

# OncoMed Pharmaceuticals, Inc. (OMED)

Overweight

Emerging Cancer Antibody Play; Initiating Coverage with Overweight & \$30 Target

## CONCLUSION

OncoMed is developing therapeutic antibodies that target pathways essential to cancer stem cells (CSCs). While perhaps not the most precise term, think of CSCs as the seed cells that enable a tumor to regrow after initial response to radiation or chemotherapy. OncoMed is the premier CSC play with industry leading discovery efforts, intellectual property, partnerships and a rich pipeline with five novel cancer antibodies in the clinic. We look for clinical data, pipeline progress, IND filings and new partnerships to drive value at OncoMed. In July, OncoMed successfully completed an IPO, bringing pro forma cash to ~\$147 million. We are initiating coverage of OncoMed with an Overweight rating and \$30 price target.

- Leading Cancer Stem Cell Play.** Cancer stem cells (CSCs) have emerged as a promising area of cancer research over the last decade. We view OncoMed as the premier CSC play with industry leading pathway biology, discovery efforts and intellectual property. This has yielded a rich clinical pipeline of five cancer antibodies and two validating Big Pharma partnerships.
- Demcizumab First-in-Class Antibody.** Demcizumab is a wholly-owned, anti-DLL4 antibody presently in two Phase Ib combination trials with Alimta + carboplatin in non-small cell lung cancer (NSCLC) and with Abraxane + gemcitabine in pancreatic cancer. OncoMed expects to initiate a new Phase Ib/II trial of demcizumab + paclitaxel in recurrent ovarian cancer soon. We have observed initial signs of activity, but PoC combination data will drive the stock and inform future regulatory paths. OncoMed also intends to file an IND on wholly-owned, bi-specific antibody targeting DLL4 and VEGF in 2014.
- GSK Partnership.** In 2007 OncoMed signed an alliance with GSK to develop antibodies targeting the Notch pathway. OncoMed received \$35 million upfront and is eligible for up to \$1.4 billion in milestones and double-digit royalties. The partners are conducting two Phase Ib/II trials of OMP-59R5 targeting Notch 2/3 and two Phase Ia trials on OMP-52M51 targeting Notch 1.
- Bayer Alliance.** In 2010, OncoMed signed an alliance with Bayer to develop antibodies targeting the Wnt pathway. OncoMed has received \$80 million to date and is eligible for significant milestones plus double-digit royalties. The partners are conducting Phase I trials of OMP-18R5 targeting Fzd7 and OMP-54F28 targeting Fzd8-Fc.

## RISKS TO ACHIEVEMENT OF PRICE TARGET

Cancer is a competitive space. Demcizumab or OncoMed's other antibodies may fail in the clinic. OncoMed may not sign new partnerships and will likely require future cash.

## COMPANY DESCRIPTION

OncoMed is developing therapeutic antibodies to treat cancer.

PRICE: US\$19.84

TARGET: US\$30.00

Proj EV of \$684 million + \$164 million  
mid'14E cash

Edward A. Tenthoff

Sr Research Analyst, Piper Jaffray & Co.

212 284-9403, edward.a.tenthoff@pjc.com

| Changes         | Previous | Current    |
|-----------------|----------|------------|
| Rating          |          | Overweight |
| Price Tgt       |          | US\$30.00  |
| FY13E Rev (mil) | —        | US\$44.7   |
| FY14E Rev (mil) | —        | US\$58.7   |
| FY13E EPS       | —        | US\$(0.28) |
| FY14E EPS       | —        | US\$(0.13) |

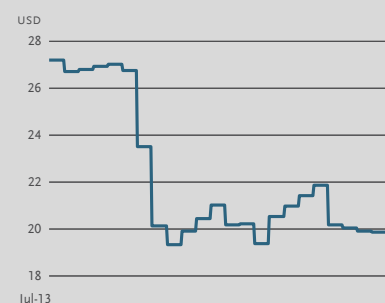
52-Week High / Low US\$31.00 / US\$17.00  
Shares Out (mil) 27.8

Incl. shares issued in IPO + over allotment

|                       |           |
|-----------------------|-----------|
| Market Cap. (mil)     | US\$551.6 |
| Book Value/Share      | US\$3.68  |
| Net Cash Per Share    | US\$5.31  |
| Debt to Total Capital | 0%        |
| Div (ann)             | NA        |
| Fiscal Year End       | Dec       |

Pro forma cash following IPO

## Price Performance - 1 Year



Source: Bloomberg

| YEAR  | REVENUE (US\$ m) |      |     |      |      |       | EARNINGS PER SHARE (US\$) |        |        |      |        |        |
|-------|------------------|------|-----|------|------|-------|---------------------------|--------|--------|------|--------|--------|
|       | Mar              | Jun  | Sep | Dec  | FY   | FY RM | Mar                       | Jun    | Sep    | Dec  | FY     | FY P/E |
| 2012A | —                | —    | —   | —    | 24.7 | 22.3x | —                         | —      | —      | —    | (1.00) | NM     |
| 2013E | 2.9A             | 10.9 | 2.9 | 27.9 | 44.7 | 12.3x | (0.39)A                   | (0.06) | (0.38) | 0.48 | (0.28) | NM     |
| 2014E | 3.9              | 28.9 | 3.9 | 21.9 | 58.7 | 9.4x  | (0.36)                    | 0.47   | (0.42) | 0.18 | (0.13) | NM     |

2013 qtrly EPS does not add to annual b/c of IPO

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## WAVE OF CLINICAL DATA TO VALIDATE ONCOMED'S ANTIBODY PIPELINE OVER NEXT 12-MONTHS

OncoMed is developing therapeutic antibodies that inhibit critical pathways for cancer stem cells (CSCs). While perhaps not the most precise term, CSCs were so named due to their ability to self-renew and differentiate; similar characteristics that define stem cells in healthy tissue. The easiest way to think of CSCs is as the **seed cells** that enable a tumor to regrow after initial response to radiation or chemotherapy. CSCs rely on different signaling pathways in order to survive and proliferate, often resulting in relapsed or refractory cancers that are more aggressive and harder to treat than the initial malignancy. It is for this reason that patient response to follow-on lines of therapy is of shorter duration, representing a huge unmet medical need for advanced and metastatic cancer patients.

OncoMed was founded in 2004 based on work by Drs. Michael Clarke and Max Wicha at the University of Michigan School of Medicine to identify and isolate CSCs. The company wisely focused on understanding the biological pathways that enable these CSCs to proliferate, differentiate and metastasize. Today OncoMed is the premier CSC play with industry leading discovery efforts, intellectual property and partnerships. This work has yielded a rich pipeline with five first-in-class cancer antibodies in the clinic and another two proprietary INDs planned for 2014.

