revenues	**$674**	**$674**	**$681**	**$681**	**$2,710**	**$681**	**$681**	**$681**	**$681**	**$2,724**
Expenses										
COGS										0
Gross profits	**674**	**674**	**681**	**681**	**2,710**	**681**	**681**	**681**	**681**	**2,724**
Research & development	2,022	3,320	1,925	2,968	10,235	3,250	3,750	4,250	4,750	16,000
Selling, general & admin	1,081	1,391	1,030	730	4,232	1,000	1,300	1,400	1,400	5,100
Total operating expenses	3,103	4,711	2,955	3,698	14,467	4,250	5,050	5,650	6,150	21,100
Income (loss) from ops	**(2,429)**	**(4,037)**	**(2,274)**	**(3,017)**	**(11,757)**	**(3,569)**	**(4,369)**	**(4,969)**	**(5,469)**	**(18,376)**
Interest income, net	209	169	200	112	690	100	100	100	100	400
Income taxes										
other inc / fin expense	(323)	180	(210)	(91)	(444)	(50)	(50)	(50)	(50)	(200)
Net income (loss)	**(2,543)**	**(3,688)**	**(2,284)**	**(2,996)**	**(11,511)**	**(3,519)**	**(4,319)**	**(4,919)**	**(5,419)**	**(18,176)**
EPS as reported	**($0.15)**	**($0.21)**	**($0.10)**	**($0.13)**	**($0.56)**	**($0.13)**	**($0.16)**	**($0.17)**	**($0.19)**	**($0.65)**
Weighted avg. shares (000)	17,472	17,818	23,215	23,622	20,532	26,622	27,122	28,622	29,122	27,872
Fully diluted shares (000)	21,839	22,659	28,409	29,325	25,558	33,122	33,622	35,372	35,872	34,497

Source: FactSet; Company reports; AGP estimates

Figure 23: Annual Income Statement

Oramed Pharmaceuticals
Annual income statement

($000 except per share)	2019A Aug 19	2020A Aug 20	2021E Aug 21	2022E Aug 22	2023E Aug 23	Comments
Revenues						
Revenues	$2,703	$2,710	$2,724	$2,724	$2,724	License agreement here
Total revenues	**$2,703**	**$2,710**	**$2,724**	**$2,724**	**$2,724**	
Expenses						
COGS	90	0	0	0	0	
Gross profits	2,613	2,710	2,724	2,724	2,724	
Research & development	13,522	10,235	16,000	25,250	26,000	2 Phase 3 trials 2021-2023
Selling, general & admin	3,722	4,232	5,100	5,450	5,900	
Total operating expenses	17,244	14,467	21,100	30,700	31,900	
Inc (loss) from ops	**(14,631)**	**(11,757)**	**(18,376)**	**(27,976)**	**(29,176)**	
Interest income	1,061	690	400	400	400	
Income tax	(300)	0	0	0	0	
other inc / fin expense	(485)	(444)	(200)	(200)	(200)	
Net income (loss)	**(14,355)**	**(11,511)**	**(18,176)**	**(27,776)**	**(28,976)**	
EPS as reported	**($0.82)**	**($0.56)**	**($0.65)**	**($0.75)**	**($0.75)**	
Weighted avg. shares (000)	17,454	20,532	27,872	36,872	38,872	
Fully diluted shares (000)	21,878	25,558	34,497	43,372	38,872	
Cash & equivalents	**$33,577**	**$30,383**	**$29,176**	**$45,555**	**$43,828**	

