Initiation
Overweight

CLVS, CLVS US
Price: $14.09

Price Target: $20.00

Clovis Oncology

More than Just a LEAP of Faith; Initiating at Overweight

We are initiating coverage of CLVS with an OW rating primarily based on the potential of CO-101, the company's lead asset for pancreatic cancer. Underpinning CO-101 and the rest of Clovis' early but interesting pipeline is a strong management team with an excellent track record of success. Additionally, a unique feature of all of the company's candidates is the development of companion diagnostics for patient selection, which could provide a regulatory and commercial benefit. The key event for 2012 is top-line results from the pivotal LEAP study in 4Qe, and we suspect shares could rise in anticipation of data. Our Dec 12 price target of $20 reflects a 55% probability of approval and market assumptions that leave several major potential upside levers.

- **Exploiting the hENT1 theory to overcome resistance in pancreatic cancer (PC).** It is increasingly believed that the majority of first-line PC patients do not respond to standard-of-care gemcitabine (gem) because the drug is not able to gain entry into the cell. CO-101 – a reformulated version of gem – is designed to facilitate greater cellular uptake independent of the presence of gem's key transporter (known as hENT1). This, in theory, should make CO-101 more broadly effective in PC.
- **LEAP is putting this theory to the test; the result could be a new standard of care**. The pivotal LEAP trial is randomizing patients to receive CO-101 or gem, and data in 4Q12e should tell whether CO-101 improves survival in patients with low levels of hENT1 expression. If there's a survival advantage, physicians we spoke with believe CO-101 will quickly become the standard of care for this patient population, which makes up at least 50% of the overall PC market.
- **Management's track record of value creation.** The Clovis team is best known for building Pharmion and subsequently selling it to Celgene. In addition, we believe a key strength of management is their significant experience with drug development, regulatory approvals, global commercialization, and business development.
- **A binary story for 2012.** While we are intrigued with the company's early stage pipeline (the EGFR inhibitor in particular), we believe that near-term performance will be driven by the outcome of LEAP. Given the relative lack of validating data to date, this sets up as a significant binary event in 2H12.
- **Dec 12 PT of $20 leaves room for upside.** Our target is derived from our risk adjusted sum of the parts and NPV models. It reflects a 55% probability of approval for CO-101. Importantly, we believe our peak sales assumptions (~$500M in US; ~$336M in EU) are potentially quite conservative based on the size of the eligible patient population, market penetration, and pricing.

Biotechnology

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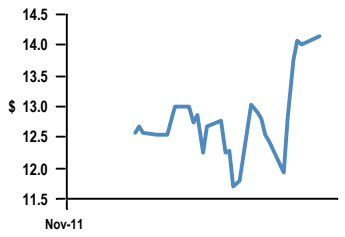
Price Performance



SMid Cap Research
THINK BIG, BUY SMALL

Clovis Oncology, Inc. (CLVS;CLVS US)

FYE Dec	2011E	2012E	2013E	2014E
EPS - Recurring ($)				
Q1 (Mar)	(2.15)A	(0.80)	-	-
Q2 (Jun)	(4.38)A	(0.65)	-	-
Q3 (Sep)	(1.38)A	(0.67)	-	-
Q4 (Dec)	(0.63)	(0.53)	-	-
FY	(5.33)	(2.62)	(2.57)	(1.83)

Source: Company data, Bloomberg, J.P. Morgan estimates.

Company Data	
Price ($)	14.09
Date Of Price	30-Dec-11
52-week Range ($)	14.85 - 11.45
Mkt Cap ($ mn)	331.17
Fiscal Year End	Dec
Shares O/S (mn)	24
Price Target ($)	20.00
Price Target End Date	31 Dec 12

See page 38 for analyst certification and important disclosures.

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J.P.Morgan

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Investment Thesis

Clovis Oncology (CLVS)

Overweight

CO-101 is tackling drug resistance in pancreatic cancer

Clovis has an opportunity to develop a drug that could become standard of care for a significant portion of patients with pancreatic cancer (PC). The subset, characterized by low expression of hENT1 (the key transporter necessary to facilitate gemcitabine's uptake into a cell), is not a small group. At least 50% of front-line (1L) patients fall into the hENT1 low category (and are thus likely to be resistant to gemcitabine) and more recent evidence suggests the proportion is closer to two-thirds of all PC patients. The pivotal LEAP study is randomizing patients to CO-101 or gemcitabine, and will assess whether CO-101 improves survival in the hENT1 low patients.

Favorable physician feedback on CO-101

We spoke with a handful of doctors who have hands-on experience with CO-101, and they have a generally positive view of the drug. Though most evidence at this point is anecdotal in nature (given relatively few treated patients and short exposures), the efficacy and safety profile of CO-101 so far seems to be as good as gemcitabine, if not better. Furthermore, these physicians are compelled by the availability of a marker (hENT1) that can prospectively identify patients that are unlikely to respond to gemcitabine and hence will be candidates for CO-101. Because of this, these physicians predict that hENT1 testing will become routine after diagnosis and that CO-101 could become standard of care in hENT1 low patients.

hENT1 low pancreatic cancer offers a substantial market opportunity

CO-101's market opportunity is not insignificant. The hENT1 low subset was initially estimated at 50% of the total 1L PC population, but more recent studies suggest the proportion is closer to two-thirds of patients. Indeed this would explain why the majority of 1L PC patients do not respond to gemcitabine. There are an estimated 43,130 new cases in the US each year and ~120,000 in the US, EU and Japan combined. Whether the eventual cut-off is 50% or 65%, we believe the market potential is substantial, especially for a company the size of Clovis.

Multiple upside drivers to our CO-101 sales assumptions

We currently assume peak CO-101 revenues of roughly $500M in the US and $336M in the EU. However, if LEAP is positive, we suspect three key levers could render our current forecasts overly conservative. First, we assume that 50% of the PC population is hENT1 low (and thus candidates for CO-101), but as just described this could be as high as 65%. Second, we currently assume a peak penetration rate of 65%, but if CO-101 is on the market with a survival advantage (primary endpoint of LEAP) and companion diagnostic to prospectively identify patients, we see little reason why penetration couldn't be materially higher. Third, based on recent comments from management and industry precedent, we suspect our $40k/pt price point could be understating the actual price by at least 25-50%.

All pipeline products have a companion diagnostic

One of Clovis' primary initiatives is to develop drugs with a companion diagnostic. This puts the company at the cutting edge of where we believe drug development is heading. Physicians are also very receptive to having a test to prospectively identify

patients that might benefit the most. For these reasons, we believe this strategy will help adoption in the early stages of launch.

Emerging pipeline should generate more interest over time

CO-101 is the main valuation driver for the story and likely will be for the next couple of years, in our view. That said, we don't believe the company is a one-trick pony as the earlier, in-licensed pipeline also looks promising and follows a similar clinical strategy to CO-101. Specifically, all products are being developed with a companion diagnostic and a potentially accelerated path to market. We are particularly intrigued by the EGFR inhibitor (CO-1686), as we believe the opportunity to treat patients with either initial activating mutations or the T790M resistance mutation is significant and represents an unmet medical need. Lastly, an oral PARP inhibitor (CO-338) in-licensed from Pfizer is also in early to mid-stages of development and targeting a "hot pathway" in oncology.

Management's track record and reputation are strong positives

Several members of the executive team have a long history together that is highlighted by the successful stint at building Pharmion and ultimately selling it to Celgene for ~$3B. This team has joined forces once again at Clovis, and in our view, brings significant and valuable clinical, regulatory, commercial and strategic experience. Importantly, they are not trying to reinvent the wheel and do something different with Clovis, but rather trying to do more or less the same thing all over again. We believe management's record is already recognized by investors as a material positive for the company.

Our conservative assumptions derive a 2012 price target of $20

CO-101 is wholly owned and thus the company will profit from all sales, at least in the US and EU (partnerships possible in other parts of the world). We assume a 55% probability of approval and peak sales of $500M in the US and $336M in the EU. Even with conservative expectations for the clinical, regulatory and commercial success of CO-101, we believe it looks attractively valued at current levels. Our $20 PT is derived from a blended average (50:50) of our risk-adjusted sum of the parts and NPV models.

Risks to Rating and Price Target

Clovis is susceptible to the standard risks that apply to the entire biotechnology industry, including development, regulatory, commercial, manufacturing, financing and IP pitfalls. Other risks specific to the company are listed below.

LEAP outcome in 2H12 is a highly binary event

CO-101 is the main component of the company's valuation and future performance is highly dependent on the outcome of the LEAP trial. This makes for a very binary story with significant downside risk if the trial fails.

Limited proof-of-concept data

Rationale for the pivotal LEAP trial is based on evidence from an abbreviated Phase 2 program. Moreover, dosing studies were not highly robust and the safety profile of CO-101 is relatively immature, in our view. Additionally, the hENT1 theory is based primarily on retrospective analyses and has not been definitively proven in a

prospective clinical trial. Thus, until the more rigorous LEAP study proves otherwise, we believe CO-101's potential is more hypothesis based than data driven.

Companion diagnostic adds an element of complexity to the regulatory process

While we believe the hENT1 diagnostic will help drive rapid adoption and ultimately be an advantage, it also adds an element of risk. Approval of CO-101 is contingent on approval of the hENT1 test, which is currently in development and projected to be filed along with the CO-101 drug application. Our understanding is that it is a very standard test and we believe that the approval process will also be relatively straightforward; however, we can't totally discount some unforeseen risk that could delay the approval of CO-101.

Enough cash for now but more capital needed for commercialization

Management believes it has sufficient cash (~$140M at YE11) to complete the clinical and regulatory development of CO-101 but will require additional funding to globally commercialize the drug. Seeing that management plans to market CO-101 in the US and EU, we assume an additional financing post LEAP data, albeit at a materially higher valuation (if the results are indeed positive).

Company Description

Clovis Oncology is a biotechnology company founded in 2009 and based in Boulder, Colorado. The company's pipeline is focused on developing oncology drugs for a broad range of tumor types using companion diagnostics to prospectively identify likely responders. Lead product, CO-101, has the potential to overcome resistance to gemcitabine, the standard of care for pancreatic cancer, and pivotal data are expected by the end of 2012. Two other compounds, CO-1686 (EGFR inhibitor) and CO-388 (PARP inhibitor), are either in early stages or nearing clinical testing. Clovis has an experienced management team that is one of the company's notable strengths, in our view, having been together since inception and in prior successful endeavors with a well recognized track record. Clovis had 45 employees as of October 2011.

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Upcoming Events

Data from the pivotal LEAP study evaluating CO-101 in pancreatic cancer are the key event for CLVS in 2012

CO-101 is Clovis' lead asset for pancreatic cancer that is in pivotal stages of development. The pivotal LEAP study is currently enrolling and will evaluate overall survival in a subset of patients associated with resistance to standard-of-care, gemcitabine. The resistant patients (hENT1 low) are identified by way of a companion diagnostic for hENT1, a transporter that enables entry of gemcitabine into cells. By the end of 1Q12, the hENT1 status of all patients enrolled in the LEAP study should be determined, though the company has not definitively guided whether it will report the distribution of hENT1 high and low patients. We expect enrollment to complete in early 2012 with data by the end of 2012. Pending a survival benefit in the hENT1 low patients, regulatory filing will follow and we anticipate priority review with a potential launch by early 2014.

As for the earlier stage pipeline, an IND filing for CO-1686, a mutant selective EGFR inhibitor for lung cancer, is expected early in 2012. This program has the potential to head down an accelerated path as it also has a companion diagnostic for the primary resistance mutation in NSCLC, T790M (2L indication). Data from the proof-of-concept trial are expected in 2H13 followed by initiation of pivotal trials. We highlight this program second, as it has the potential to become a higher priority from both an expense and timing perspective seeing that there is an opportunity for an accelerated regulatory path, much like CO-101. CO-338 is a PARP inhibitor being developed for tumors with BRCA mutations. The drug is in mid-stages now as an IV formulation but Clovis has replaced the IV drug with an oral formulation that has just begun Ph1 testing as a monotherapy.

Table 1: CLVS Upcoming Events

Program	Event	Expected Timing	Significance
CO-101	Complete enrollment for pivotal Ph2 LEAP study	1Q12	Low-Medium
	Report top-line results (OS in low hENT1 pts)	4Q12	High
	Complete enrollment for Ph2 study in 2L panc cancer	4Q12	Low
	File NDA with FDA and MAA with EMA	mid-2013	Medium
	Potential FDA approval	1Q14	High
CO-1686	File an Investigational Drug Application (IND) with FDA	1Q12	Low
	Commence Ph1/2 clinical trial in 1L and 2L lung cancer	1H12	Low
	Data from Ph1/2 POC trial	2H13	Medium-High
	Goal to file NDA within 4 years of IND filing	1Q16	Low-Medium
CO-338	Data from two Ph1 monotherapy (oral) trials in solid tumors	2013	Low

Source: J.P. Morgan estimates and company reports.