The company's lead antibody is demcizumab, which targets Delta Like Ligand 4 (DLL4). DLL4 is a member of the Notch signaling pathway and was originally part of the GlaxoSmithKline (GSK) alliance. Despite early signs of activity, GSK did not exercise its option on demcizumab due to cardiopulmonary toxicity, so rights stayed with OncoMed. OncoMed has worked hard to optimize the dosing regimen for demcizumab and is currently conducting Phase Ib trials in pancreatic cancer in combination with *Abraxane* and gemcitabine and in Non-Small Cell Lung cancer (NSCLC) with *Alimta* and carboplatin. We expect updated data at the AACR-NCI-EORTC Conference on Molecular Targets and Cancer Therapeutics in Boston in October. OncoMed intends to initiate a Phase Ib study of demcizumab with paclitaxel in ovarian cancer in the near-term. Demcizumab remains wholly-owned, so OncoMed could seek an overseas partner to bring in non-dilutive cash and help fund clinical development. We anticipate demcizumab could gain FDA approval in 2018 with sales of \$2.7 billion by 2023.

In 2007 OncoMed signed an alliance with GSK to develop antibodies targeting the Notch pathway. OncoMed received \$35 million upfront and is eligible for up to \$1.4 billion in milestones plus double-digit royalties. The lead antibody under the partnerships is OMP-59R5, which targets Notch 2 and 3. The partners reported encouraging Phase I data at the EORTC meeting in Dublin last fall and have now embarked upon two Phase Ib/II trials: ALPINE in pancreatic cancer and PINNACLE in small cell lung cancer. OncoMed is also conducting two Phase I studies in hematologic and solid tumors on OMP-52M51, which targets Notch 1. We expect data on both antibodies at the AACR-NCI-EORTC Conference in October and for GSK to exercise its options on both programs next year, triggering up to \$43 million in milestones to OncoMed in 2014.

In 2010, OncoMed signed an alliance with Bayer to develop drugs targeting the Wnt pathway. OncoMed has received \$80 million to date and is eligible for significant milestones on any antibody and/or small molecule drugs developed plus double-digit royalties. OncoMed reported encouraging Phase I data on the lead antibody vantiactumab (OMP-18R5) at the American Society of Clinical Oncology (ASCO) meeting in June and will update data at the European Society for Molecular Oncology (ESMO) in late September in Amsterdam and the AACR-NCI-EORTC Conference in October. The partners are also working on OMP-54F28 (Fzd8-Fc) with first-in-man Phase I data also potentially at the AACR-NCI-EORTC Conference. We expect Bayer will initiate three Phase Ib combination trials on each antibody this year and next.

Beyond these programs, OncoMed intends to file INDs on 2 new wholly-owned antibodies in 2014. Building on its experience with demcizumab, OncoMed will advance a bi-specific antibody that targets DLL4 and VEGF into the clinic next year. OncoMed has also identified a novel CSC pathway called RSPO-LGR and expects to file an IND on a novel antibody in early 2014. This will position OncoMed with as many as seven wholly-owned and partnered antibodies in the clinic this time next year; a rich biotherapeutic pipeline by any measure and a steal at OncoMed's current \$551 million market cap. Over the past decade, several antibody companies such as MicroMet, Medarex and even Genentech were acquired resulting in premium valuations being placed on the remaining biotherapeutic companies.

**We are initiating coverage of OncoMed with an Overweight rating and \$30 price target.** In July, OncoMed successfully completed an upsized IPO of 5.52 million shares priced above the range at \$17 per share. OMED shares rallied as high as \$31 on its debut and closed Friday, August, 9<sup>th</sup> below \$20, offering an attractive entry point. We look for a busy calendar of data releases over the next 12 months including as many as five abstracts at the AACR-NCI-EORTC Conference in Boston in October. We expect these proof-of-concept data to validate OncoMed's rich antibody pipeline and drive value.

## Upcoming Events

- Initiate a Phase Ib/II trial of demcizumab + paclitaxel in recurrent ovarian cancer
- Bayer and OncoMed to report additional Phase I data on vantiactumab at ESMO in late September and the AACR-NCI-EORTC meeting in October
- Report interim Phase Ib data on demcizumab in NSCLC and pancreatic cancer likely at the AACR-NCI-EORTC meeting in October
- Potentially report first-in-man Phase I data on OMP-52M51 (GSK, Notch 1) and OMP-54F28 (Bayer, Fzd8-Fc) at the AACR-NCI-EORTC meeting in October
- Expect Bayer to pay milestones of up to \$25 million for dose-escalation in Phase I trials before year-end
- Begin three Phase Ib combination trials of vantiactumab this year
- Begin three Phase Ib combination trials of OMP-54F28 potentially this year and early next
- Potentially report data from the ALPINE trial of OMP-59R5 in pancreatic cancer at ASCO-GI in San Francisco in January 2014
- File an IND on wholly-owned bi-specific antibody targeting DLL4 and VEGF in 2014
- File an IND on novel RSPO-LGR antibody in 2014
- GSK could opt-in on both OMP-59R5 and OMP-52M51 next year, triggering milestones up to \$43 million in 2014
- OncoMed could sign new CSC antibody partnerships

## INVESTMENT RECOMMENDATION

We are initiating coverage of OncoMed with an Overweight rating and \$30 price target based on a projected enterprise value of \$684 million plus \$164 million mid'14E net cash. We value wholly-owned demcizumab at \$266 million by applying an industry standard 5x multiple to 2020 U.S. NSCLC and pancreatic cancer sales of \$1.13 billion, discounted back at 60% annually to mid'14. This discount rate is high, however we believe captures the safety and clinical risks associated with demcizumab and could come down with positive clinical data. We presently value OMP-59R5 (partnered with GSK) at \$168 million by applying a 5x multiple to OncoMed's royalties on 2021 U.S. sales in pancreatic and small cell cancer of \$544 million, discounted back at 45% annually to mid'14. We view this discount rate as appropriate for this Phase Ib/II antibody having reported early signs of activity. We add \$250 million for the rest of OncoMed's wholly-owned and partnered cancer antibody pipeline, which we will adjust based on +/- clinical results. To this we add mid'14 net cash of \$164 million, which assumes several milestone payments over the next 12 months. Any delay or failure to achieve these milestones would lower our \$30 target. OncoMed had preferred stock that converted at the IPO leaving the company with no meaningful long-term debt.

OncoMed is currently trading at a market cap of \$551 million with cash of \$147 million, equating to an EV of \$404 million. Our biotherapeutic comp group is currently trading at an average market cap of \$623 million and an EV \$530 million. Recent oncology IPOs, Epizyme (EZPM) and Agios (AGIO), are trading at respective market caps of \$997 million and \$930 million. We argue OncoMed should be trading in-line with these other premier cancer drug discovery IPOs. If successful, OncoMed could ultimately trade in-line with Seattle Genetics (SGEN), another cancer antibody play with its first drug on the market, which is currently trading at a market cap of \$5 billion. (Please see Exhibit 1 below).

