CEO CFO

AMDL

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# With 124% Growth Year-Over-Year Growth From 07 To 08, And Three Distinct Business Units That Include In Vitro Diagnostics, High-End Skin Care Products And Traditional Pharmaceuticals, AMDL Inc. Is Achieving Their Goal Of Building An Ever-Expanding Profitable Business

**Healthcare**
**Off-Label Pharmaceuticals; Cancer**
**In Vitro Diagnostics & Therapeutics;**
**High End Skin Care Products**
**(ADL-AMEX Alternext US)**

**AMDL Inc.**

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**Douglas C. MacLellan**
**Chairman, CEO**

**BIO:**
**Douglas C. MacLellan is Chairman of the Board of Directors and Chief Executive Officer of AMDL Inc. -- a US-based pharmaceutical company with major operations in China.**
Through MacLellan's leadership, AMDL is on an aggressive growth trajectory, expanding from a China-only focused pharmaceutical company to an emerging international leader that offers a broad portfolio of diagnostic, pharmaceutical and high-end skin care products.

MacLellan has been a member of AMDL's Board of Directors since 1992, previously serving as Chairman of the Company's audit and governance committees. With more than twenty-five years international business management and active board experience, MacLellan has been a catalyst for the development, growth and success of many public and privately held businesses worldwide. Additionally, MacLellan has extensive business management experience in the People's Republic of China, where he has been actively involved since 1983. He is a recognized authority on Chinese joint venture and foreign owned enterprise (WFOE) structuring and considered an expert on the China government and regulator and compliance system.

Throughout his professional career, MacLellan has served on the board of 18 separate companies where he has played an instrumental role in strategic planning, general operations, corporate finance activities, economic policy, asset allocation and mergers & acquisitions. In addition, he has supported the raise of over US$715 million in capital for development stage, start-up and mid-cap companies.

MacLellan received advanced training in classical economic theory and international relations from the University of Southern California and was a student of Arthur Laffer, Ph.D., who later employed him as an economist. Mr. MacLellan has also authored numerous industry-specific research papers, portfolio strategy, and economic forecasts over the past 25 years.

**Company Profile:**
Founded in 1987, AMDL is a US-based pharmaceutical company with three distinct business divisions that include: (i) *In Vitro* Diagnostics, (ii) High End Skin Care Products, and (iii) China-based Pharmaceuticals. Collectively, these business units focus on the manufacture and sales of high quality generic pharmaceuticals, nutritional supplements, high-end skin care and medical diagnostic products in the US, China, Korea, Taiwan and other markets throughout the world. The Company employees 510 people in the US and China.

**Interview conducted by:**
**Walter Banks, Publisher**
**CEOCFOinterviews.com**

**CEOCFO:** Mr. MacLellan, what is your vision for AMDL?
**Mr. MacLellan:** "AMDL is a pharmaceutical company headquartered in Tustin, CA with key operations in China. The company was founded in 1987 and together with our China-based subsidiary – Jade Pharmaceuticals, or (JPI) – we manufacture and sell a portfolio of high-quality generic pharmaceuticals, nutriceutical supplements, high-end skin care products, and in vitro diagnostic products through the US, China, Korea, Taiwan, and other markets throughout the world. AMDL's business operations focus on three distinct business units that include in vitro diagnostics, high-end skin care products, and off-label pharmaceuticals. Our growth strategy is to build an ever expanding, profitable business. Our FY 2008 revenues were approximately $33.6 million, which represents approximately 125% growth year-over-year from our 07 gross revenues. Our FY09 forecasted sales are estimated to be between $64 and $72 million with FY09 earnings between $8 and $12 million. We have approximately $42 million on gross assets, and shareholder equity of ap-

proximately $34 million. We are currently trading at $1.20, which we think represents a very low stock price given Company's record of accomplishment of growth and the asset base we currently have in place. We are affectively trading at 50% of our net equity value."

**CEOCFO:** Tell us about your business operations.

**Mr. MacLellan**: "AMDL was founded and grew as a pure-play diagnostic company competing in the In Vitro Diagnostic, or "IVD" space. In 2006, we acquired Jade Pharmaceuticals Inc. (JPI)—a China-based pharmaceuticals company to broaden our product portfolio and expand AMDL's addressable market, allowing us to also manufacture and sell traditional pharmaceuticals and traditional Chinese medicines specifically in China for the Chinese market. This is where our growth and profitability have come from to date. This year, following last year's US FDA approval for our DR-70 IVD cancer test, we have begun to realize sales revenues for our diagnostic division. Our growth over the last several years has primarily been driven by our Chinese operations. Our business is obviously more that. We believe our IVD division is going to be a substantial segment for us that will grow and should become certainly the same size revenue generator as our Chinese pharmaceutical divisions. Additionally, we are aggressively working on establishing a third division of our business focused on the manufacture of high-end, high quality skin care products marketed and sold in the US, China and various other international markets. Our plans are to launch that cosmetic and skin care line during the late part of the 2nd Quarter of this year and we expect to have sales in North America I would say in the 3rd, or the beginning of the 4th Quarter. These are our big drivers. Three separate segments and three business units all contributing to a very successful business."