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Pipeline Overview

Table 2: CLVS Pipeline at a Glance

Program	P/C	Ph1	Ph2	Ph3	FDA	Mkt.	Partner	Comments
CO-101								Lipid conjugated gemcitabine, In-licensed from Clavis Pharma in Nov 2009
1L met pancreatic cancer								LEAP: pivotal, randomized, controlled, 360 pt study - CO-101 vs. gemcit
2L met pancreatic cancer								Open-label, single arm. Enrollment began Feb 2011
Solid tumors								Ph1 planned in combination with cisplatin
CO-1686								In-licensed from Avila Therapeutics in May 2010
NSCLC								Oral EGFR mutant-selective inhibitor
CO-338								In-licensed from Pfizer in June 2011
Solid tumors								IV PARP inhibitor (Completed Ph 2 in comibination with TMZ)
Solid tumors								Oral PARP inhibitor (Ongoing dose-ranging Ph1 study in combination with chemo)

Source: J.P. Morgan estimates and company reports.

The major clinical products in Clovis's pipeline are all in-licensed drugs with the added advantage of a companion diagnostic. While we expect additional business development for the company in the future, the current pipeline includes the following three compounds:

- **CO-101.** Gemcitabine resistance in pancreatic cancer is thought to be mediated by the lack of the hENT1 transporter and to overcome this, lipid molecules were conjugated to gemcitabine by Clavis Pharma. The lipid conjugated gemcitabine is able to enter pancreatic tumor cells passively to deliver the cytotoxic component. Clovis then in-licensed global rights from Clavis in 2009. An ongoing Phase 2 pivotal trial (referred to as LEAP) is expected to report results by the end of 2012 with potential approval in late 2013 or early 2014. Another favorable component of the drug is a companion diagnostic that can prospectively identify patients that may respond to CO-101 but not gemcitabine (hENT1 low).
- **CO-1686**. A pre-clinical asset that inhibits EGFR, a well known pathway associated with cancer. Global rights were in-licensed from Avila. One potential advantage with CO-1686 over other drugs in its class is that activity is seen against tumors with the initial EGFR activating mutations but also those with the primary resistance mutation, T790M. Additionally the drug spares the wild type EGFR, which has the potential to improve tolerability. A companion diagnostic is also being developed to identify patients with a higher probability of responding to the drug and who have the T790M mutation, which could create a path for rapid development.
- **CO-338.** This is an oral PARP inhibitor, in-licensed from Pfizer, in Ph1 trials for tumors with BRCA mutations. A monotherapy strategy will be used in breast and ovarian tumors with BRCA mutations and also for solid tumors as a combination with chemotherapy. Ongoing trials initially treated patients with an IV formulation, however, the company plans to replace this with an oral formulation. As with the other pipeline drugs, there are plans to develop a companion diagnostic to identify patients that will benefit the most from CO-338 therapy.

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CO-101: Aspiring to Be a New Standard of Care for Pancreatic Cancer

Pancreatic cancer basics

The 5 year survival rate is 22.5% for localized (surgery eligible) pancreatic cancer and only 1.9% for metastatic disease

Pancreatic cancer is the fourth leading cause of cancer-related death. A recent publication on cancer statistics from the American Cancer Society estimates that there were 43,140 new cases of pancreatic cancer in 2010, up from 30,700 in 2003. The severity of the condition is clearly demonstrated by the 36,800 estimated deaths in 2010. Clovis estimates that each year, 120,000 new cases of pancreatic cancer are diagnosed in the US, EU and Japan combined.

Symptoms are usually vague (anorexia, abdominal pain, nausea, early satiety) and so most cases are diagnosed in advanced stages when surgery, the only potential cure, is generally no longer an option. A pancreatic tumor is considered inoperable if there is invasion in the surrounding arterial systems or distant metastases.

At time of diagnosis, only 15% of patients have resectable disease where the tumor is contained and surgery can be performed. Even then, for patients that are eligible for surgery, survival is poor as adjuvant therapies are not effective. The remaining patients have either locally advanced or metastatic disease and undergo other treatments such as chemotherapy. Because the symptoms of pancreatic cancer make it tough to obtain an early diagnosis, 50% of patients have metastatic disease at diagnosis. Overall, at the time of diagnosis, the majority of patients (85%) have a poor prognosis and are typically candidates for chemotherapy (Table 3). Among the more sobering pancreatic cancer related statistics is that the 5 year survival rates between 1999 and 2006 were 22.5% for localized disease and only 1.9% for metastatic disease, the most common form at diagnosis.

Table 3: Most Patients Are in Advanced Stages at Time of Diagnosis

Disease Stage	% of Patients at Diagnosis	Median Survival (mos)
Metastatic	**50**	**6**
Locally advanced	35	9
Resectable	15	15

Source: Defined Health (2009)

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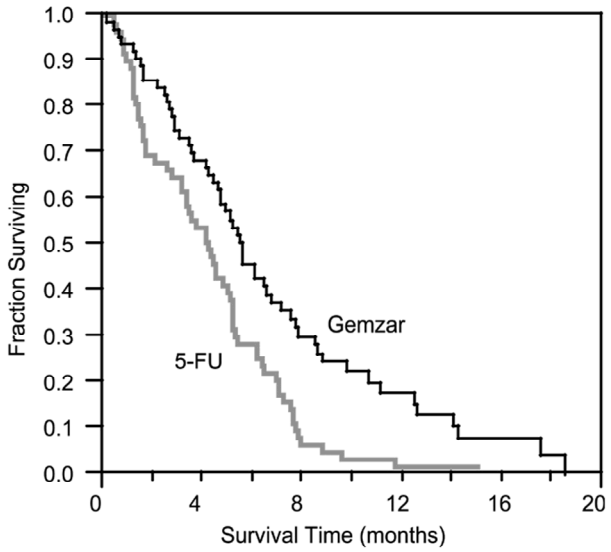
Gemcitabine: entrenched standard-of-care leaves plenty of room for improvement

Patients with unresectable PC have a survival expectancy of 6-9 mos with current standard of care. For the majority of these cases, chemotherapy is most commonly used to treat the disease. Initial agents used to include 5-FU and then a combination with leucovorin. Over a decade ago, gemcitabine (branded as Gemzar), a pyrimidine nucleoside analog, showed prolonged survival compared to the original agents (5.7 months vs 4.2 months, p = 0.0025; and 18% vs. 2% 12 month survival, n = 126 pts). Based on these data, gemcitabine became the standard of care for unresectable pancreatic cancer.

Gemcitabine increased survival over 5-FU to 5.7 mos from 4.2 mos (p = 0.00245)

Figure 1: Modest Survival Increase with Gemzar (gemcitabine)



Source: Burris JCO 1997; 15:2403

Gemzar, the formerly branded name for gemcitabine, was approved for front-line PC based on a primary endpoint of clinical benefit response (analgesic consumption, pain intensity, performance status and weight change). Results from the pivotal trials showed a clinical benefit response of 22.5% (n = 14/63) vs. 4.8% (n = 3/63) in favor of Gemzar over 5-FU. In the second line setting, as a monotherapy after 5 FU, Gemzar has shown a clinical benefit response of 27% with 3.9 mos median survival (n = 63). Gemzar is now generically available and approved for use in pancreatic, lung, breast, and ovarian cancer. Gemcitabine as adjuvant therapy to surgery has also been increasingly used after showing an improvement in disease free survival over surgery alone (13.9 mos vs. 6.9 mos, p <0.001). For the remainder of the report, gemcitabine will be used to collectively refer to the generic and branded versions of the drug.

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Other agents have had little success in pancreatic cancer

FOLFIRINOX chemotherapy has the best survival data but is not widely used due to toxicity

There are few alternative chemotherapeutic regimens that have shown promise, with the exception of FOLFIRINOX (5-FU+leucovorin+ irinotecan+oxaliplatin), which has shown to improve PFS (6.4 vs. 3.3 mos) and OS (11.1 vs. 6.8 mos) compared to gemcitabine. While FOLFIRINOX has reported the best survival rate, it is also associated with significant added toxicity. Accordingly, oncologists we spoke with confirmed that the combination is not largely used but rather saved for a smaller proportion of younger patients who can tolerate greater toxicity.

Tarceva was approved by adding *two weeks* of survival on top of gemcitabine

Other chemotherapeutic and biologic agents have proven to be ineffective or not clinically meaningful, by comparison. The only targeted therapy that has shown promise in pancreatic cancer is Tarceva, which when combined with gemcitabine improved survival by roughly *two weeks* compared to gemcitabine alone (6.2 vs. 5.9 mos, HR = 0.82 and p = 0.038). Despite being approved for first-line (1L) PC, physicians we spoke with are not convinced the benefit is clinically meaningful, or at least enough to warrant the added toxicity and cost of another drug.

Gemcitabine's main limitation is that the majority of patients do not respond to the drug

Beyond the modest improvement in survival, the main limitation to gemcitabine is that the majority of patients do not respond to the drug. And, until recently, there were no markers that could be used to predict responsiveness to gemcitabine so most patients (company estimates 80%) with non resectable disease were treated regardless.

hENT1 may be the answer to gemcitabine resistance

Since the approval of gemcitabine, much of the aim of subsequent research has been to better understand the mechanism of gemcitabine resistance. One possible explanation lies in how gemcitabine gains entry into a target cell. Gemcitabine uses specific transmembrane proteins known as equilibrative nucleoside transporter (ENT) proteins to gain entry into cells where it exerts its cytotoxic effects from within. One protein in particular, human ENT1 (hENT1), was found to be the major transporter for gemcitabine in human cell culture studies. From there, it was hypothesized that pancreatic tumors that lacked the hENT1 protein would likely not respond to gemcitabine.

Initial preclinical studies showed that tumor shrinkage correlated with the level of detectable hENT1 expression in mouse models. More specifically, in mice tumor models with low hENT1 expression, the degree of tumor shrinkage is comparable between gemcitabine and control (i.e. placebo) treated mice. In contrast, in mice with high hENT1 expression, tumors are more responsive to gemcitabine with greater shrinkage compared to the control.

Gemcitabine patients with high hENT1 expression survived 3 times longer than patients with low hENT1 expression in a retrospective analysis of 1L PC data

The first evidence in humans was shown in a retrospective analysis by Spratlin et al, which looked at the hENT1 levels in tumors of 21 metastatic patients treated with gemcitabine (Figure 2). When the analysis segregated patients based on hENT1 expression, median survival with gemcitabine was 3x more in the hENT1 high group than in the hENT1 low group (13 mos vs. 4 mos). Although small numbers, this data provided the first clinical evidence that hENT1 deficiency might be used as a marker to predict response to gemcitabine.

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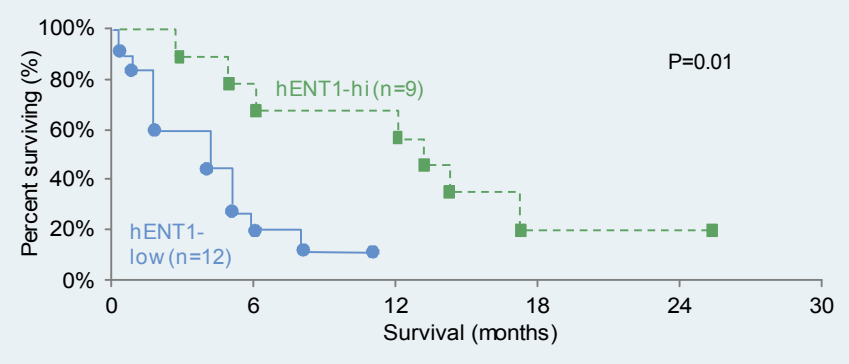
Figure 2: Kaplan-Meier Curves of Survival Based on hENT1 Status

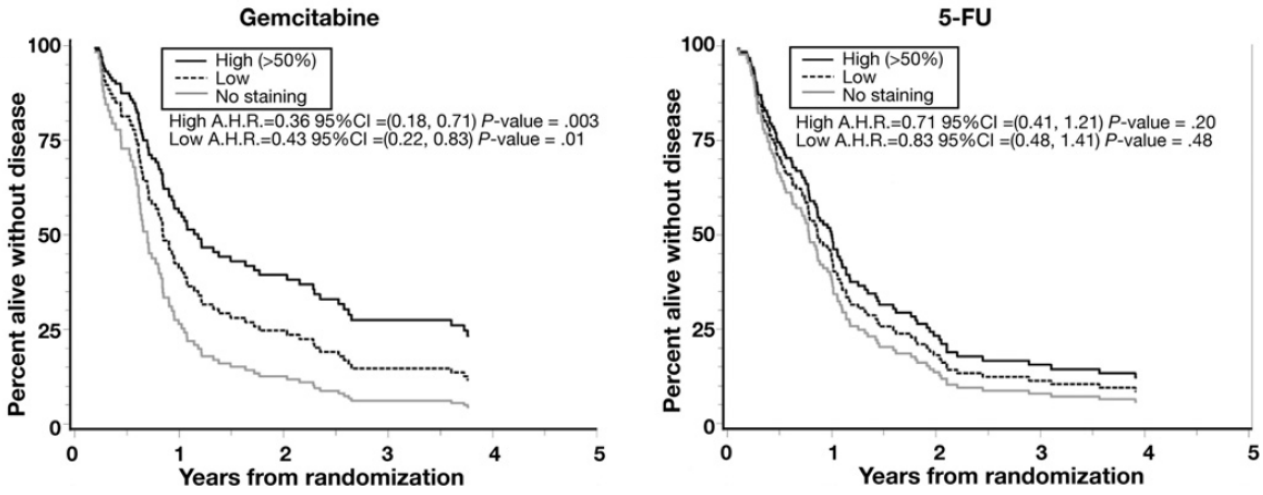


Source: Spratlin et al. Clinical Cancer Research (2004)