Exhibit 1

## ONCOMED COMPARABLE COMPANY ANALYSIS

| Company          | Ticker | Price<br>8/10/2013 | Shares<br>Out. | Market<br>Cap. | Cash    | LTD   | Ent.<br>Value |
|------------------|--------|--------------------|----------------|----------------|---------|-------|---------------|
| Seattle Genetics | SGEN   | \$41.55            | 121.3          | \$5,041        | \$338   | \$0   | \$4,703       |
| Exelixis         | EXEL   | \$4.95             | 184.1          | \$911          | \$524   | \$463 | \$850         |
| Epizyme          | EPZM   | \$35.11            | 28.4           | \$997          | \$149   | \$0   | \$848         |
| Array            | ARRY   | \$6.23             | 116.8          | \$728          | \$125   | \$132 | \$735         |
| Agios            | AGIO   | \$30.00            | 31.0           | \$930          | \$240   | \$0   | \$691         |
| Infinity         | INFI   | \$18.78            | 48.0           | \$901          | \$277   | \$0   | \$624         |
| Dyax             | DYAX   | \$3.99             | 100.3          | \$400          | \$22    | \$80  | \$458         |
| Endocyte         | ECYT   | \$16.38            | 36.0           | \$590          | \$170   | \$0   | \$420         |
| NewLink Genetics | NLNK   | \$17.43            | 25.6           | \$446          | \$63    | \$0   | \$383         |
| Verastem         | VSTM   | \$14.72            | 25.5           | \$376          | \$127   | \$125 | \$374         |
| Merrimack        | MACK   | \$4.36             | 102.2          | \$446          | \$258   | \$162 | \$350         |
| Stemline         | STML   | \$33.20            | 12.4           | \$413          | \$100   | \$1   | \$314         |
| Xoma             | XOMA   | \$4.02             | 83.2           | \$334          | \$58    | \$37  | \$313         |
| Average          |        |                    |                | \$623          | \$176   | \$83  | \$530         |
| TOTAL            |        |                    |                | \$7,472        | \$2,112 | \$999 | \$6,360       |
| OncoMed          | OMED   | \$19.84            | 27.8           | \$551          | \$147   | \$0   | \$404         |

**Bold: covered companies**

Source: Company Reports and Piper Jaffray estimates

## CANCER STEM CELL OVERVIEW

Genetic models of cancer attribute unregulated tumor growth to either turning on oncogenes, turning off tumor suppressor genes, and/or circumventing apoptotic genes. These processes can be initiated by mutation, over-expression or other causes. The cancer stem cell (CSC) model adds that tumor genesis can result from the disruption of genes involved in the regulation of stem cell self-renewal. Some cancer cells within a tumor share the characteristics of normal stem cells, namely the ability to self-renew and differentiate, and were thus named.<sup>1</sup>

The term 'cancer stem cell' is defined as a cancer cell that has the ability to self-renew giving rise to another malignant stem cell, as well as undergo differentiation to give rise to the phenotypically diverse non-tumorigenic cancer cells (*Current Opinion in Genetics & Development* 2004, 14:43–47, Muhammad Al-Hajj, Michael W Becker, Max Wicha, Irving Weissman, and Michael F Clarke). The term 'tumor initiating cell' (TIC) can be used interchangeably with CSC.

CSCs were identified by findings that tumors are composed of diverse cell types that promote cancer growth and metastasis. Research has born out that these actions are driven by a hardy sub-population of CSCs within the tumor. These CSCs produce a variety of factors and proteins that affect tumor growth and survival. Moreover, CSCs have been found to pose clinical challenges because of their intrinsic resistance to chemotherapy, preventing eradication of minimal residual disease (MRD). It is these cells that cause the cancer to recur, often more aggressively than the original malignancy. The ability to characterize CSCs through surface markers has enabled the discovery of novel agents that specifically target this CSC population to treat cancer.

OncoMed was founded in 2004 based on work by Drs. Michael Clarke and Max Wicha while at the University of Michigan School of Medicine, where they invented a proprietary technique to isolate and identify CSCs. (U.S. Patent #7,115,360 titled "Isolation and Use of Solid Tumor Stem Cells" is exclusively licensed to OncoMed from the University of Michigan.) This approach enabled OncoMed to research the pathways that are critical to the CSCs and identify key targets for inhibition.

### Notch Signaling Pathway

The Notch signaling pathway is driven by four Notch family receptors (NOTCH1-4) and five canonical Notch ligands (DLL1, DLL3, DLL4, JAG1 and JAG2). In humans, the Notch signaling pathway is critical in the regulation of key functions during embryonic development, in addition to stem cell maintenance and differentiation in adult tissues.

Altered Notch signaling activity has been documented in many types of cancers. Activating mutations in the NOTCH1 receptor have been identified in hematopoietic cancers including T-cell acute lymphoblastic leukemia (ALL) and chronic lymphoblastic leukemia (CLL). With advances in high-throughput genomic sequencing, mutations in the NOTCH genes have also been identified in solid tumors, albeit at lower frequencies.

<sup>1</sup>. Stem cells are defined by three common properties: a.) the capacity for self-renewal, b.) the ability to differentiate and c.) strict regulation of stem cell numbers. (*Current Opinion in Genetics & Development* 2004, 14:43–47, Muhammad Al-Hajj, Michael W Becker, Max Wicha, Irving Weissman, and Michael F Clarke).

**DEMCIZUMAB (ANTI-DELTA LIKE LIGAND 4 ANTIBODY)**

Demcizumab (OMP-21M18) is a humanized IgG2 antibody that blocks Delta Like Ligand 4 (DLL4) in the Notch signaling pathway. DLL4 contributes to CSC self-renewal and vascular development. In human tumor xenograft models, demcizumab was active against a variety of cancers including colorectal, breast, lung, pancreatic, ovarian and melanoma. In these models, chemotherapy alone debulked the tumor, however resulted in an increase in the proportion of CSCs in residual tumors. In contrast, demcizumab alone decreased the number of CSCs and showed the greatest effect when used with chemotherapy.

In 2011, OncoMed conducted a single-agent Phase I study of demcizumab in 55 advanced solid tumor patients. A total 17 patients (31%) had prolonged stable disease or better for at least three months, including refractory NSCLC, colorectal, head & neck, renal cell, sarcoma and melanoma patients. At the highest dose of 10mg/kg weekly demcizumab (n=25), a disease control rate of 64% was observed.

That said, continuous dosing of demcizumab resulted in hypertension and rare cardiovascular toxicity. The hypertension was seen in one-third of the patients and generally manageable. Three patients developed Grade 3 and one patient Grade 4 congestive heart failure, and one patient experienced right ventricular failure, all of which were considered treatment related. This safety signal resulted in demcizumab being put on **partial** clinical hold by the FDA. Other treatment related AEs included fatigue, anemia, diarrhea, headache, nausea, hypoalbuminemia and blood pressure increases.