Source: FactSet; Company reports; AGP estimates

Figure 24: Balance Sheet

Oramed Pharmaceuticals
Balance sheet model

(values in 000's)	2019A Aug 19	1Q20A Nov 19	2Q20A Feb 20	3Q20A May 20	2020A Aug 20	2021E Aug 21	2022E Aug 22	2023E Aug 23
Assets								
Cash & equiv.	$3,329	$3,171	$5,934	$9,313	$19,296	$33,309	$42,156	$13,120
Short term deposits	25,252	23,755	17,288	23,185	11,060			
Mktbl securities	3,701	3,207	5,704	8,335	9,544			
Prepaid expenses + other	1,042	609	563	470	611			
Total current assets	**33,324**	**30,742**	**29,489**	**41,303**	**40,511**	**34,059**	**42,931**	**13,945**
LT deposits & invstmnts	1	1	1	2	2	2	2	2
Mktbl securities	1,295	250	250	4,722	3,928			
Empl retire rights	19	16	17	17	18			
PP&E	24	27	25	22	99			
Op lease right of use		106	99	89	75			
Total assets	**34,663**	**31,142**	**29,881**	**46,155**	**44,633**	**34,261**	**43,198**	**14,252**
Liabilities								
Accounts payable	2,541	1,796	2,377	1,350	1,699			
Deferred revenues	2,703	2,703	2,703	2,703	2,703			
Related party payables	64	96	43	50	90			
Op lease liabs		46	32	32	44			
Total current liabilities	**5,308**	**4,641**	**5,155**	**4,135**	**4,536**	**4,750**	**5,275**	**6,500**
Deferred revenues	9,658	8,983	8,309	7,629	6,947	7,000	7,000	7,000
Empl retire rights	22	17	17	17	18			
Tax provision	11	11	11	11	11			
Op lease liabs		60	67	57	31			
Other	271	270	232	194	211			
Total liabilities	**15,270**	**13,922**	**13,724**	**11,986**	**11,754**	**12,025**	**12,600**	**13,865**
Common stock	208	209	214	279	284	300	300	325
Additional paid-in capital	100,288	100,597	103,210	123,451	125,209	132,726	168,864	167,604
Accumulated deficit	(81,103)	(83,646)	(87,334)	(89,618)	(92,614)	(110,790)	(138,566)	(167,542)
Shareholders' equity	**19,393**	**17,160**	**16,090**	**34,112**	**32,879**	**22,236**	**30,598**	**387**
Total liab & net worth	**34,663**	**31,082**	**29,814**	**46,098**	**44,633**	**34,261**	**43,198**	**14,252**