In adjuvant patients post surgery, the hENT1 low groups treated with gemcitabine also showed poor survival compared to hENT1 high patients. The variation was not seen with patients treated with 5-FU

As further proof, the RTOG 9704 trial, a Phase 3 randomized postoperative adjuvant study in resectable pancreatic cancer, showed a similar trend. Tumor samples (from ~20% of patients) were designated as hENT1 high if more than 50% of tumor cells had strong hENT1 expression. Patients were designated as no hENT1 if at least 50% of cells had no staining. Anything in between was considered low hENT1 status, such as a combination of weak and strong staining (with strong staining less than 50%). Again, patients with high hENT1 levels experienced longer disease-free survival with gemcitabine treatment than patients with low hENT1. *Moreover, response to 5-FU was the same irrespective of hENT1 status, suggesting that hENT1 is a predictive market specific to gemcitabine.*

Figure 3: Sensitivity to Gemcitabine but Not 5-FU Is Associated with hENT1 Expression



Source: Company reports

We are aware of 5 analyses that support the thesis that low hENT1 expression is associated with poor gemcitabine outcomes

There are now several analyses that support the correlation between low survival with gemcitabine treatment and hENT1 low expression and at least 5 of the studies are listed in Table 4. While the patient populations differed, all studies confirm the correlation and provide supportive evidence to Clovis' approach.

Table 4: Summary of Studies Corroborating hENT1 Expression with Gem-Assoc Survival

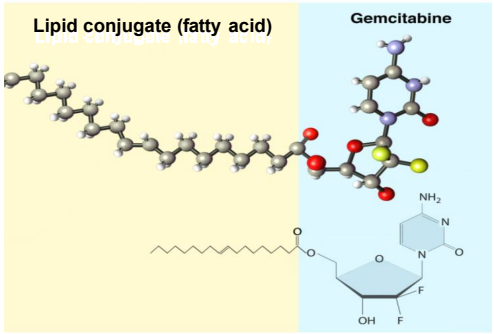
Study Author	Year	No. of Patients	Median OS by hENT1 status (mos)	P-value (s)
Spratlin	2004	21	High: 13 **Low: 4**	0.01
Giovanetti	2006	83	High: 22 **Low: 12**	<0.001
Farrell	2009	198	High: 21 **Low: 16** **No hENT1: 12**	0.002 0.03
Morinaga	2011	27	High: 22 **Low: 12**	0.02
Marechal	2011	434	High: 48 **Low: 26**	<0.001

Source: See listed author and year of publication for each study

CO-101: potential to overcome resistance tied to low hENT1

With the knowledge of what hENT1 status means with regards to gemcitabine sensitivity and survival, a Norwegian biotechnology company, Clavis Pharma, set out to design a drug that would offer better efficacy to hENT1 low patients. In order to get around the dependence of the hENT1 transporter for entry into tumor cells, Clavis conjugated lipids onto gemcitabine (Figure 4). On its own, gemcitabine is a polar molecule that cannot passively transfer across a cellular membrane, which is the reason why a transporter such as hENT1 is required for entry.

Figure 4: CO-101: Lipid-Conjugated Form of Gemcitabine

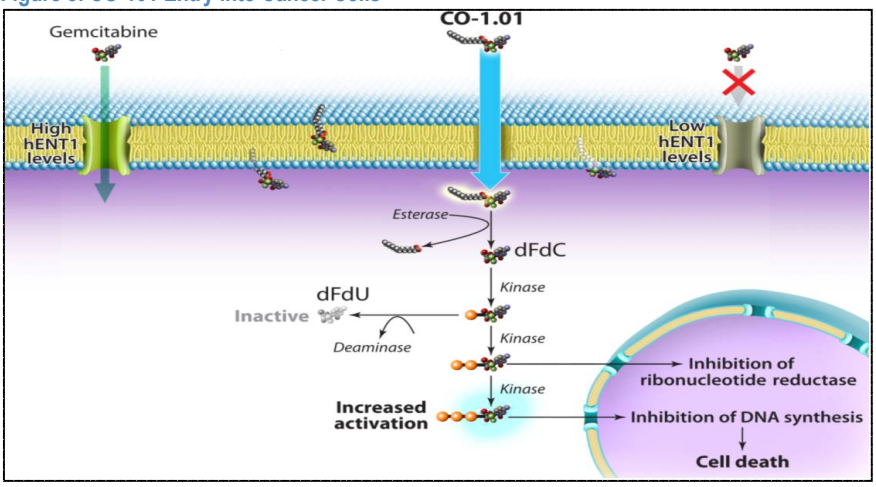


Source: Company reports, with permission

CO-101 is lipid conjugated form of gemcitabine that can passively enter tumor cells without using hENT1

As a lipid conjugated version of gemcitabine, CO-101 no longer requires the hENT1 transporter to enter cells (Figure 5). Once inside the cell, the lipids are removed, and CO-101 is converted into an active gemcitabine molecule.

Figure 5: CO-101 Entry into Cancer Cells



Source: Company reports, with permission

Pilot Ph2 trial showed that CO-101 improves survival in hENT1 low patients compared to gemcitabine (9.1 vs. 3.3 mos) but this was generated with very small numbers (4 patients)

A pilot Phase 2 trial initiated by Clavis Pharma attempted to show proof of concept that CO-101 had greater activity in hENT1 low patients compared to the high subgroup. The trial was an open label, multicenter study in patients with advanced pancreatic adenocarcinoma. The small trial measured survival as a secondary endpoint and the results were promising. Below we show an analysis from the trial, which is representative of the patients in the LEAP pivotal trial (metastatic patients only). In patients treated with gemcitabine, median, overall survival in the hENT1 low patients was 3.3 mos vs. 8.4 mos in the hENT1 high subset. Conversely, in the patients treated with CO-101 that had low hENT1 status, survival was much higher at 9.1 mos (Table 5). These results support the thesis behind the pivotal LEAP study that is currently being conducted by Clovis, though it is important to remember that these Phase 2 results are based on a very small number of patients (only 4 hENT1 low patients).

Table 5: Early Ph2 Data Shows That CO-101 Improves Survival in hENT1 Low Patients

Drug Arm	Subgroups	N (Events, Censored)	Median OS (95% CI) Mos	Hazard Ratio
CO-101 Gemcitabine	All Patients All Patients	14 (13,1) 4 (3,1)	7.6 (4.8, 9.2) 5.9 (2.6, 8.4)	0.44
CO-101	hENT1 Low hENT1 High	3 (3,0) 10 (9,1)	9.1 (5.2, 11.7) 6.1 (1.0, 9.2)	0.745
Gemcitabine	**hENT1 Low hENT1 High**	**1 (1,0) 3 (2,1)**	**3.3 (NA) 8.4 (2.6, 8.4)**	**2.45**
CO-101 Gemcitabine	**hENT1 Low hENT1 Low**	**3 (3,0) 1 (1,0)**	**9.1 (5.2, 11.7) 3.3 (NA)**	**NA**

Source: J.P. Morgan estimates and company reports.

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Terms of the agreement with Clavis Pharma

In 2009, Clovis entered into a license agreement with Clavis to develop and commercialize CO-101 in North America, Central America, South America and Europe. Asian rights were subsequently acquired after the initial transaction. To gain rights to CO-101, Clovis paid a total of $25M in upfront payments and is responsible for royalties on sales (we assume 15% based on company commentary) as well as $115M in development and regulatory milestones and $445M in commercial milestones.

Pivotal LEAP trial designed to show survival benefit

If positive, we believe the LEAP study should be sufficient to support approval of CO-101

The Phase 2 LEAP trial was initiated to provide definitive evidence of a benefit in the hENT1 low patients and the data will be the basis for an accelerated filing. If the results are positive, we believe the chances for an accelerated approval are good based on: 1) the trial is randomized and not a single arm trial, 2) there is a companion diagnostic that will identify which patients are sensitive to either CO-101 or gemcitabine, 3) there is a clear unmet need in the hENT1 low patients that do not respond to available therapies, 4) the hENT1 low population is not a small subset but is estimated at at least 50% of PC patients, if not more based on more recent evidence, and 5) LEAP has a primary endpoint of overall survival.

The LEAP trial enrolled its first patient in May 2010 and is expected to complete enrollment of roughly 360 patients by 1Q12. Both hENT1 low and high patients with metastatic disease are being included in the open label study, and patients will be randomized to receive CO-101 or gemcitabine in a 1:1 split. The primary endpoint is overall survival in the hENT1 low patients with a number of secondary endpoints (listed below). Results are expected near the end of 2012 with no interim efficacy update, which is not surprising given the short OS expectations in this patient population.

Table 6: Pivotal LEAP Trial for CO-101 in Pancreatic Cancer

Patients	Design	Dose	Primary Endpoint	Secondary Endpoint	Data Timing
N = 360 Pancreatic cancer Metastatic disease 1L, Chemo-naïve	Open label, interventional Safety/ Efficacy study Randomized, multicenter 1:1 with Gemcitabine	CO-101: 1250mg/m2 QW (3 wks/4 wk cycle) Gemcitabine:1000mg/m2 QW (7 wks/8 wk cycle then 3 wks/4 wk cycle)	OS (hENT1- low pts)	OS (all pts) ORR, PFS DOR Safety Tolerability CA19-9	4Q12 (FPI: May 2010)

OS: Overall Survival, ORR: Overall Response Rate, PFS: Progression Free Survival, DOR: Duration of Response

Source: J.P. Morgan estimates and company reports.

LEAP powering is cushioned for a range of hENT1 ratios

Pivotal LEAP trial enrolled enough patients to show a doubling in survival with cushion if the hENT1 low ratio is less than 50%

The powering of the LEAP study is somewhat dictated by the split in the number of hENT1 low and high patients. In prior literature, the hENT1 split was assumed to be roughly 50:50. More recent work from 3 studies shows that the hENT1 low patients might be closer to two-thirds of the total population. All comers (hENT1 high and low) are being enrolled in LEAP and the ratio of hENT1 high to low patients was not determined prior to enrollment. To be prudent, Clovis also enrolled additional patients in order to maintain powering in the event that the proportion of hENT1 low patients is less than 50%. Thus, if 50% of patients in the LEAP trial are hENT1 low, the study is 95% powered to detect a hazard ratio (HR) of 0.55 ($p = 0.05$) or 75% powered to detect a HR of 0.65. If the ratio of hENT1 patients is biased toward the low group, for example two thirds hENT1 low, then the study is 98% powered to

detect a HR of 0.55 or over 80% powered to show a HR of 0.65. If the LEAP data show a statistically significant improvement in survival, we believe it will make a strong case to the FDA that CO-101 offers a clinically meaningful benefit in a population with unmet need.

We assume a 55% probability of approval of CO-101

We assume a 55% chance of approval with help from a companion diagnostic to identify potential responders to CO-101

Although in pivotal testing, LEAP is technically a Phase 2 study. Accordingly, our probability of success assumption is somewhat higher than what we would normally assign a product at this stage of development given the modest amount of data we have seen thus far. However, our optimism stems from the 1) availability of the hENT1 marker that can be used to prospectively predict responsiveness to CO-101 and 2) early and supportive data that suggest an unmet need in hENT1 low patients. If a significant survival advantage is shown from the LEAP trial, we also believe there is a good chance the regulatory path proceeds under priority review and we project a US launch in early 2014.

Safety profile of CO-101 vs. gemcitabine

For gemcitabine, hematologic toxicities were the main dose limiting toxicities seen in clinical trials. Grade 3 or higher hematologic adverse events included anemia (10%), leukopenia (9%), neutropenia (24%) and thrombocytopenia (8%). Also in the trials, 19% of patients received red blood cell transfusions but the discontinuation rate due to anemia was less than 1%. Overall, discontinuations in the trials were within a generally acceptable range at 10% in the monotherapy trial and 14% in the comparator trial against 5-FU. Other non-hematological adverse events include asthenia (loss of strength), reversible liver enzyme elevations, nausea and rare pulmonary toxicity. The gemcitabine label includes pulmonary, renal and hepatic toxicity in the warnings and precautions section.