OncoMed subsequently created a risk mitigation plan and initiated intermittent dosing of demcizumab in order to mediate these rare, but severe cardiovascular events. In addition, OncoMed instituted B-type natriuretic peptide (BNP) cardiac monitoring, blood testing, echocardiography and intervention with ACE inhibitors. This dosing schedule and these measures have been employed in the on-going Phase Ib combination trials of demcizumab. In November 2012, OncoMed submitted an extensive data package to the FDA including interim Phase Ib data that resulted in a lifting of the partial clinical hold last December.

Demcizumab is presently in two Phase Ib combination trials with Alimta (pemetrexed) and carboplatin in non-small cell lung cancer (NSCLC) and with Abraxane and gemcitabine in pancreatic cancer. In addition, OncoMed will initiate a new Phase Ib/II trial of demcizumab + paclitaxel in recurrent ovarian cancer near-term.

In the front-line NSCLC trial, 22 patients were evaluable as of May 15th. Nine patients (41%) achieved a partial response and 10 patients (45%) had stable disease for an impressive disease control rate of 86%. Only three patients (14%) progressed. The median progression free survival (PFS) for patients having received the highest 2.5mg/kg or 5mg/kg demcizumab doses were 129 days and 160 days, respectively.

The Data Safety Monitoring Board (DSMB) reviewed the safety and efficacy data from the Phase Ib NSCLC trial and approved proceeding with the expansion cohort. While enrollment in the expansion cohort was ongoing, two patients in the 5mg/kg cohort on treatment for >150 days developed pulmonary hypertension and heart failure. The DSMB reconvened and recommended the addition of two new cohorts to evaluate higher dose therapy (7.5mg/kg) for a limited number of cycles.

In the front-line pancreatic cancer trial, 16 patients were evaluable as of May 15<sup>th</sup>. In this study, four patients (25%) achieved a partial response and seven patients (44%) had stable disease for a disease control rate of 69%. Five patients (31%) progressed. The median PFS for patients on the 2.5mg/kg every 2 weeks, 2.5mg/kg every 4 weeks and 5mg/kg every 4 weeks doses were 101 days, 50 days and 143 days, respectively.

The DSMB also reviewed the data from the first three cohorts in the Phase Ib pancreatic cancer trial. One patient in the third dose cohort who had been treated for >125 days developed pulmonary hypertension and heart failure. Similarly, the DSMB recommended adding an additional cohort to evaluate shorter duration therapy.

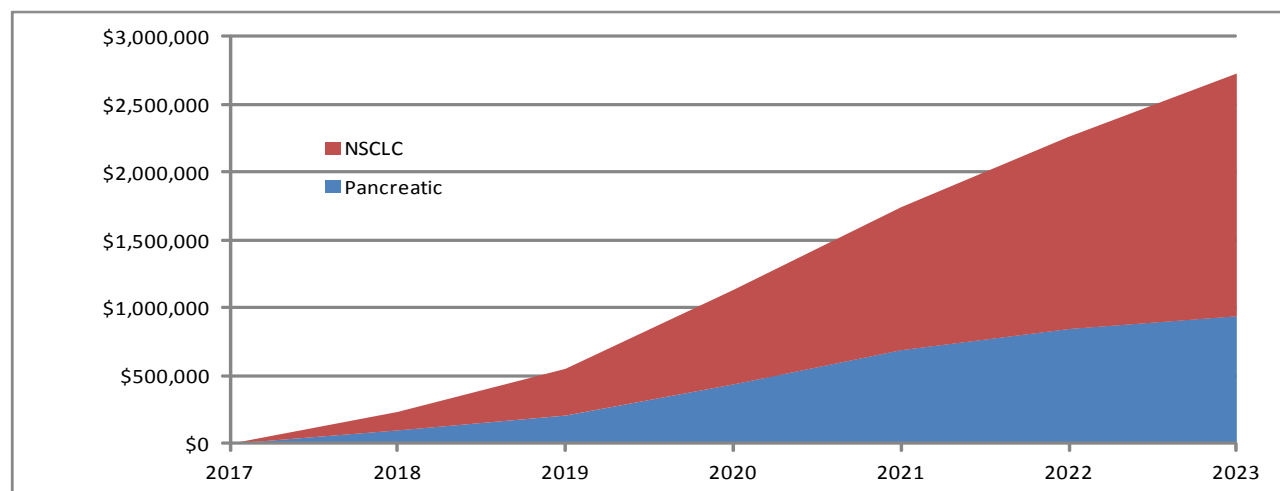
Important to note, none of these three new cases of pulmonary hypertension and heart failure resulted in death. We are impressed by the combination activity in these heavily pretreated lung and pancreatic cancer patients. We look forward to additional safety and efficacy data including potentially preliminary results from the shorter duration regimens at the AACR-NCI-EORTC Conference in Boston in October.

We presently anticipate demcizumab could reach the market in 2018. As a result of the shortened dosing regimen due to the observed cardiotox, we limit utilization to four cycles. Even so, we forecast U.S. pancreatic cancer sales of \$99 million in 2018, \$208 million in 2019 and growing to \$937 million in 2023. Due to the larger patient population, we project NSCLC sales of \$136 million in 2018 and \$344 million in 2019, and could reach \$1.78 billion in 2023. (Please see Exhibit 2 below.)

If the company is unable to manage the toxicity profile of demcizumab with shorter courses of therapy, OncoMed may be unable to achieve our sales forecast. Keep in mind that *Avastin* (bevacizumab) has similar on-target hypertension and CV toxicity, yet sold \$6.29 billion globally last year! Demcizumab remains wholly owned and OncoMed could partner the drug overseas bringing in non-dilutive cash and helping to fund clinical development. We presently forecast no O.U.S. sales for demcizumab or in cancer indications beyond NSCLC or pancreatic cancer.

Exhibit 2

**U.S. DEMCIZUMAB SALES FORECAST**



| <b>Pancreatic Cancer</b>        | <b>2017</b> | <b>2018</b>     | <b>2019</b>      | <b>2020</b>      | <b>2021</b>      | <b>2022</b>      | <b>2023</b>      |
|---------------------------------|-------------|-----------------|------------------|------------------|------------------|------------------|------------------|
| Pancreatic Cancer Patients      | 48,491      | 49,461          | 50,450           | 51,459           | 52,488           | 53,538           | 54,609           |
| Demcizumab Treated              |             | 2,473           | 5,045            | 10,292           | 15,747           | 18,738           | 20,205           |
| Penetration %                   |             | 5%              | 10%              | 20%              | 30%              | 35%              | 37%              |
| Demcizumab Price                |             | \$40,000        | \$41,200         | \$42,436         | \$43,709         | \$45,020         | \$46,371         |
| <b>Demcizumab Sales ('000s)</b> |             | <b>\$98,922</b> | <b>\$207,855</b> | <b>\$436,745</b> | <b>\$688,267</b> | <b>\$843,609</b> | <b>\$936,941</b> |