Source: FactSet; Company reports; AGP estimates

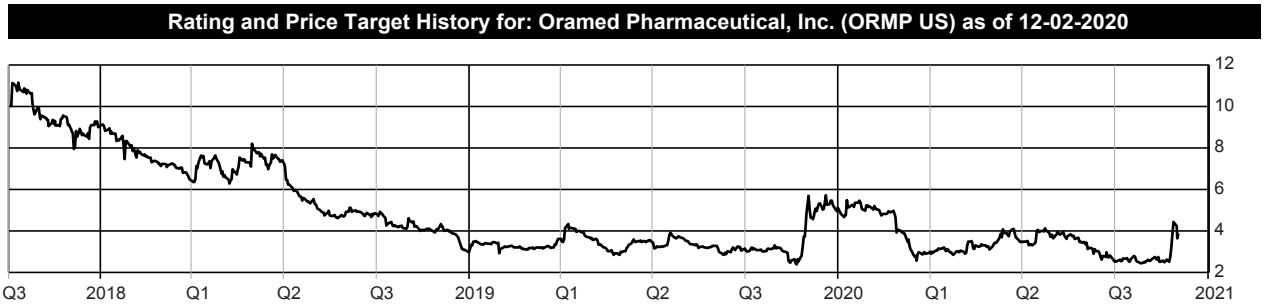
Figure 25: Cash Flow Statement

Oramed Pharmaceuticals
Statement of cash flows model

(values in 000's)	2019A	1Q20A	2Q20A	3Q20A	2020A	2021E	2022E	2023E
	Aug 19	Nov 19	Feb 20	May 20	Aug 20	Aug 21	Aug 22	Aug 23
Operating cash flow								
Net loss	($14,355)	($2,543)	($6,231)	($8,515)	($11,511)	($18,176)	($27,776)	($28,976)
Depreciation & amort.	8		2	5	7	10	10	10
Exchange diff on deposits	(183)	(92)	(17)	23	546	500	500	500
Stock based comp	808	303	569	888	1,173	2,000	2,500	3,000
Change at fair value	437	280	121	323	465	475	500	525
Shares issued for services	55	17	30	38	38	40	40	40
Change in assets & liabs	290	(961)	(1,099)	(2,744)	(3,158)	(3,250)	(3,750)	(4,000)
Other liabilities	(42)		(38)	(77)	(59)			
Cash from operations	**(12,650)**	**(3,957)**	**(7,724)**	**(12,726)**	**(15,598)**	**(18,401)**	**(27,976)**	**(28,901)**
Investing cash flow								
Purchase of PP&E	(15)	(3)	(3)	(3)	(82)	(100)	(125)	(150)
Purchase ST deposits	(24,990)	(3,000)	(10,200)	(6,000)	(27,204)			
Purchase mutual funds				(3,211)	(3,750)			
Purchase LT deposits	(4,237)							
Purchase securities	(1,357)			(7,408)	(8,428)			
Proceeds ST deposits	38,611	4,600	15,000	7,986	40,891			
Proceeds securities	3,250	1,225	2,100	2,300	3,200			
Employee retirement funds	(3)	3	3	(1)	(1)			
Cash from investing	**11,259**	**2,825**	**6,900**	**(6,337)**	**4,626**	**(100)**	**(125)**	**(150)**
Financing cash flow								
ST deposits to cash						24,532		
Common stock proceeds		1	2,316	22,295	23,773	10,835	36,933	-
Warrant & option proceeds		12	13	13	13	15	15	15
Cash from financing		**13**	**2,329**	**22,308**	**23,786**	**35,382**	**36,948**	**15**
FOREX impact	14		1	(5)	(5)			
Net change in cash	**(1,377)**	**(1,119)**	**1,506**	**3,240**	**12,809**	**16,881**	**8,847**	**(29,036)**
Cash at start	4,996	3,619	3,619	3,619	3,619	16,428	33,309	42,156
Cash at end	**3,619**	**2,500**	**5,125**	**6,859**	**16,428**	**33,309**	**42,156**	**13,120**

Source: FactSet; Company reports; AGP estimates

Important Research Disclosures



Distribution of Ratings/IB Services

			IB Serv./Past 12 Mos.	
Rating	**Count**	**Percent**	**Count**	**Percent**
BUY [BUY]	86	86.87	31	36.05
HOLD [NEUTRAL]	11	11.11	1	9.09
SELL [SELL]	0	0.00	0	0
NOT RATED [NR]	2	2.02	0	0
UNDER REVIEW [UR]	0	0.00	0	0

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Regulation Analyst Certification ("Reg AC") — James Molloy, , Jacob Silverman, Associate

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- The analyst or member of the analyst's household does not serve as officer, director or advisory board member of the company that is the subject of this report.
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Buy: Expected to materially outperform sector average over 12 months and indicates total return of at least 10% over the next 12 months.

Neutral: Returns expected to be in line with sector average over 12 months and indicates total return between negative 10% and 10% over the next 12 months.

Sell: Returns expected to be materially below sector average over 12 months and indicates total price decline of at least 10% over the next 12 months.

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Under Review: The rating will be updated soon pending information disclosed from a near-term news event.

Volatility Index

1 (Low): Little to no sharp movement in stock price in a 12 month period

2 (Low to medium): Modest changes in stock price in a 12 month period

3 (Medium): Average fluctuation in stock price in a 12 month period

4 (Medium to High): Higher than average changes in stock price in a 12 month period

5 (High): Extremely sharp movements in stock price in a 12 month period

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