CO-101 has a relatively thin safety database for a drug in pivotal stages. We do know that the half-life is significantly longer than gemcitabine (~30 min vs. 5 min), which has the potential to increase the risk of any adverse events. Also, adding lipids to gemcitabine to achieve non-specific entry into tumor cells has the potential to cause a problem in other non-cancerous tissues. So far, however, the company claims the safety profiles of CO-101 and gemcitabine are quite similar. The only added toxicity seen with CO-101 is GI distress, although this is characterized as manageable by Clovis.

As for more direct evidence, there were several DLTs identified in the early Phase 1 trials that included fatigue (Gr 3), acute lung damage leading to death, ALT/AST elevations (Gr 3) and neutropenia (Gr 4). While several of these toxicities were observed at doses higher than the pivotal trial (1250mg/m2), the fatigue and lung damage were seen at lower doses. Overall, fatigue was considered the major DLT, which is not that uncommon with cancer drugs and was also seen with gemcitabine (Gr3+ in 6-7% of patients).

While the safety profile seems acceptable so far, the patient exposure is not to the level of a large rigorous Ph3 program. As more patients are exposed to the drug for longer periods, we recognize there is the risk that a safety signal arises in the LEAP trial.

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hENT1 diagnostic strengthens the CO-101 story

Ventana is developing the companion diagnostic for CO-101

A companion diagnostic for CO-101 was developed and is being validated by Ventana Medical Systems, a division of Roche. The test uses immunohistochemistry (IHC) to quantify the level of hENT1 expression in biopsied tumors from patients in the trial. The test is relatively quick (~4 hrs) and uses standard equipment that pathology labs in hospitals and large centers likely already have. An algorithm that combines the number of positive cells and the intensity of expression is ultimately used to assign status as hENT1 high or low. The analysis of the hENT1 test will be done by pathologists who apply the algorithm. From conversations with the company, we learned there was high concordance in hENT1 analysis among pathologists used to generate the earlier data.

A pre-Investigative Device Exemption (IDE) meeting will take place early next year when we expect the company will update the FDA on recent validation data. The pre-Marketing Approval Application (PMA) for the hENT1 test will be submitted at the time of NDA filing for CO-101, and approval of CO-101 will be contingent on approval of the diagnostic.

Commercially, Clovis is considering having several high volume test centers for practices that are not equipped, unfamiliar with pancreatic tissue histology, or expecting sporadic use of the drug. We believe this would be a prudent move and might help adoption in the early months of launch. Lastly, the hENT1 marker test falls within a class of diagnostics for which there is a reimbursement code. An established reimbursement path should be an incentive for the centers with pancreatic cancer patients as they will make a small profit for each hENT1 test.

Feedback from physicians with direct CO-101 experience

Our initial conversations with a handful of physicians regarding CO-101 were generally favorable, although there is a relatively small population given the limited use of the drug to date. The availability of a companion diagnostic to guide the choice between gemcitabine and CO-101 is one of the aspects that physicians are most excited about. Physicians predicted that determining hENT1 status would become the first step for drug selection. Any hENT1 low patients will receive CO-101 and in hENT1 high patients, physicians will defer to their current methodology for drug choice. From an efficacy standpoint, physicians anecdotally believed that CO-101 is equally effective if not slightly better than gemcitabine. As for safety, there were no major issues encountered and physicians remarked that CO-101 seemed to have better tolerability (though this is early days with short exposures). Furthermore, while we expect little use of CO-101 in the hENT1 high patients given the cost of generic gemcitabine, one physician commented that he may still use CO-101 in the high status patients that have coverage.

On the drug landscape, it was noted that gemcitabine would be a tough standard of care to displace given tolerability and cost. Other combinations such as FOLFIRINOX (5-FU+ leucovorin+irinotecan+oxaliplatin) are used modestly given a survival benefit over gemcitabine but it is reserved for a small subset of younger and generally healthier patients given incremental toxicity. Though not yet approved, one physician was also treating patients with Abraxane, though he did not predict significant use if the drug were approved. Lastly, the survival benefit by adding Tarceva to gemcitabine was marginal and the physicians we spoke with feel it is not enough to justify the added cost and toxicity. Thus with a diagnostic to identify

patients and similar safety profile to gemcitabine, doctors believed that adoption of CO-101 would be significant.

Where we could be wrong regarding CO-101

Lack of clinical data to lean on

One of the biggest risks to our thesis is that the small amount of data that has been released to date makes it tough to have high conviction in the LEAP trial. With minimal Ph1 dose escalation data and a small Ph2 trial (21 patients), proof of concept may be questioned. We believe the retrospective analyses of other pancreatic cancer trials are helpful but not necessarily scientifically rigorous.

hENT1 distribution and threshold

The early evidence of a hENT1 distribution that is split 50:50 between high and low patients was not well documented in the literature. Since then, three retrospective analyses from gemcitabine trials suggest that the hENT1 low population makes up roughly two-thirds of the overall PC patient population. While this will bodes well for the LEAP trial, the hENT1 distribution in the LEAP trial is not yet known and the company has not guided whether the hENT1 analysis will be released before the survival results. We are not anticipating a low proportion of hENT1 low patients, based on prior data but, should the hENT1 low subset end up being meaningfully below 50%, we believe the trial would lose some level of powering to show a survival benefit in the hENT1 low patients.

Confidence in pivotal dose

The maximum tolerated dose (MTD) in early trials was set at 1250 mg/mL with fatigue as the most common dose limiting toxicity (DLT). According to management, this translates to roughly 625 mg/ml of regular gemcitabine, below the standard 1000 mg/ml dose. We do not question the MTD given the 6 DLTs observed in the early studies. However, the effective dose of gemcitabine that CO-101 patients ultimately receive is lower. It is possible that with a greater rate of entry, less drug will be needed but again, with little data at the MTD, it is tough to say. Overall, at least in the hENT1 low patients, the level of entry should be higher than gemcitabine, which should improve comparative effectiveness.

Approval of a companion diagnostic adds incremental risk

The CO-101 strategy can't work without an easy and cost efficient way to determine hENT1 status in patients. Currently, this is not a routine diagnostic for pancreatic cancer. The hENT1 assay is being developed by partner, Ventana Medical , which also plans to globally commercialize the test. Filing of the diagnostic test is expected to be coordinated with the regulatory submission of CO-101, and approval of the drug is dependent on concomitant approval of the hENT1 test.

Competitive landscape

There are a number of competitive drugs and regimens in development, but the majority are combinations with gemcitabine

Due to the lack of good options for the treatment of pancreatic cancer, it should come as no surprise that there are several drugs or regimens in development to find a potent product with acceptable safety. It's notable, though, that with gemcitabine entrenched as the standard of care for 1L PC, most of the strategies involve combinations with gemcitabine, several of which are in late stages. One study not included in Table 7 but we believe is worth mentioning is the HyperAcute Pancreas vaccine by NewLink Genetics that is being developed as adjuvant therapy post

surgery. The primary outcome measure is disease-free survival and results are expected in 2H12. This is not a directly competitive approach to gem and CO-101.

Table 7: Select Pancreatic Cancer Drugs or Combinations in Development

Company	Drug Name	Line of Therapy	Regimen	Phase
Clovis Oncology	**CO-101**	**1st**	**Monotherapy**	**Phase II**
Celgene	Abraxane	1st	With gemcitabine	Phase III
Amgen	AMG-479 (ganitumab)	1st	With gemcitabine	Phase III
KAEL-GemVax	GV-1001 (terotomide)	1st	With gemcitabine	Phase III
AB Science	Masitinib (AB-1010)	1st	With gemcitabine	Phase III
Bristol-Myers Squibb	IMC-A12	1st	With gemcitabine and erlotinib	Phase II
Threshold Pharmaceuticals	TH-302	1st	With gemcitabine	Phase II
Onconova Therapeutics	Estybon	1st	With gemcitabine	Phase II/III
Immunomedics	Clivatuzumab	1st	With gemcitabine	Phase Ib/II
Merck	MK-0646 (dalotuzumab)	1st	With gemcitabine and erlotinib	Phase I/II
Merrimack Pharmaceuticals	MM-398	2nd	Monotherapy	Phase III

Source: Company reports.

Combination strategies have the potential to improve response and survival over gemcitabine alone. They may not, however, overcome the lack of response in the hENT1 low patients. Already, many chemotherapy regimens and targeted therapy combinations with gemcitabine have tried and failed to show a benefit.

In the end, if the LEAP study is successful, we believe that future development of pancreatic cancer candidates will be stratified by hENT1 high and low, with CO-101 being the standard of care in those with low levels of expression. And as we mentioned earlier, the physicians we spoke with share our view. In our opinion, it simply does not make sense to unnecessarily expose hENT1 low patients to gemcitabine as it would add toxicity without effectiveness.

CO-101 formulation patent may extend protection to 2030

CO-101 could have patent protection out to 2030

As CO-101 is the key near term driver for Clovis, possessing an effective patent estate is critical. CO-101 has conventional composition of matter protection to 2020-21 (incl. extensions), which is a relatively short window of exclusivity assuming approval in 2014. There is, however, the potential for an extension to 2030 through a formulation patent that would considerably lengthen the IP protection. After discussions with the company's internal counsel, we gained greater comfort that the unique formulation patent will be sufficient to gain exclusivity until 2030. The patent's claims are centered around the steps to formulate CO-101, a process that we understand is finicky and not easy to replicate. We understand this difficulty is common with lipid conjugated drugs, which is illustrated by examples of lipid drugs without IP protection (Ambisome, Doxil) where a generic version has not yet been successfully developed.

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CO-101 revenue build and upside levers

Our detailed CO-101 revenue model can be seen in Table 8. As previously discussed, we assume positive LEAP data in late 2012 could lead to regulatory filings in mid-2013 and subsequent US and EU approvals in early 2014 and mid-2014, respectively. Constructing a model for pancreatic cancer is depressingly simplistic given the poor outcomes for the majority of patients (really just an incidence based disease with a limited prevalent patient population). Overall, we believe this model could actually prove quite conservative if the pivotal results are indeed positive. We run through several of the potential upside drivers below.

Table 8: CO-101 Patient Revenue Model

Pancreatic cancer		2011	2012	2013	2014	2015	2016	2017	2018	2019
U.S.										
New cases of pancreatic cancer	0.5%	43,140	43,356	43,572	43,790	44,009	44,229	44,450	44,673	44,896
% with unresec locally adv/met disease		*85%*	*85%*	*85%*	*85%*	*85%*	*85%*	*85%*	*85%*	*85%*
New cases - unresec locally adv/met PC		36,669	36,852	37,037	37,222	37,408	37,595	37,783	37,972	38,162
% ECOG Performance Status <3		*88%*	*88%*	*88%*	*88%*	*88%*	*88%*	*88%*	*88%*	*88%*
New cases of unresect locally adv/met PC eligible for gemcitabine		32,269	32,430	32,592	32,755	32,919	33,084	33,249	33,415	33,582
% of pts with low hENT1 expression		*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*
New cases of unresec locally adv/met PC on gemcitabine low hENT1 expression		16,134	16,215	16,296	16,378	16,459	16,542	16,624	16,708	16,791
Penetration into 1st-line treatment		***0.0%***	***0.0%***	***0.0%***	***10.0%***	***25.0%***	***45.0%***	***55.0%***	***60.0%***	***65.0%***
Number of pts treated with CO-101		0	0	0	1,638	4,115	7,444	9,143	10,025	10,914
Price per month of treatment	3.0%	$0	$0	$0	$10,000	$10,300	$10,609	$10,927	$11,255	$11,593
Avg. number of months of treatment per patient		4	4	4	4	4	4	4	4	4
Total U.S. revenues for Pancreatic cancer		**$0**	**$0**	**$0**	**$66**	**$170**	**$316**	**$400**	**$451**	**$506**
Europe										
New cases of PC in big 5 EU countries	0.5%	53,925	54,195	54,466	54,738	55,012	55,287	55,563	55,841	56,120
% with unresec locally adv/met disease		*85%*	*85%*	*85%*	*85%*	*85%*	*85%*	*85%*	*85%*	*85%*
New cases - unresec locally adv/met PC		45,836	46,065	46,296	46,527	46,760	46,994	47,229	47,465	47,702
% ECOG Performance Status <3		*88%*	*88%*	*88%*	*88%*	*88%*	*88%*	*88%*	*88%*	*88%*
New cases of unresect locally adv/met PC eligible for gemcitabine		40,336	40,538	40,740	40,944	41,149	41,354	41,561	41,769	41,978
% of pts with low hENT1 expression		*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*	*50%*
New cases of unresec locally adv/met PC on gemcitabine low hENT1 expression		20,168	20,269	20,370	20,472	20,574	20,677	20,781	20,885	20,989
Penetration into 1st-line treatment		***0.0%***	***0.0%***	***0.0%***	***2.0%***	***10.0%***	***25.0%***	***35.0%***	***45.0%***	***50.0%***
Number of pts treated with CO-101		0	0	0	409	2,057	5,169	7,273	9,398	10,494
Price per month of treatment	0.0%	$0	$0	$0	$8,000	$8,000	$8,000	$8,000	$8,000	$8,000
Avg. number of months of treatment per patient		4	4	4	4	4	4	4	4	4
Total E.U. revenues for Pancreatic cancer		**$0**	**$0**	**$0**	**$13**	**$66**	**$165**	**$233**	**$301**	**$336**
Total WW revenues for Pancreatic cancer		**$0**	**$0**	**$0**	**$79**	**$235**	**$481**	**$632**	**$752**	**$842**

Source: J.P. Morgan estimates and company reports.