| <b>NSCLC</b>                               | <b>2017</b> | <b>2018</b>      | <b>2019</b>      | <b>2020</b>        | <b>2021</b>        | <b>2022</b>        | <b>2023</b>        |
|--------------------------------------------|-------------|------------------|------------------|--------------------|--------------------|--------------------|--------------------|
| Lung Cancer Incidence in the US            | 204,431     | 200,342          | 196,335          | 192,409            | 188,560            | 184,789            | 181,093            |
| Number of NSCLC                            | 173,766     | 170,291          | 166,885          | 163,547            | 160,276            | 157,071            | 153,929            |
| Percent NSCLC                              | 85.0%       | 85.0%            | 85.0%            | 85.0%              | 85.0%              | 85.0%              | 85.0%              |
| Demcizumab Treated                         |             | 3,406            | 8,344            | 16,355             | 24,041             | 31,414             | 38,482             |
| Penetration %                              |             | 2.0%             | 5.0%             | 10.0%              | 15.0%              | 20.0%              | 25.0%              |
| Demcizumab Price                           |             | \$40,000         | \$41,200         | \$42,436           | \$43,709           | \$45,020           | \$46,371           |
| <b>Demcizumab Sales ('000s)</b>            |             | <b>\$136,233</b> | <b>\$343,783</b> | <b>\$694,029</b>   | <b>\$1,050,830</b> | <b>\$1,414,277</b> | <b>\$1,784,464</b> |
| <b>TOTAL U.S. Demcizumab Sales ('000s)</b> |             | <b>\$235,155</b> | <b>\$551,638</b> | <b>\$1,130,774</b> | <b>\$1,739,096</b> | <b>\$2,257,885</b> | <b>\$2,721,404</b> |

Source: Centers for Disease Control, Company reports, Piper Jaffray estimates.



## NOTCH PATHWAY ANTIBODIES

In 2007, OncoMed signed an alliance with GSK to develop antibodies targeting the Notch pathway. OncoMed received \$35 million upfront and is eligible for up to \$1.4 billion in milestones and double-digit royalties. GSK retains an option to exclusively license OMP-59R5 through the end of Phase II trials and an early option through the end of Phase I or a standard option through the end of Phase II on OMP-52M51. We presently anticipate GSK will exercise its options on both programs triggering up to \$43 million milestone in 2014.

### OMP-59R5

OMP-59R5 is an anti-Notch2/3 antibody derived from phage display library licensed from MorphoSys. In addition to down-regulating Notch pathway signaling and impacting CSCs, OMP-59R5 also affects pericytes (cells that wrap around the endothelial cells of blood vessels) and is anti-angiogenic. OMP-59R5 is part of the Notch pathway collaboration and GSK has the option on an exclusive license through the completion of Phase II trials. We expect GSK will exercise this option next year triggering a \$25 million milestone.

Two activating mutations in NOTCH3 have been identified by OncoMed scientists. One is a frameshift mutation in the PEST domain, and the other is a frameshift mutation in the NCR domain. The PEST frameshift mutation leads to the production of C-terminally truncated NOTCH3 protein. Via Western Blotting of nuclear fractions of tumor tissue and Immunohistochemistry (IHC), OncoMed has shown that this mutant NOTCH3 accumulates stably in the nuclei of breast cancer cells. Breast xenograft tumors carrying this mutation are highly sensitive to OMP-59R5 suggesting that the mutation, although activating, is still ligand dependent.

In vitro, the NCR mutant NOTCH3 has higher baseline activity than wild-type NOTCH3 in the absence of ligands and remains highly responsive to ligands. Colon xenograft tumors carrying this NOTCH3 NCR mutation are also sensitive to OMP-59R5. This suggests that NOTCH3 is oncogenic in certain tumor types, and that genotypic identification of patients with activating mutations may predict sensitivity to Notch3 antibodies.

Interim Phase Ia data on OMP-59R5 were presented at the EORTC-NCI-AACR International Conference on Molecular Targets and Cancer Therapeutics in Dublin, Ireland, in November 2012. A total of 42 patients were treated in eight escalating cohorts at doses of 0.5, 1, 2.5, and 5mg/kg administered weekly; 5, 7.5, and 10mg/kg administered every other week; and 7.5mg/kg administered every 3 weeks. OMP-59R5 was well tolerated and maximum tolerated doses (MTD) of 2.5mg/kg weekly, 7.5mg/kg every other week and 7.5mg/kg administered every 3 weeks were established.

As of the last database analysis on January 23rd, diarrhea was the most common AE observed in ~2/3 of patients. Other treatment-related AEs included fatigue, nausea, anemia, decreased appetite, hypokalemia and vomiting. Pharmacodynamic analyses suggest that Notch pathway modulation was sustained for at least one week following dosing. In addition, there was clear downregulation of the Notch3 target in serial tumor biopsies after treatment with OMP-59R5. Several patients had prolonged stable disease for 56 days or longer.

In 2012 OncoMed initiated the Phase Ib/II ALPINE (Antibody therapy in first-Line Pancreatic cancer Investigating anti-Notch Efficacy and safety) trial. ALPINE was originally designed to evaluate OMP-59R5 in combination with gemcitabine, but has now been amended to add Abraxane. This combination has emerged as the new standard of care due to Phase III data presented by Dan Von Hoff and colleagues at the ASCO Gastrointestinal Cancer Symposium earlier this year showing a statistically significant survival benefit of Abraxane + gemcitabine over gemcitabine alone.

As of data cut-off of June 21st, 3 of 4 patients (75%) had stable disease in both the 2.5mg/kg and 5mg/kg OMP-59R5 + gemcitabine cohorts. In the 5mg/kg OMP-59R5 + Abraxane + gemcitabine cohort, 2 of 4 patients (50%) achieved a partial response and 1 patient (25%) had stable disease. Observed AEs in the ALPINE trial include Grade 1 or Grade 2 fatigue, nausea, rash, diarrhea, thrombocytopenia and flu-like symptoms. We anticipate OncoMed will report Phase Ib ALPINE data at ASCO-GI in San Francisco in January 2014.

Earlier this year, OncoMed initiated a second Phase Ib/II trial of OMP-59R5 entitled PINNACLE (Phase Ib/II Investigation of anti-Notch Antibody therapy with Cisplatin and etoposide in small cell Lung carcinoma Efficacy and safety). In this trial, OMP-59R5 is being evaluated with cisplatin and etoposide in first-line extensive-stage small cell lung cancer. Both the ALPINE and PINNACLE trials incorporate predictive biomarker analysis in order to identify patients that might benefit the most from OMP-59R5 therapy.

#### OMP-52M51

OMP-52M51 is a humanized monoclonal antibody that targets the Notch1 receptor. OncoMed is conducting two Phase I studies of OMP-52M51 in hematologic and solid tumors. We expect OncoMed will report first-in-man data from the Phase I solid tumor study of OMP-52M51 at the AACR-NCI-EORTC Conference in October and Phase I data from the hematologic cancer study in 2014. We presently anticipate that GSK will also exercise its option on OMP-52M51 after completion of Phase I trials next year triggering an additional \$18 million milestone to OncoMed.