Setting our base case for CO-101

In the US, we assume roughly 43,130 new cases of pancreatic cancer based on data from the American Cancer Society. The literature estimates ~15% of cases are resectable with the remaining 85% candidates for 1L therapy. Of the addressable 1L patients, roughly 88% have ECOG status <3 (as in the LEAP trial) and for now we assume hENT1 distribution to be 50:50. Our market assumptions work down to an addressable hENT1 low opportunity of a little over 16,000 patients and we project US launch in early 2014. We assume penetration in the hENT1 low patients for 2014 to be 10%, which increases to 65% by 2019 with revenues going from $66M to $506M. In the EU, we expect approval to take longer with a launch in 2H14 and a slower ramp as well as price discounted by 20%. Our 2019 EU assumption for CO-101 revenues is $336M based on 50% penetration.

We believe our CO-101 sales estimates are potentially too conservative based on what we view as 3 readily achievable upside levers

Why our CO-101 forecast could prove conservative…

We believe our market assumptions for CO-101 are more than sufficient to justify significant upside potential in CLVS. However, our favorable view of CO-101 and the company is also partially driven by several possible upside drivers to our projections. Working down the respective line items, these levers specifically include **1) higher hENT1 low ratio, 2) greater market penetration, and 3) cost per patient** (driven by both pricing and duration of therapy). Below we go through each lever and potential upside scenarios using our 2019 US revenue estimate of $506M as a base case. Our scenarios are summarized in Table 10 where we calculate the impact of each potential upside lever while keeping all else the same.

1. The ratio of hENT1 low patients could be closer to 65% rather than the 50% we currently assume

POTENTIAL UPSIDE LEVER #1: hENT1 distribution

We currently assume that the distribution of hENT1 expression in patients with pancreatic cancer is essentially equal between high and low. However, there is now recently available information that suggests that closer to two-thirds of patients are low expressers of hENT1, making them potential candidates for CO-101. We plan to wait for more definitive data from the LEAP study before reconsidering our assumption. *We calculate that if the ratio is closer to the two-thirds (65%) seen in recent analyses, our 2019 US sales estimate could rise by about $150M, to about $655 from $506M, all else remaining the same.*

2. CO-101 would be on the market with a survival advantage and companion diagnostic, which could facilitate greater share than the 65% we currently assume at peak

POTENTIAL UPSIDE LEVER #2: C0-101 penetration

We assume CO-101 is used in 65% of the hENT1 low PC patients in 2019. However, if LEAP is indeed successful, then CO-101 would be associated with an overall survival benefit, which we believe more than likely could drive greater penetration of the market than we currently project. Consider the current use of gemcitabine as a proxy for the future uptake of CO-101. Despite the fact that gemcitabine only works in a minority of patients, Clovis estimates that ~80% of the PC population is treated with the agent given the lack of options. Accordingly, if CO-101 is not only linked with a survival benefit but also has a companion diagnostic to prospectively identify patients most likely to be sensitive to the agent, then we don't see why the vast majority of eligible patients would not be treated with the drug. It's also quite possible that the time to peak sales would be shortened. *If we simply increase our penetration rate in 2019 to 80% of the hENT1 low patients from 65%, our US sales estimate would grow an estimated $117M, to $623M instead of $506M .*

Regarding the *high* hENT1 population, we expect minimal adoption of CO-101 in this population seeing that generic versions of gemcitabine are cost effective and physicians have years of experience with the drug. However, physicians we spoke with noted some potential use in this setting. We, nevertheless, still assume a very compelling benefit in the hENT1 high patients over and above gemcitabine would have to be seen in LEAP (a remote outcome based on the early data) to facilitate uptake of CO-101. Our model assumes zero use in hENT1 high patients.

3. We suspect our current price assumption of $40k/pt may be underestimating the ultimate price of CO-101 by 25-50%

POTENTIAL UPSIDE LEVER #3: pricing

Pricing is probably the most obvious area where we are too conservative. Our model currently reflects a monthly price of $10,000 for CO-101 with an average duration of 4 monthly cycles, putting total cost of therapy at around $40,000 per patient. While we are comfortable with our cost/patient projection, we recognize that our estimate is conservative compared to other recently approved oncology drugs (Table 9). Indeed, management has even recently been suggesting a potential price of $50-60k per

patient. Once again if CO-101 does in fact reach the market, we believe it would almost certainly be with a survival advantage (the primary endpoint of LEAP) and with a companion diagnostic. Under those circumstances, we believe a higher price point would certainly seem justified. So while we recognize that we are probably too conservative at this point, we are, nevertheless, comfortable with our assumptions but would likely review them when we see the eventual magnitude of benefit in LEAP.

Table 9: Cost comparison of recent oncology drug approvals

Drug	Description	Manufacturer	Cost/cycle	No Cycles	Total Cost
Xalkori	Oral, targeted sm molecule	PFE	9572	11	**108 K**
Adcedtris	Infusion, biologic	SGEN	13,500	7-9	**95-122K**
Yervoy	Infusion, biologic	BMS	24000	4	**96 K**
Jakafi	Oral, targeted sm molecule	INCY	7000	12	**84 K**
Jevtana	Infusion, chemotherapy	SNY	8080	10	**81 K**

Source: J.P. Morgan estimates, company reports and PriceRx.com.

For added context, the monthly price of Gemzar is ~$2,900 while generic versions are estimated at $1,000 per month. These prices total to roughly 11.6K and 4K (for 4 cycles) per patient, respectively. Pending the approval of CO-101, we assume that cost will drive the preference for gemcitabine in hENT1 high patients.

We do grow our estimated CO-101 price at 3% per year in the US (keep flat in EU), so our $40k starting point in 2014 increases to $46.3k by 2019. This is the price behind our current forecast of ~$506M in US sales in 2019. *If, however, the price at launch is closer to $60K per patient, then there could be about an estimated $125M upside risk to our 2019 US sales estimate, to about $630M, all else remaining the same.*

Our assumption for duration of therapy is 4 months based on historical data in PC. If survival is doubled or near the 9.1 mos seen in the pilot Ph2 study, we believe patients are likely to be on therapy longer than 4 months. *If we assume patients stay on CO-101 for 6 months instead of 4 (but keep our current monthly price assumption of $10k), it could add about $250M to our 2019 US sales forecast of $506M, to about $760M.*

Table 10: Scenarios of Potential Upside Levers using 2019 CO-101 Revenues

Scenario/ Upside Lever	Cost/month	Duration (cycles)	Total Cost per patient	hENT1 low (%)	Penetration (2019)	CO-101 Revenues	Upside to JPMe
Current JPMe 2019 (base case)	$11,593	4	$46,371	50%	65%	**$506M**	-
Higher price/cycle	**$14,491**	4	**$57,964**	50%	65%	**$633M**	$127M
Longer duration	$11,593	**6**	**$69,556**	50%	65%	**$759M**	$253M
Greater % hENT1 low	$11,593	4	$46,371	**65%**	65%	**$658M**	$152M
Greater penetration	$11,593	4	$46,371	50%	**80%**	**$623M**	$117M
Total Potential Upside (best case)	**$14,491**	**6**	**$86,946**	**65%**	**80%**	**$1.16B**	**$654M**

Source: J.P. Morgan estimates and company reports.

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Early Pipeline Overview

CO-1686 for NSCLC is targeting a rapid path to market

CO-1686 is an oral small molecule mutant selective EGFR inhibitor that was in-licensed from Avila Therapeutics. There are already two approved oral EGFR inhibitors, Tarceva (Roche/Genentech) and Iressa (AstraZeneca), though many patients develop resistance to these drugs after exposure. The added benefit of CO-1686 is that the drug has activity in both initial activating EGFR mutations as well as the primary resistance mutation, T790M. Based on this, the development program for CO-1686 is broad and includes development for both 1L and 2L patients. Furthermore, a companion diagnostic is also being developed by Roche Molecular Systems to help identify potential patients for both indications.

Quick overview of NSCLC: large markets with significant mortality

The American Cancer Society estimates there were approximately 223,000 new cases of lung cancer in the US in 2010. Outside of the US, there are an estimated 288,000 new cases in the EU each year (Cancer Research UK) and 85,000 cases in Japan (Cancer White Paper – Shinoharashinsha Inc.). Similar to pancreatic cancer, patients are often diagnosed in advanced stages of disease when local therapy (surgery and radiation) is no longer a practical option. Non-small cell lung cancer (NSCLC) accounts for 85% of diagnosed lung cancers and standard of care is generally a combination of platinum plus paclitaxel chemotherapy. More recently, the addition of Avastin has shown to prolong survival in a specific histologic subtype (non-squamous) and Alimta (LLY) has now replaced paclitaxel. Despite improvements to standard of care, 5 year survival of 24% (advanced) and 4% (metastatic) is only marginally better than that of pancreatic cancer patients.

TKIs can achieve significant responses in patients with activating mutations

For patients that failed chemotherapy, two tyrosine kinase inhibitors (TKIs), Iressa and Tarceva, were found to induce clinical response and were approved in 2003 and 2004, respectively. It was later found that more dramatic responses with the TKIs were seen in patients with activating mutations in EGFR (ex, L858R). A 2008 study in Clinical Cancer Research estimates that patients with initial EGFR activating mutations represent ~10-15% of Caucasians with NSCLC and 30-35% of East Asians. It has since been more definitively shown that TKIs are more effective than standard chemotherapy in patients with activating mutations and molecular testing has become standard in many countries.

TKI therapy can also trigger resistance

Despite an initial response, most patients will progress after a year of TKI therapy, primarily because a second mutation, T790M, appears and enables resistance. At least three drugs, PF299804 (Pfizer), XL647 (Exelixis) and Afatinib (Boehringer Ingelheim) considered second generation TKIs have been developed to overcome the resistance. However, either the programs did not advance or responses were not seen with the drugs. Based on a 2007 study in Nature Reviews Cancer, approximately half of patients treated with Tarceva or Iressa develop the T790M resistance mutation, making this a substantial market. For context, 2010 sales of Tarceva were $1.3B and for Iressa, $393M (limited access in the US). Until better drug options are available, patients that fail TKIs will generally receive standard chemotherapy.

CO-1686 was designed as a covalent inhibitor of EGFR with potentially improved safety

Avila's proprietary Avilomics platform was designed to discover and develop targeted covalent inhibitors. This type of inhibitor forms strong durable bonds with its target in order to achieve high potency. The Avilomics platform was used to develop CO-1686 against a site on the EGFR protein where a covalent bond could be formed. *In vitro*, C0-1686 has 200-fold higher binding selectivity for EGFR mutations (including T790M) compared to the normal EGFR receptor. This is a benefit as binding to normal EGFR can cause significant toxicity (rash, diarrhea). Encouragingly, preclinical models show low intestinal toxicity (surrogate measure of weight loss).

Potentially fast path to market with a companion diagnostic

Management has set an aggressive path forward, with the goal of filing the NDA only four years after filing the IND (1Q12). This is partially driven by the companion diagnostic that is being developed to identify patients with EGFR mutations. A Phase 1/2 trial is expected to begin enrolling patients with either activating or the T790M mutations in 1H12. The preliminary data, expected in 2H13, includes a dose ranging portion that will help design an expansion cohort of patients with the T790M mutation. A pivotal trial in 2L TKI failures with the T790M mutation will follow if successful. Finally, a companion diagnostic to help quickly identify patients with the T790M mutation is being developed simultaneously by Roche Medical systems. It is very early days with this drug, but the path could enable rapid development (and is not all that different than what Pfizer recently did with crizotanib/Xalkori).

Significant competition, though the T790M focus could be an advantage

There are several oral EGFR inhibitors in development for NSCLC (Table 11). The indication is indeed a dynamic field with a large number of classes and also several drugs within a class that is being evaluated for potential use. The one edge is that CO-1686 has potency against the T790M resistance mutation while sparing wild type EGFR and the only direct competitor is Ariad's AP-26113 (targets ALK and EGFR). The Ph1 portion of theAP-26113 trial was initiated in 2H11 and we expect data 2H12. That said, we believe CO-1686 is not far behind.

Table 11: Summary of Select Oral EGFR Inhibitors for NSCLC

Drug	Company	Activity against	Indication	Stage of Development
Afatinib (Tomtovok)	Boehringer Ingelheim	EGFR, HER2 binds irreversibly	NSCLC	Ph3
PF299804	PFE	HER1, HER2, HER4, EGFR binds irreversibly	NSCLC 2L	Ph2
AP26113	ARIA	ALK, EGFR - T790M mutant	NSCLC	Ph1/2
AV-412	Aveo Pharma	EGFR, HER2	NSCLC	Ph1
Iressa (gefinitnib)	AZN	EGFR	met NSCLC 2L	Approved in 2003
Tarceva (erlotinib)	Genentech, Roche	EGFR	met NSCLC 2L & 3L, Pancreatic cancer 1L with Gem	Approved in 2004 Approved in 2005

Source: J.P. Morgan estimates and company reports.

Terms of the CO-1686 agreement with Avila

In May 2010, Clovis entered into a worldwide agreement to discover, develop and commercialize preclinical covalent inhibitors of mutant forms of EGFR. CO-1686 was identified as the lead asset from Avila's portfolio. An upfront payment of $2M was paid when the agreement was struck and royalties are due on net sales should any of the assets be commercialized. In addition, Clovis is responsible for $119M in potential development and regulatory milestones as well as $120M in commercial payments as certain sales targets are achieved.

CO-338 is a dual PARP inhibitor in early development

CO-338 is a poly-ADP ribose polymerase (PARP) inhibitor in-licensed from Pfizer (covered by JPM's Pharmaceuticals analyst Chris Schott) in June 2011. Clovis possesses global development and commercial rights, similar to the other in-licensed products. The drug has two formulations (IV and oral), and the company intends to develop the drug as both a monotherapy and in combination with other products.

PARP background

PARP enzymes synthesize poly ADP-ribose (PAR), a component of the early warning system for DNA damage. PAR is synthesized on regions of damaged DNA where it signals for DNA repair. The DNA damage can be caused by everyday exposures such as sunlight or by DNA-binding chemicals. There are two major forms of PARP that help signal DNA damage, PARP-1 and PARP-2. In animal models, loss of either of these genes causes an increase in DNA damage and loss of both (double knockout) is lethal. In general, if the DNA repair mechanisms become overwhelmed or overly impaired, the cells will shut down and induce cell suicide.

BRCA synergy in breast and ovarian cancers

Initially PARP inhibitors were being developed as chemo-potentiators based on preclinical studies. However, early clinical results did not demonstrate a dramatic effect and showed the need for patient selection to see significant responses. Greater utility for the PARP inhibitors was postulated when mutations in the BRCA genes (associated with high rates of hereditary breast and ovarian cancers) were also shown to cause impairment in DNA repair. The concept is that cells with BRCA mutations have impaired DNA repair but not enough to induce cell suicide. These cells are, however, likely more susceptible to incremental repair inhibition than normal cells. From this emerged the theory that inhibition of PARP in BRCA mutant cells might induce the cell suicide pathway.

Development strategy for CO-338 focused on an oral drug formulation

Clovis' PARP drug is a potent inhibitor of both PARP-1 and PARP-2. It is available as both an IV and oral formulation but focus will be on advancement of the oral version as a monotherapy or in combination for solid tumors predisposed to PARP inhibition. Two investigator sponsored trials with the IV formulation are ongoing (Table 12) and CLVS plans to replace the IV formulation with the oral version in these studies. Two Ph1 monotherapy trials directed by Clovis began recently with the oral formulation that will evaluate dose and schedule for long term administration in solid tumors with data expected in 2012.

Development as a monotherapy will be focused on breast and ovarian cancer patients with BRCA germ-line mutations. Clovis is also evaluating use for sporadic BRCA

mutations that are not germ-line derived, a term referred to as BRCA-ness. Work to identify a molecular signature is under way, and Clovis plans to also treat these patients with monotherapy CO-338.

Table 12: Summary of Current CO-338 Trials

Formulation	Stage	Patients	Design	Dose	Primary Endpoint	Secondary Endpoint	Data Timing
Oral	Ph1/2	Ph1 n = 30 solid tumors Ph2 n = 54 BC	Dose ranging Monotherapy	Start at 40 mg QD Escalates to MTD 21 day cycle Ph2 at MTD	Gr3/4 AEs MTD ORR (Ph2)	PK Profile Change in QT/QTc AEs DOR	2012
Oral	Phase 1	Solid tumors	Dose escalation with carboplatin	CO-338 D1-14 20 day cycles 80 mg complete 120 mg in progress	MTD	PK Profile Change in QT/QTc AEs DOR	Ph1 2012
IV switched to oral	Ph1/2	Breast, Ovarian BRCA germ-line mutations	Dose ranging Monotherapy Duration exploration	CO-338 D1-7 21 day cycle	ORR		2013 IST
Oral and IV	Ph2	n = 135 BC Adjuvant BRCA mutations and high risk triple negative	1. CO-338 + cisplatin 2. Cisplatin alone	CO-338: C1-4 30 mg IV D1-3, 100 mg oral QW for 6 mos Cisplatin: 75mg/m^2, 60 min, D1 Q3W for 4 cycles	2 yr DFS	1 yr DFS Tolerability OS PK	2014-2015 IST

BC: Breast Cancer, OS: Overall Survival, ORR: Overall Response Rate, DOR: Duration of Response, DSF: Disease Free Survival; MTD: Maximum Tolerated Dose, IST: Investigator Spondored Study

Source: Company reports.

The companion diagnostic theme will continue with CO-338

Clovis believes that in most cases, patient selection will be needed to prospectively identify patients that have the best response to its drug. Much like the other two pipeline products, a companion diagnostic is being considered and the company will again look for a partner to oversee the development. CO-338 is relatively new to the Clovis pipeline and at this time, details on the diagnostic and even the overall development strategy are not yet well defined.

Competition also a factor but the late stage candidates are falling off

There have been two major setbacks in the PARP field. First, inaparib (SNY) failed to show a benefit (PFS and OS) in triple negative breast cancer patients in early 2011. At the time, inaparib was the most advanced PARP inhibitor and since the negative data, there has been some debate on whether it is in fact a true PARP inhibitor. Despite the disappointment, Sanofi is continuing Phase 3 development in NSCLC (squamous) with OS data expected in 2013. Outside of this trial, a search on clinicaltrials.gov shows no other Phase III trials with any PARP inhibitor but a significant number in Phase 2 stages. A more recent setback came toward the end of December 2011. AstraZeneca decided not to advance olaparib into Phase 3 trials after an interim Phase 2 analysis predicted a lack of overall survival benefit in ovarian cancer patients. Issues with formulation were cited as the reason for lack of effectiveness. As for earlier programs, Abbott's velaparib has the highest number of ongoing trials (~40) with a Phase 2 neo-adjuvant breast cancer trial as the most advanced study. Cephalon's CEP-9722, Merck's MK-4827 and BioMarin's BMN-673 are also in early stages.

Table 13: Summary of Select PARP Inhibitors in Development

Drug	Company	Activity against	Indication	Stage of Development	Entry
Inaparib	Sanofi-Aventis	PARP-1	NSLCL Neo adj BC, Ovarian	Ph3 Ph2	iv
Olaparib (AZD2281)	KuDOS pharmaceuticals, Astra Zeneca	PARP-1	Ovarian	Ph2 program halted on lack of benefit	oral
Velaparib (ABT-888)	Abbott Therapeutics	PARP-1 and PARP-2	Neo adj BC Ovarian, Melanoma, Solid tumors	Ph2 Ph1	oral
MK4827	Merck	PARP-1 and PARP-2	Adv solid tumors	Ph1	oral
CEP-9722	Cephalon	PARP-1 and PARP-2	Solid tumors Mantle cell lymphoma	Ph1/2 Ph1	oral
BMN-673	BioMarin	PARP-1	Solid tumors AML, CLL, Mantle cell lymphoma	Ph1	oral

Source: Company reports and clinicaltrials.gov.

Terms of the agreement with Pfizer

In June 2011, Clovis entered into license agreement with Pfizer for rights to CO-338 (also known as rucaparib/PF-01367338/AG-014699). An upfront payment of $7M was made to Pfizer by issuing a promissory note initially due 2012, however, the notes were converted to common stock at the time of the public offering. Clovis is responsible for all development and commercialization costs and if approved, will pay royalties on sales (mid-teens). Additional milestones will also be due for certain regulatory events ($89M) as well as commercial thresholds ($170M), most of which are for over $500M in sales.

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SWOT Analysis

Strengths	Weaknesses
• Compelling hypothesis: established correlation for hENT1 screening and lack of gemcitabine responsiveness	• Dependence of adoption of hENT1 screening
• Well respected management with recognized track record of success	• Aggressive filing strategy and approval may require full Ph3 program
• Companion diagnostic to identify patients most likely to respond puts Clovis at cutting edge of drug development	• Lack of substantial Phase 2 data
	• Limited liquidity post IPO
Opportunities	**Threats**
• Potential to become standard of care in pancreatic cancer patients with low hENT1 expression	• Many new drugs are in development for the treatment of pancreatic cancer, though most are in combination with gemcitabine
• hENT1 low market may be larger than we currently assume	• Relatively near-term capital needs if a partnership is not formed
• Initial CO-101 approval is targeting large first-line pancreatic cancer market	• FDA may require more than the LEAP study for approval of CO-101
• Potential CO-101 IP extension to 2030 from pending formulation patent	
• Accelerated approval pathway	

Source: J.P. Morgan estimates and company reports.

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Financial Outlook

Clovis is an early-stage company whose earnings potential and profitability will still take some time to materialize, in our view. We estimate sustainable profitability beginning in 2015, which corresponds with the *first full year* of potential CO-101 sales (we assume launch in early 2014). While we believe that CO-101 has the potential to be a game changing therapy in pancreatic cancer, we also must acknowledge the significant risk tied to our assumptions given the very modest amount of existing data. Furthermore, at this juncture, we do not assume any positive financial contribution from the rest of the company's emerging pipeline, either in the form of potential partnership payments of product sales. Rather, our numbers only reflect an increasing R&D burden. Thus with a cash balance that is primarily earmarked for completing the clinical and regulatory development of CO-101, we believe there will be a need for additional funding for commercialization and driving the rest of the pipeline into later stages of clinical testing.

Enough cash to take CO-101 to approval

As of Sept 30, Clovis had $22M in cash (~$2.2/sh) and no debt. Including ~$130M in net proceeds from the IPO, we project a cash balance of ~$140M at year-end ($5.64/sh)

Clovis has a relatively quick path to market for CO-101 with potential approval as soon as late 2013 or early 2014. With net proceeds of ~ $130M after the recent Initial Public Offering (JPM served as a joint bookrunner) and no debt, we believe the company has sufficient funds to complete the ongoing pivotal LEAP trial and navigate CO-101 through the regulatory process. We estimate that cash used in operations in 2011 will be ~$45-50M and that this will increase to ~$60M in 2012. From there, we don't predict a significant boost as advancement in the earlier pipeline should be offset by the completion of the pivotal CO-101 trial.

Management estimates that the post-IPO cash balance will sustain operations for two years. This will cover the remaining development and regulatory expenses for CO-101, but we believe the company will need to replenish its resources to commercialize the product and cover ~$50M in milestones to Clavis if approval in all geographies is attained. We assume a second financing in late 2012/early 2013 following positive LEAP data. From there, we believe the company will be able to manage US and EU commercialization.

Profitability to be determined by CO-101

Pending approval of CO-101, we project profitability in 2015

As is common with young biotech companies, Clovis will not be profitable in the near term, though our forecast for profitability in 2015 is relatively soon after a potential CO-101 launch in 2014. That said, we do not expect the company's earnings outlook to be a material investment factor near term.

Our current EPS estimates of $(2.62) in 2012, $(2.57) in 2013 and $(1.83) in 2014 are driven by increasing R&D expenses and modest revenues for CO-101 that begin in 2014. We do not anticipate significant revenue growth until CO-101 is approved and begins to generate sales. As for general operating trends, we expect R&D to ramp over time as the pipeline progresses, and we assume a gap up in SG&A as CO-101 commercialization approaches (note that we anticipate the company will retain rights in the US and EU). There is the potential for other partnerships or in-licensing, but those are not currently reflected in our estimates.

Share count

We estimate Clovis will have roughly 24.4M shares heading into 2012 which fully reflects shares from the IPO and conversion of shares from both the 2011 convert as well as preferred shares (includes approximately 23.5M common shares, 0.9M options, and no warrants or converts).

Table 14: CLVS Key Financial Metrics

	2009A	2010A	2011E	2012E	2013E	2014E	2015E	2016E
In $ M								
December financial year-end								
Cash	58.4	12.3	108.1	190.9	107.8	45.0	57.8	169.9
Debt	-	-	-	-	-	-	-	-
CFOp + CapEx (burn)	(18.0)	(33.2)	(59.2)	(67.2)	(83.2)	(59.6)	36.4	179.5
Expected financing	75.5	-	155.0	150.0	-	-	-	-
Revenue	-	-	-	-	-	78.6	235.4	481.3
EPS	(5.30)	($9.85)	($5.33)	($2.62)	($2.57)	($1.83)	$0.70	$4.02
Consensus EPS	-	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Average shares outstanding	3.2	3.8	10.4	25.7	32.5	33.5	34.5	35.5
Fully diluted shares outstanding	3.2	3.8	10.9	26.6	33.3	34.3	35.3	36.3

Source: J.P. Morgan estimates and company reports.