## WNT PATHWAY INHIBITORS

In 2010, OncoMed signed an alliance with Bayer to develop drugs targeting the Wnt pathway. OncoMed received \$40 million upfront, \$40 million for two IND filings and is eligible for significant milestones on any antibody or small molecule drugs developed plus double-digit royalties. Bayer retains an option to exclusively license either vantictumab or OMP-54F28 at any point through completion of Phase I trials. OncoMed and Bayer are also working on a third bi-specific antibody targeting the Wnt pathway that could enter the clinic in 2014 or 2015.

**VANTICTUMAB**

Vantictumab is a fully-human monoclonal antibody that modulates Wnt pathway signaling by binding to Frizzled receptors 1, 2, 5, 7 and 8. Vantictumab is currently in a dose escalation Phase I study in solid tumors. OncoMed presented preliminary data at ASCO in June on 24 patients at doses up to 10mg/kg every 3 weeks. Most common AEs were fatigue (30%), nausea (22%), vomiting (17%), increased alkaline phosphatase (13%), constipation (13%), decreased appetite (13%) and hypercalcemia (13%). One patient experienced Grade 3 diarrhea and vomiting. While early, three neuroendocrine tumor patients had prolonged stable disease. We anticipate OncoMed will report updated data at ESMO in late September and the AACR-NCI-EORTC meeting in October. OncoMed plans to initiate 3 Phase Ib combination trials this year in distinct solid tumors with standard-of-care therapy.

**OMP-54F28**

OMP-54F28 is OncoMed's second Wnt pathway modulator that binds to Wnt ligands rather than the Frizzled receptors distinguishing it from vantictumab. OMP-54F28 is a fusion protein that contains part of the Fzd8 receptor fused to a human Immunoglobulin Fc domain. OMP-54F28 has shown evidence of strong anti-tumor activity and reduction of CSC numbers in multiple preclinical solid tumors models including pancreatic, breast, hepatocellular, ovarian and colorectal cancers. OncoMed is conducting a Phase I trial of OMP-54F28 in advanced solid tumors. As of the cut-off date of May 28th, most common treatment-related AEs have been decreased appetite (23%), fatigue (23%), hypocalcemia (23%), nausea (23%), altered taste (15%), increased blood pressure (15%), peripheral edema (15%) and vomiting (15%). One case of Grade 3 anemia was observed. We anticipate first-in-man data potentially at the AACR-NCI-EORTC meeting in October and for OncoMed to begin three Phase Ib combination trials in late 2013/early 2014.

**RSPO-LGR PATHWAY**

R-spondin (RSPO) comprises a family of evolutionary conserved, 4 cysteine-rich secreted proteins containing structurally distinct domains that signal through the LGR receptor. RSPO genes were first identified by Kazanskaya et al. as potent activators of wnt/beta-catenin signaling in *Xenopus* and mouse (Developmental Cell, 2004).

Biological functions of RSPOs include a role in female sex determination (RSPO1); limb, craniofacial and lung development (RSPO2); angiogenesis (RSPO3); and nail development (RSPO4). In addition, RSPO1 has been shown to increase the proliferation of intestinal crypt epithelial cells in adult mice, and effectively support the survival and proliferation of LGR5+ intestinal stem cells in vitro.

RSPOs are active in multiple tumor types including ovarian, pancreatic, colon, breast and non-small cell lung cancer. In human tumor xenograft models, anti-RSPO treatment markedly inhibited tumor growth in several tumor types. Moreover, RSPO blockade promoted tumor differentiation and reduced the frequency of CSCs. OncoMed has identified RSPO-LGR targeting agents and intends to file an IND next year. RSPO-LGR is OncoMed's third distinct CSC signaling pathway and demonstrates the company's leading discovery efforts and intellectual property.

## COLLABORATIONS

### GlaxoSmithKline

In 2007, OncoMed signed an alliance with GSK to develop antibodies targeting the Notch pathway. OncoMed received \$35 million upfront and is eligible for up to \$1.4 billion in milestones and double-digit royalties. Demcizumab was originally part of the GSK alliance; however due to cardiopulmonary toxicity, GSK never exercised its option so rights stayed with OncoMed.

The lead antibody in the partnership now is OMP-59R5 (Notch 2/3), which is currently being evaluated in two Phase Ib/II trials: ALPINE in pancreatic cancer and PINNACLE in small cell lung cancer. GSK retains an option through the end of Phase II trials to obtain an exclusive license to OMP-59R5, which we expect GSK will exercise next year triggering a \$25 million milestone to OncoMed.

The partners are also conducting two Phase Ia studies in hematologic and solid tumors on OMP-52M51 targeting Notch 1. Under terms of the alliance, GSK retains an early option through the end of Phase I trials or a standard option through the end of Phase II trials to the anti-Notch 1 antibody. We presently anticipate GSK will exercise this option early triggering another \$18 million milestone in 2014.

### BAYER

In 2010, OncoMed signed an alliance with Bayer to develop drugs targeting the Wnt pathway. OncoMed received \$40 million upfront plus two \$20 million milestone for IND filings. OncoMed is eligible for milestones of up to \$387.5 million for each antibody and \$112 million for any small molecule drugs plus double-digit royalties.

OncoMed and Bayer are developing vantictumab (OMP-18R5), a first-in-class Frizzled7 antibody, which should advance into three Phase Ib combination trials this year. OncoMed is also conducting a Phase I trial of OMP-54F28, a proprietary fusion protein based on a truncated form of the Frizzled8 receptor, which should begin three Phase Ib combination trials by early 2014. Based on dose-escalation on both programs, we anticipate Bayer will pay OncoMed \$25 million in milestones this year. Bayer retains an option to exclusively license either vantictumab or OMP-54F28 at any point through completion of Phase Ib trials. The partners are also working on a 3rd bi-specific antibody targeting the Wnt pathway that could enter the clinic in 2014 or 2015.

## MANAGEMENT TEAM

### **Paul Hastings President & CEO**

Mr. Hastings joined OncoMed as President and CEO in 2006. Mr. Hastings has extensive experience having been President and CEO of QLT, Inc.; President and CEO of Axys Pharmaceuticals, which was acquired by Celera in 2001; President of Chiron BioPharmaceuticals; and President and CEO of LXR Biotechnology. Mr. Hastings has also held various management positions at Genzyme, Synergen and Hoffmann-La Roche. Recently, Mr. Hastings was Chairman of the Board of Proteolix, which was acquired by Onyx Pharmaceuticals in 2010, and served on the Board of ViaCell, which was acquired by Perkin-Elmer in 2007. He currently serves on the boards of Pacira Pharmaceuticals and Relypsa, as well as Chairman of the Emerging Companies Section of the Biotechnology Industry Organization (BIO). Mr. Hastings earned his Bachelor of Science degree in pharmacy from the University of Rhode Island.