Valuation

We are setting a Dec 2012 price target of $20 for CLVS

We are setting a December 2012 price target of $20. Our target is based on a blended average of our proprietary probability-adjusted sum-of-the-parts scenario analysis (50% weighting) and risk-adjusted NPV model (50% weighting).

Table 15: CLVS Valuation Summary

CLVS : Valuation Summary			
Discount rate	20.0%		
Main value driver	Prob of approval	Peak sales est (avg. scenario)	Avg peak yr
CO-101, US	55%	$ 500	2019
CO-101, EU	55%	$ 300	2020
Valuation methodology	Value	Weighting	Adj. value/ share
P/E 2015	$ -	0%	$ -
Real options scenario analysis	$ 20.49	50%	10.25
Risk adjusted NPV analysis	$ 20.36	50%	10.18
Total			$ 20.43
Catalyst/liquidity discount			0%
YE 2012 Price Target			**$ 20**

Source: J.P. Morgan estimates and company reports.

Proprietary real options scenario analysis (50% weighting)

Using this model, we estimate the value of the company's development programs (predominantly CO-101) by assigning a range of probabilities to six different commercial scenarios (ranging from an ineffective product that generates zero value to a breakthrough treatment option) and analyze them over several possible peak sales years. Discount rates in our universe are typically based on the company's

weighted average cost of capital and generally fall within a range of 10% to 15%. We apply a rate of 20%, higher than our typical range, which we believe is appropriate for a new issue, though we expect the rate will track down.

We currently ascribe a 55% probability of success for CO-101 in the US and EU

Value contribution of CO-101

Below, we demonstrate our analysis for CO-101 in the US and EU. As Clovis' key value driver, this product contributes $12 to our SOTP analysis. We assume a 55% probability that CO-101 reaches the market in each territory (slightly above historical success rates for clinical candidates in randomized Phase 2 trials in oncology given the support for the hENT1 thesis, the companion diagnostic, and early survival data). Our timeline to reach peak sales is 2019-2020 depending on the geographic location, which we acknowledge may be a bit too conservative. Typically, drugs for life threatening cancer conditions peak quickly (often within a few years for a given indication) as opposed to a more gradual ramp (as we are assuming). However, we await LEAP data prior to reconsidering our expectations. We also assume a 15% royalty paid to Clavis Pharma on CO-101 sales. As indicated, a discount rate of 20% is applied, which also may be conservative given the probability adjustments already in place. See Table 16 for a detailed view of our analysis.

Table 16: CLVS CO-101 Scenario Analysis

CLVS: Real Options Sum-of-the-parts Parts Valuation Analysis

Assumptions:			Discount rate (WACC):	20.0%			4Q12 Fully diluted shares (mm):				33.2			
Product:	**CO-101**		Peak year	2018			2019			2020			Average
Indication:	**Pancreatic cancer**		Discount period	6.0			7.0			8.0			prob-adj
Assumption:	**US Market**												value
			Price/sales mult.	3	4	5	3	4	5	3	4	5	
	Prob.	Peak sales (millions)	Share of peak sales					Value					
Ineffective	45%	$ -	$ -	$0	$0	$0	$0	$0	$0	$0	$0	$0	$ -
Disappointment	5%	250	213	$6	$9	$11	$5	$7	$9	$4	$6	$7	0.36
Below average	15%	330	281	$8	$11	$14	$7	$9	$12	$6	$8	$10	1.43
Average	20%	500	425	$13	$17	$21	$11	$14	$18	$9	$12	$15	2.89
Above average	10%	750	638	$19	$26	$32	$16	$21	$27	$13	$18	$22	2.17
Breakthrough	5%	1,000	850	$26	$34	$43	$21	$29	$36	$18	$24	$30	1.44
Total	100%												**$ 8.29**

Product:	**CO-101**		Peak year	2019			2020			2021			Average
Indication:	**Pancreatic cancer**		Discount period	7.0			8.0			9.0			prob-adj
Assumption:	**EU Market**												value
			Price/royalty mult.	3	4	5	3	4	5	3	4	5	
	Prob.	Peak sales (millions)	Share of peak sales					Value					
Ineffective	45%	$ -	$ -	$0	$0	$0	$0	$0	$0	$0	$0	$0	$ -
Disappointment	5%	99	84	$2	$3	$4	$2	$2	$3	$1	$2	$2	0.12
Below average	15%	198	168	$4	$6	$7	$4	$5	$6	$3	$4	$5	0.71
Average	20%	300	255	$6	$9	$11	$5	$7	$9	$4	$6	$7	1.44
Above average	10%	450	383	$10	$13	$16	$8	$11	$13	$7	$9	$11	1.08
Breakthrough	5%	600	510	$13	$17	$21	$11	$14	$18	$9	$12	$15	0.72
Total	100%												**$ 4.08**

Source: J.P. Morgan estimates and company reports.

Risk-adjusted NPV analysis (50% weighting)

In our risk-adjusted NPV analysis, we estimate the revenues and associated expenses (including taxes) over the expected patent life of a product. We complete this exercise for conservative, moderate, and aggressive sales scenarios and then assign a range of probabilities to each of these outcomes as well as to the possibility that the

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product is ineffective and generates zero value. For CO-101, we assume the formulation patent will be granted so that protection extends to 2030. As with our scenario analysis, we apply a discount rate of 20%, which we believe is appropriate given the applied probability adjustments. The key assumptions in our rNPV model are outlined below.

Table 17: CLVS NPV Key Assumptions and Summary

NPV Assumptions	US	EU
Revenues	$506M	$336M
Year	2019	2019
GM	89%	88%
SG&A (% sales)	15%	20%
Royalties (to Clavis)	15%	15%
Tax Rate	30%	30%
Discount Rate	20%	20%
NPV term	2030	2030

CLVS : rNPV Sum-of-the-PartsAnalysis

Assumptions:	Disc. rate:	20.0%	4Q12 Fully diluted share	33.2

CO-101 Assume 2030 patent expiry	Peak sales or royalty	NPV	NPV/share	Probability	Value
Ineffective	$ -	$ -	$ -	45%	$ -
Aggressive	790.0	820.0	24.68	10%	$ 2.47
Moderate	526.7	447.8	13.48	30%	$ 4.04
Disappointing	395.0	297.2	8.95	15%	$ 1.34
Total				100%	$ 7.85

CO-101, ex-US Assume 2030 patent expiry	Peak sales or royalty	NPV	NPV/share	Probability	Value /share
Ineffective	$ -	$ -	$ -	45%	$ -
Aggressive	524.2	428.6	12.90	10%	$ 1.29
Moderate	349.5	260.9	7.85	30%	$ 2.36
Disappointing	251.9	163.4	4.92	15%	$ 0.74
Total				100%	$ 4.38

Source: J.P. Morgan estimates and company reports.

P/E analysis (no weighting)

We assign no weighting to our P/E analysis given that we project the first year of profitability to be 2015 and the variation in multiples in the first year of profitability is extremely broad.

Management

Patrick J. Mahaffy, President and Chief Executive Officer; Director

Patrick J. Mahaffy is a co-founder and has served as president and chief executive officer and a member of the board of directors since inception. Previously, Mr. Mahaffy served as president and chief executive officer and as a member of the board of directors at Pharmion Corporation, which he founded in 2000 and sold to Celgene Corporation in 2008. From 1992 through 1998, Mr. Mahaffy was president and chief executive Officer of NeXagen, Inc. and its successor, NeXstar Pharmaceuticals, Inc., a biopharmaceutical company. Prior to that, Mr. Mahaffy was a vice president at the private equity firm E.M. Warburg Pincus and Co. Mr. Mahaffy also serves on the boards of directors of Orexigen Therapeutics, Inc. (NASDAQ: OREX) and Flexion Therapeutics, Inc. He is also a trustee of Lewis and Clark College. Mr. Mahaffy has a B.A. in international affairs from Lewis and Clark College and an M.A. in international affairs from Columbia University.

Andrew R. Allen, BM, BCh, MA, MRCP, PhD, Executive Vice President of Clinical and Pre-Clinical Development and Chief Medical Officer

Dr. Andrew R. Allen is also a co-founder and has served in his current role since inception. Previously, Dr. Allen served in the same role at Pharmion Corporation, beginning in 2006. From 2004 through 2006, Dr. Allen served as vice president of BioPharma development and Head of the Oncology Therapeutic Unit for Chiron Laboratories' oncology franchise, and prior to that he progressed through positions of increasing responsibility at the management consulting firm McKinsey & Company, with a focus on oncology strategy. Dr. Allen serves on the board of directors of Nodality, Inc., a privately held biotechnology company. Dr. Allen qualified in medicine at Oxford University and earned his Ph.D. from the Imperial College of Science, Technology and Medicine in London. Dr. Allen also obtained post-graduate internal medicine qualification as a Member of Royal College of Physicians (MRCP).

Gillian C. Ivers-Read, Executive Vice President, Technical Operations and Chief Regulatory Officer

Gillian C. Ivers-Read is another co-founder that has served since inception. Previously, Ms. Ivers-Read served as executive vice president, development operations at Pharmion Corporation, beginning in 2002. From 1996 to 2001, she held various regulatory positions with Hoechst Marion Roussel and its successor, Aventis Pharmaceuticals, Inc., where she most recently held the position of vice president, global regulatory affairs. From 1994 to 1996, Ms. Ivers-Read was vice president, development and regulatory affairs for Argus Pharmaceuticals, and from 1984 to 1994, she served as a regulatory affairs director for Marion Merrell Dow. Ms. Ivers-Read serves on the board of Bio-Path Holdings, Inc. (OTC BB: BPTH). She received a B.Sc. in pharmacology from University College London.

Erle T. Mast, Executive Vice President and Chief Financial Officer

Erle T. Mast is also a co-founder and has served as executive vice president and chief financial officer since inception. Previously, Mr. Mast served in the same role at Pharmion Corporation, beginning in 2002. From 1997 through 2002, Mr. Mast worked for Dura Pharmaceuticals, Inc., and its successor, Elan Corporation. From 2000 to 2002, he served as chief financial officer for the Global Biopharmaceuticals

business unit for Elan. From 1997 to 2000, he served as vice president of finance for Dura Pharmaceuticals. Prior to that, Mr. Mast was a partner with Deloitte & Touche, LLP. Mr. Mast also serves on the boards of directors of Somaxon Pharmaceuticals, Inc. (NASDAQ: SOMX) and Zogenix, Inc. (NASDAQ: ZGNX). Mr. Mast received a B.Sc. in business administration from California State University Bakersfield.

Steven L. Hoerter, Senior Vice President, Commercial Operations

Steven L. Hoerter has served as senior vice president of commercial operations since August 2011. From 2010 to 2011, Mr. Hoerter was general manager and management center Head at F. Hoffmann-La Roche Ltd. for the Sub-Saharan Africa and Indian Ocean Region, based in Johannesburg, South Africa. From 2005 to 2010, Mr. Hoerter held a variety of positions at Genentech, Inc., including serving on the senior leadership team for Genentech's BioOncology business as Senior Director, Pipeline Development and Commercial Operations. Prior to that, he worked at Chiron Corporation and Eli Lilly and Company. During Mr. Hoerter's 11-year career at Lilly, he held positions in sales, business development, marketing and business unit management in the US, Europe and Africa. Mr. Hoerter has a B.A. in Russian and Political Science from Bucknell University, an M.B.A. from Tilburg University and a M.S. in Management from Purdue University.