### **John Lewicki, Ph.D. EVP, CSO**

Dr. John Lewicki is CSO of OncoMed. Previously, Dr. Lewicki was SVP, Research and Development of an early-stage biotechnology company working in the infectious disease area. Prior, Dr. Lewicki was at Scios from 1983-2000 where he co-discovered *Natreco*, an FDA approved drug for congestive heart failure. Dr. Lewicki earned his Ph.D. in Physiology/Pharmacology from UC San Diego and conducted his post-doctoral training at University of Virginia and Stanford University. He has authored numerous research papers and is listed as inventor on over 30 issued U.S. patents.

### **Jakob Dupont, M.D. SVP, CMO**

Dr. Dupont joined OncoMed as CMO in 2011. Previously, Dr. Dupont was Global Medical Director for Avastin at Genentech, where he oversaw the blockbuster's late-stage medical development including managing the cardiovascular toxicity. Prior to that, Dr. Dupont led development of Avastin in breast and ovarian cancer, and worked in the Exploratory Clinical Development group overseeing the development of Genentech's anti-angiogenesis pipeline. Dr. Dupont has helped develop a number of key oncology drugs including: Zaltrap, Alimta, XyotaxT and Velcade. Previously, Dr. Dupont held a faculty appointment and completed his Medical Oncology Fellowship at Memorial Sloan-Kettering Cancer Center. Dr. Dupont received his M.D. from Weill Medical College of Cornell and completed his Internal Medicine training at the University of Michigan and New York-Presbyterian Hospital. Dr. Dupont has received numerous grants and awards, and has been an author on more than 40 peer-review publications.

### **William D. Waddill SVP, CFO**

Will Waddill has served as OncoMed's CFO since October 2007. Previously Mr. Waddill was SVP, CFO at Ilypsa, and the founder and principal of Square One Finance consultancy. Prior to that, Mr. Waddill held various positions at Exelixis and was CFO of Medical Science Partners, a venture capital firm in Boston. Mr. Waddill is on the board of the Association of Bioscience Financial Officers, is Co-chair of the Biotechnology Industry Organization (BIO) Finance and Tax Committee, and is Chairman of the BIO Business Solutions Advisory Board. Mr. Waddill earned a BS in accounting from the University of Illinois, Chicago.

## FINANCIALS

### Revenues

OncoMed currently recognizes the amortization of upfronts and receives milestone payments from the GSK and Bayer partnerships. Specifically, we forecast Bayer will pay OncoMed another \$25 million in milestones resulting in total revenues of \$45 million this year. We anticipate GSK will pay OncoMed \$43 million in milestones resulting in total revenues of \$59 million in 2014.

### Operating Expenses

OncoMed invested \$40 million in R&D in 2012 and \$9.6 million in 1Q:13. We project total R&D expense of \$43 million in 2013 growing to \$53 million in 2014 as OncoMed increases investment in its antibody pipeline and files new INDs.

In 2012, OncoMed spent \$7 million on G&A and \$2 million in 1Q:13. We budget total SG&A expenses to grow to \$9 million in 2013 and \$10 million in 2014.

### Net Loss

OncoMed reported a net loss of \$22 million or (\$1.00) per *pro forma* share in 2012 and \$8.6 million or (\$0.39) per *pro forma* share in 1Q:13. We estimate net loss of \$6.9 million or (\$0.28) in 2013 and a net loss of \$3.7 million or (\$0.13) in 2014 as OncoMed will recognize meaningful partner milestones this year and next.

### Balance Sheet

OncoMed ended 1Q:13 with cash of \$60.3 million. The company completed a successful IPO and raised gross proceeds of \$93.8 million in July by issuing 5.52 million shares, including the over-allotment, at \$17 per share. We estimate this brings pro forma cash to \$147 million, which we project should fund operations into 2017. OncoMed had preferred stock valued at \$183 million that converted at the IPO leaving the company now with no meaningful long-term debt.

## INVESTMENT RISKS

Risks associated with OncoMed are typical with all cancer drug discovery/development companies including clinical, regulatory and commercial. Cancer is a competitive field and cancer stem cells represent a novel therapeutic approach with no approved drugs. Cardiovascular toxicity observed with demcizumab could result in the drug not gaining approval. Even if approved, demcizumab utilization may be limited and thus not achieve our sales projections. Other of OncoMed's antibodies may fail in the clinic. OncoMed may be unable to file new INDs. The company's partnerships with GSK and Bayer may falter, resulting in lower milestone payments or royalties than forecast. OncoMed may be unable to attract new partners. OncoMed may need to invest more than projected to develop its drugs and will likely need to raise additional capital in the future. The company could face future unforeseen litigation.

**OncoMed Pharmaceuticals, Inc.**  
**Quarterly Earnings Estimates**  
( \$ in thousands, except per share data)

8/12/13

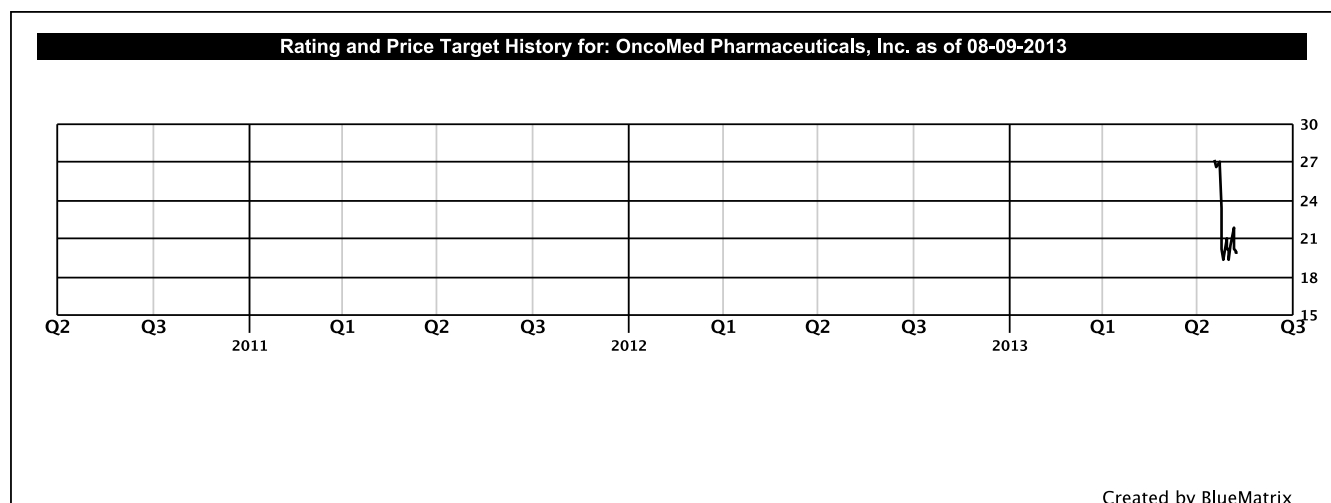
|                                     | <u>2012A</u>      | <u>1QA</u>       | <u>2QE</u>       | <u>3QE</u>        | <u>4QE</u>      | <u>2013E</u>     | <u>1QE</u>        | <u>2QE</u>      | <u>3QE</u>        | <u>4QE</u>      | <u>2014E</u>     |
|-------------------------------------|-------------------|------------------|------------------|-------------------|-----------------|------------------|-------------------|-----------------|-------------------|-----------------|------------------|
| <b>Revenues:</b>                    |                   |                  |                  |                   |                 |                  |                   |                 |                   |                 |                  |
| Collaborative R&D                   | \$24,659          | \$2,932          | \$10,932         | \$2,932           | \$27,932        | \$44,726         | \$3,932           | \$28,932        | \$3,932           | \$21,932        | \$58,726         |
| Grants                              | 22                | 0                | 0                | 0                 | 0               | 0                | 0                 | 0               | 0                 | 0               | 0                |
| <b>Total Revenues</b>               | <b>\$24,681</b>   | <b>\$2,932</b>   | <b>\$10,932</b>  | <b>\$2,932</b>    | <b>\$27,932</b> | <b>\$44,726</b>  | <b>\$3,932</b>    | <b>\$28,932</b> | <b>\$3,932</b>    | <b>\$21,932</b> | <b>\$58,726</b>  |
| <b>Operating Expenses:</b>          |                   |                  |                  |                   |                 |                  |                   |                 |                   |                 |                  |
| Research and Development            | \$39,893          | \$9,576          | \$10,000         | \$11,000          | \$12,000        | \$42,576         | \$12,000          | \$13,000        | \$13,500          | \$14,000        | \$52,500         |
| General and Administrative          | 7,157             | 1,985            | 2,250            | 2,500             | 2,500           | 9,235            | 2,250             | 2,500           | 2,500             | 2,750           | 10,000           |
| <b>Total Operating Expenses</b>     | <b>\$47,050</b>   | <b>\$11,561</b>  | <b>\$12,250</b>  | <b>\$13,500</b>   | <b>\$14,500</b> | <b>\$51,811</b>  | <b>\$14,250</b>   | <b>\$15,500</b> | <b>\$16,000</b>   | <b>\$16,750</b> | <b>\$62,500</b>  |
| <b>Operating Loss</b>               | <b>(\$22,369)</b> | <b>(\$8,630)</b> | <b>(\$1,319)</b> | <b>(\$10,569)</b> | <b>\$13,432</b> | <b>(\$7,085)</b> | <b>(\$10,319)</b> | <b>\$13,432</b> | <b>(\$12,069)</b> | <b>\$5,182</b>  | <b>(\$3,774)</b> |
| Operating Margin                    | NM                | NM               | NM               | NM                | NM              | NM               | NM                | NM              | NM                | NM              | NM               |
| Other Income/(Expense):             |                   |                  |                  |                   |                 |                  |                   |                 |                   |                 |                  |
| Interest and Other Income           | \$140             | \$31             | \$25             | \$65              | \$55            | \$176            | \$45              | \$35            | \$25              | \$15            | \$120            |
| Interest Expense                    | (6)               | 0                | 0                | 0                 | 0               | 0                | 0                 | 0               | 0                 | 0               | 0                |
| <b>Total Other Income/(Expense)</b> | <b>\$134</b>      | <b>\$31</b>      | <b>\$25</b>      | <b>\$65</b>       | <b>\$55</b>     | <b>\$176</b>     | <b>\$45</b>       | <b>\$35</b>     | <b>\$25</b>       | <b>\$15</b>     | <b>\$120</b>     |
| <b>Pretax Loss</b>                  | <b>(\$22,235)</b> | <b>(\$8,598)</b> | <b>(\$1,294)</b> | <b>(\$10,504)</b> | <b>\$13,487</b> | <b>(\$6,909)</b> | <b>(\$10,274)</b> | <b>\$13,467</b> | <b>(\$12,044)</b> | <b>\$5,197</b>  | <b>(\$3,654)</b> |
| Pretax Margin                       | NM                | NM               | NM               | NM                | NM              | NM               | NM                | NM              | NM                | NM              | NM               |
| Income Tax/(Benefit)                | \$0               | \$0              | \$0              | \$0               | \$0             | \$0              | \$0               | \$0             | \$0               | \$0             | \$0              |
| Tax Rate                            | NM                | NM               | NM               | NM                | NM              | NM               | NM                | NM              | NM                | NM              | NM               |
| <b>Net Loss</b>                     | <b>(\$22,235)</b> | <b>(\$8,598)</b> | <b>(\$1,294)</b> | <b>(\$10,504)</b> | <b>\$13,487</b> | <b>(\$6,909)</b> | <b>(\$10,274)</b> | <b>\$13,467</b> | <b>(\$12,044)</b> | <b>\$5,197</b>  | <b>(\$3,654)</b> |
| <b>Net Loss per Share</b>           | <b>(\$1.00)</b>   | <b>(\$0.39)</b>  | <b>(\$0.06)</b>  | <b>(\$0.38)</b>   | <b>\$0.48</b>   | <b>(\$0.28)</b>  | <b>(\$0.36)</b>   | <b>\$0.47</b>   | <b>(\$0.42)</b>   | <b>\$0.18</b>   | <b>(\$0.13)</b>  |
| Shares Outstanding                  | 22,224            | 22,265           | 22,315           | 27,800            | 28,000          | 25,095           | 28,250            | 28,500          | 28,750            | 29,000          | 28,625           |

Source: Company reports and Piper Jaffray & Co. analysis.

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Notes: The boxes on the Rating and Price Target History chart above indicate the date of the Research Note, the rating, and the price target. Each box represents a date on which an analyst made a change to a rating or price target, except for the first box, which may only represent the first Note written during the past three years.

### Legend:

I: Initiating Coverage  
R: Resuming Coverage  
T: Transferring Coverage  
D: Discontinuing Coverage  
S: Suspending Coverage  
OW: Overweight  
N: Neutral  
UW: Underweight  
NA: Not Available  
UR: Under Review

| Distribution of Ratings/IB Services<br>Piper Jaffray |       |         |                       |         |
|------------------------------------------------------|-------|---------|-----------------------|---------|
| Rating                                               | Count | Percent | IB Serv./Past 12 Mos. |         |
|                                                      |       |         | Count                 | Percent |
| BUY [OW]                                             | 339   | 57.07   | 65                    | 19.17   |
| HOLD [N]                                             | 225   | 37.88   | 15                    | 6.67    |
| SELL [UW]                                            | 30    | 5.05    | 0                     | 0.00    |

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### Analyst Certification — Edward A. Tenthoff, Sr Research Analyst

The views expressed in this report accurately reflect my personal views about the subject company and the subject security. In addition, no part of my compensation was, is, or will be directly or indirectly related to the specific recommendations or views contained in this report.



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- **Overweight (OW):** Anticipated to outperform relative to the median of the group of stocks covered by the analyst.
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- **Underweight (UW):** Anticipated to underperform relative to the median of the group of stocks covered by the analyst.

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