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Models

Table 18: CLVS Income Statement

Fiscal Year Ends Dec 31	2009A	2010A	1Q11A	2Q11A	3Q11A	4Q11E	2011E	2012E	2013E	2014E	2015E	2016E
CO-101			$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ 78.6	$ 235.4	$ 481.3
Total Revenues	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ 78.6**	**$ 235.4**	**$ 481.3**
COGS & royalties	-	-	-	-	-	-	-	-	-	21.2	58.8	120.3
R&D	1.762	22.3	7.0	9.7	11.6	12.5	40.8	53.4	63.2	71.3	80.4	85.5
Acquired in-process R&D	13.1	12.0	-	7.0	-	-	7.0	4.0	-	-	-	-
SG&A	2.2	4.3	1.4	1.7	1.8	2.1	7.0	10.2	21.9	48.9	71.0	89.8
Total Operating Expenses	**$ 17.1**	**$ 38.6**	**$ 8.4**	**$ 18.4**	**$ 13.4**	**$ 14.6**	**$ 54.7**	**$ 67.7**	**$ 85.1**	**$ 141.5**	**$ 210.2**	**$ 295.6**
Operating income	(17.1)	(38.6)	(8.4)	(18.4)	(13.4)	(14.6)	(54.7)	(67.7)	(85.1)	(62.8)	25.1	185.7
Other income, net	(0.04)	0.795	0.1	(0.12)	(0.56)	(0.25)	(0.80)	0.3	1.8	1.5	1.7	4.3
Pretax Income	(17.1)	(37.830)	(8.3)	(18.5)	(13.9)	(14.8)	(55.5)	(67.3)	(83.3)	(61.3)	26.8	190.0
Income Tax (benefit)	-	-	-	-	-	-	-	-	-	-	2.7	47.5
Net Income	**$ (17.1)**	**$ (38)**	**$ (8.3)**	**$ (18.5)**	**$ (13.9)**	**$ (14.8)**	**$ (55.5)**	**$ (67.3)**	**$ (83.3)**	**$ (61.3)**	**$ 24.2**	**$ 142.5**
Average shares Outstanding	3.2	3.8 3.842	3.9	4.2	10.1	23.5	10.4	25.7	32.5	33.5	34.5	35.5
GAAP EPS	**$ (5.30)**	**$ (9.85)**	**$ (2.15)**	**$ (4.38)**	**$ (1.38)**	**$ (0.63)**	**$ (5.33)**	**$ (2.62)**	**$ (2.57)**	**$ (1.83)**	**$ 0.70**	**$ 4.02**
Margin Analysis:												
Gross margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	73%	75%	75%
Operating margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	11%	39%
Net margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	10%	30%
Cost Analysis:												
COGS as % of tot. prod. sales								NM	NM	27%	25%	25%
R&D as % of tot. revenue								NM	NM	62%	30%	19%
SG&A as % of tot. revenue								NM	NM	91%	34%	18%
Year-over-year growth:												
Total revenue	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
R&D Expense		1167%	116%	107%	102%	44%	83%	31%	18%	13%	NM	NM
SG&A Expense		95%	69%	48%	66%	68%	62%	46%	114%	124%	NM	NM
Total operating expenses		126%	107%	135%	96%	-27%	42%	24%	26%	66%	NM	NM
Operating income	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
Net income	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM
EPS	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	473%
Tax Rate	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	10%	25%

Source: J.P. Morgan estimates and company reports.

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Table 19: CLVS Balance Statement

	2009A	2010A	2011E	2012E	2013E	2014E	2015E	2016E
Assets								
Cash and cash equivalents	$ 57.3	$ 10.5	$ 106.3	$ 189.1	$ 105.9	$ 43.2	$ 56.0	$ 168.1
Available for sale securities	$ -	11.8	11.8	11.8	11.8	11.8	11.8	11.8
Prepaid research and developemnt expenses	$ 1.1	$ 1.8	$ 1.8	$ 1.8	$ 1.8	$ 1.8	$ 1.8	$ 1.8
Receivables	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Other current assets	$ 0.1	1.1	1.1	1.1	1.1	1.1	1.1	1.1
Total Current Assets	**$ 58.5**	**25.2**	**121.0**	**203.8**	**120.6**	**57.9**	**70.7**	**182.8**
Property, Plant & Equipment, net	0.3	1.0	0.7	0.5	0.4	1.9	13.2	43.6
Prepaid research and development expenses	0.8	-	-	-	-	-	-	-
Other assets	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total Assets	**$ 59.6**	**$ 26.2**	**$ 121.7**	**$ 204.4**	**$ 121.1**	**$ 59.8**	**$ 83.9**	**$ 226.4**
Liabilities & Equity								
Accounts Payable	0.5	1.4	1.4	1.4	1.4	1.4	1.4	1.4
Accrued research and development expenses	0.4	3.2	-	-	-	-	-	-
Other accrued expenses	0.2	0.7	-	-	-	-	-	-
Convertible promissary notes	-	-	-	-	-	-	-	-
Total Current Liabilities	**1.1**	**5.3**	**1.4**	**1.4**	**1.4**	**1.4**	**1.4**	**1.4**
Non-current liabilities	-	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Total Liabilities	**1.13**	**5.45**	**1.5**	**1.5**	**1.5**	**1.5**	**1.5**	**1.5**
Convertible pfd stock (36.296M shares authorized)								
Series A-1 conv pfd stock	9.9	9.9	9.9	9.9	9.9	9.9	9.9	9.9
Series A-2 convertible pfd stock	15.1	15.1	15.1	15.1	15.1	15.1	15.1	15.1
Series B convertible pfd stock	50.4	50.4	50.4	50.4	50.4	50.4	50.4	50.4
Common stock	0.004	0.004	0.004	0.004	0.004	0.004	0.004	0.004
Additional paid-in capital	0.0	0.1	155.1	305.1	305.1	305.1	305.1	305.1
Accumulated other comprehensive income	-	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Deficit accumulated during development stage	(17.1)	(54.9)	(110.5)	(177.8)	(261.1)	(322.4)	(298.3)	(155.8)
Total Shareholders' Equity	**58.4**	**20.8**	**120.2**	**202.9**	**119.6**	**58.3**	**82.4**	**224.9**
Total Liabilities & Equity	**$ 59.6**	**$ 26.2**	**$ 121.7**	**$ 204.4**	**$ 121.1**	**$ 59.8**	**$ 83.9**	**$ 226.4**

Source: J.P. Morgan estimates and company reports.

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Table 20: CLVS Cash Flow Statement

	2009A	2010A	2011E	2012E	2013E	2014E	2015E	2016E
Cash Flow from Operations								
Net Income	$ (17.1)	$ (37.8)	$ (55.5)	$ (67.3)	$ (83.3)	$ (61.3)	$ 24.2	$ 142.5
Adjustments to reconcile net loss to net operating cash								
Depreciation	0.0	0.1	0.2	0.2	0.1	0.1	0.5	3.3
Share-based compensation	0.0	0.1	-	-	-	-	-	-
Amortization of premiums and discounts on av for sale secs	-	0.3	-	-	-	-	-	-
Gain of sale of available for sale securities	-	(0.0)	-	-	-	-	-	-
Non cash acquired iin-process research and devt	-	-	-	-	-	-	-	-
Changes in assets and liabilities:								
Prepaid and accrued R&D expenses	(1.5)	2.9	-	-	-	-	-	-
Other operating assets	(0.1)	(1.0)	-	-	-	-	-	-
Accounts payable	0.5	0.9	-	-	-	-	-	-
Other accrued expenses	0.2	0.6	(3.9)	-	-	-	-	-
Cash Flow from Operations	**$ (18.0)**	**$ (34.0)**	**$ (59.2)**	**$ (67.2)**	**$ (83.2)**	**$ (61.2)**	**$ 24.6**	**$ 145.8**
Cash Flow from Investing								
Purchases of prop & equipment	(0.3)	(0.8)	-	-	-	(1.6)	(11.8)	(33.7)
Purchases of available for sale securities	-	(27.0)	-	-	-	-	-	-
Maturities and sale of available for sale secs	-	15.0	-	-	-	-	-	-
Cash Flow from Investing	**$ (0.3)**	**$ (12.8)**	**$ -**	**$ -**	**$ -**	**$ (1.6)**	**$ (11.8)**	**$ (33.7)**
Cash Flow from Financing								
Proceeds from sale of conv pfd & common stock, net of costs	75.5	-	155.0	150.0	-	-	-	-
Accumulated issuance costs of planned IPO	-	-	-	-	-	-	-	-
Proceeds from stock option exercises	0.03	0.03	-	-	-	-	-	-
Proceeds from issuance of conv promissary notes, net of costs	-	-	-	-	-	-	-	-
Cash Flow from Financing	**$ 75.5**	**$ 0.0**	**$ 155.0**	**$ 150**	**$ -**	**$ -**	**$ -**	**$ -**
Total Cash Flow	57.3	(46.8)	95.8	82.8	(83.2)	(62.8)	12.9	112.1
Beginning Balance: Cash and Investments	-	57.3	10.5	106.3	189.1	105.9	43.2	56.0
Ending Balance: Cash and Investments	**$ 57.3**	**$ 10.5**	**$ 106.3**	**$ 189.1**	**$ 105.9**	**$ 43.2**	**$ 56.0**	**$ 168.1**

Source: J.P. Morgan estimates and company reports.

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Clovis Oncology: Summary of Financials

Income Statement - Annual	FY10A	FY11E	FY12E	FY13E	Income Statement - Quarterly	1Q11A	2Q11A	3Q11A	4Q11E
Revenues	0	0	0	0	Revenues	0A	0A	0A	0
Cost of products sold	0	0	0	0	Cost of products sold	0A	0A	0A	0
Gross profit	0	0	0	0	Gross profit	0A	0A	0A	0
SG&A	4	7	10	22	SG&A	1A	2A	2A	2
R&D	22	41	53	63	R&D	7A	10A	12A	12
Operating Income	(39)	(55)	(68)	(85)	Operating income	(8)A	(18)A	(13)A	(15)
Note: EBITDA	-	-	-	-	Note: EBITDA	-	-	-	-
Net interest income / (expense)	1	(1)	0	2	Net interest income / (expense)	0A	(0)A	(1)A	(0)
Other income / (expense)	-	-	-	-	Other income / (expense)	-	-	-	-
Pretax income	-	-	-	-	Pretax income	-	-	-	-
Income taxes	0	0	0	0	Income taxes	0A	0A	0A	0
Net income - GAAP	(38)	(56)	(67)	(83)	Net income - GAAP	(8)A	(18)A	(14)A	(15)
Net income - recurring	-	-	-	-	Net income - recurring	-	-	-	-
Diluted shares outstanding	4	10	26	32	Diluted shares outstanding	4A	4A	10A	24
EPS - excluding non-recurring	-	-	-	-	EPS - excluding non-recurring	-	-	-	-
EPS - recurring	(9.85)	(5.33)	(2.62)	(2.57)	EPS - recurring	(2.15)A	(4.38)A	(1.38)A	(0.63)

Balance Sheet and Cash Flow Data	FY10A	FY11E	FY12E	FY13E	Ratio Analysis	FY10A	FY11E	FY12E	FY13E
Cash and cash equivalents	11	106	189	106	Sales growth	-	-	-	-
Accounts receivable	0	0	0	0	EBIT growth	-	-	-	-
Inventories	-	-	-	-	EPS growth	-	-	-	-
Other current assets	-	-	-	-					
Current assets	-	-	-	-	Gross margin	-	-	-	-
PP&E	1	1	1	0	EBIT margin	-	-	-	-
Total assets	26	122	204	121	EBITDA margin	-	-	-	-
					Tax rate	-	-	-	-
Total debt	-	-	-	-	Net margin	-	-	-	-
Total liabilities	5	2	2	2					
Shareholders' equity	21	120	203	120	Debt / EBITDA	-	-	-	-
					Debt / Capital (book)	-	-	-	-
Net income (including charges)	-	-	-	-	Return on assets (ROA)	-	-	-	-
D&A	-	-	-	-	Return on equity (ROE)	-	-	-	-
Change in working capital	-	-	-	-	Return on invested capital (ROIC)	-	-	-	-
Other									
Cash flow from operations	-	-	-	-	Enterprise value / sales	-	-	-	-
					Enterprise value / EBITDA	-	-	-	-
Capex	-	-	-	-	Free cash flow yield	-	-	-	-
Free cash flow	-	-	-	-					
Cash flow from investing activities	-	-	-	-					
Cash flow from financing activities	-	-	-	-					
Dividends	-	-	-	-					
Dividend yield	-	-	-	-					

Source: Company reports and J.P. Morgan estimates.
Note: $ in millions (except per-share data).Fiscal year ends Dec

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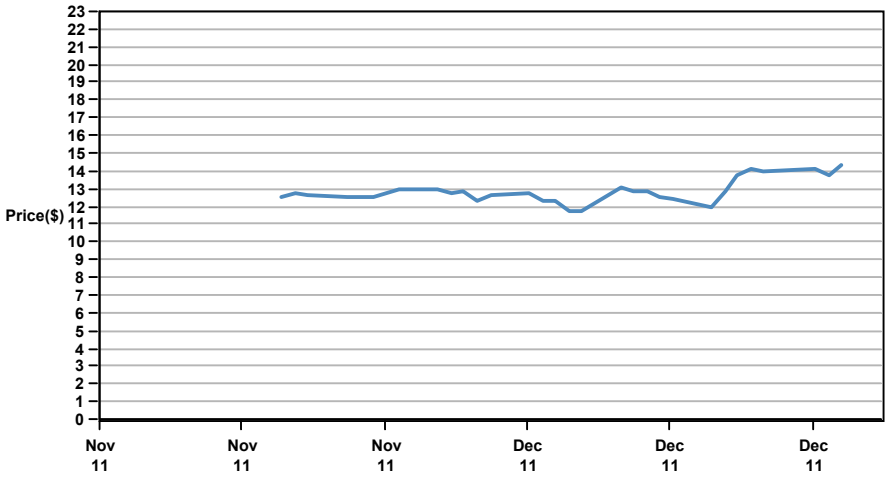
Clovis Oncology (CLVS) Price Chart



Source: Bloomberg and J.P. Morgan; price data adjusted for stock splits and dividends.

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