**CEOCFO:** Would you tell us about you collaboration agreement with the Mayo Clinic for your DR-70 test.

**Mr. MacLellan:** "We are always trying to improve on the technology that we develop and we have a next generation of the DR-70 in our product pipeline which has indicated in pilot studies appears to be much more accurate than our existing test. Consequently, we have engaged in a collaboration agreement with the Mayo Clinic in order to further our research in this area. If the results are as we expect, we would file for a new 510 k approval of our next gen product I would say sometime in 2011, and then begin commercializing the new test no later than 2011, but we could potentially get commercialized sales for that product I non-harmonized countries in 2010. The Mayo Clinic is a great collaborative partner for us as we have never before had that level of quality research facilities working with us."

**CEOCFO:** How did your collaboration with the Mayo Clinic come about?

**"AMDL's business operations focus on three distinct business units that include in vitro diagnostics, high-end skin care products, and off-label pharmaceuticals. Our growth strategy is to build an ever expanding, profitable business. Our FY 2008 revenues were approximately $33.6 million, which represents approximately 125% growth year-over-year from our 07 gross revenues." - Douglas C. MacLellan**

**Mr. MacLellan:** "Several of the scientists and doctors that work at the Mayo Clinic had seen published results about AMDL's DR-70 cancer test. They were particularly intrigued with DR-70 as it specifically relates to the monitoring of colorectal cancer. We received US FDA approval for DR-70 as a monitoring device for CRC last year and through extensive dialogs with the Mayo Clinic, we discussed the development of a next generation version of the test, which we believe will provide a substantially improved version of the test, and one that does not have significant competition to it. We think that our next gen version will be one of largest sales generators for AMDL. Equally important to know is that DR-70 is also approved as a cancer test for various other cancers in different markets. For example, it is approved for the monitoring of colorectal cancer in the US. In Canada, it is approved for the detection of lung cancer. In Taiwan, Korea and Europe it is approved as general cancer screen that currently picks up 14 different types of cancer. Our ultimate goal is to sell DR-70 into the clinical lab environment as a screening test for multiple cancers. That is our ultimate goal and certainly, in many of the global markets this year, we should have active sales on this product."

**CEOCFO:** Would you tell us more about the DR-70 test?

**Mr. MacLellan:** "It is a simple, non-invasive blood test that can assess whether a patient has one of 14 different types of cancer. It also can help monitor the recurrence in patients already diagnosed with cancer. To get the test a patient would go to their doctor and have their blood drawn. That blood would be packaged in a cold carton and shipped to a reference lab where the laboratory would run a DR-70 test to determine the level of fibrin and fibrinogen degradation products in their blood. Depending on the results, the physician can determine if the patient has cancer or if it has returned. DR-70 doesn't necessarily tell a physician what type of cancer their patient has or where it's located, but it can tell when a patient has an onset of cancer and that is what is particularly important because we are able to monitor and catch it in early stages. From an effectiveness standpoint, DR-70 is really what we think is a marvelous general cancer screen which can be use by diagnosticians to aid in the monitoring and screening of cancer. The test is similar to CEA, which is also used for the monitoring of colorectal cancer, however CEA is only useful in detecting late stage cancers, whereas DR-70 can detect cancer reoccurrence in earlier and treatable stages. There are broad indications for all sorts of cancers, however, the US FDA indicated in our approval application that they wanted us to conduct clinical studies for a specific type of cancer and we selected CRC. They also wanted us to identify an existing test already on the market to use as a comparable test to DR-70. If you want to do a short form application to get it approved, which is known as a 510 K, you must show that it is a effectively a predicate device or a test that is equiva-

lent to an existing test on the market. We picked CEA, which meant that we wee focused on colorectal cancer and obviously focused on the monitoring of colorectal cancer. We ran studies in parallel with CEA to show that we had an equivalency of CEA and how we gained US FDA approval. We have also done testing and secured approval in other markets to manufacture and sell DR-70 as a general cancer screen. Despite the fact that we have a narrow use in the US, the rest of the global market wants to focus on it as a general cancer screen."

**CEOCFO:** Do you have a razor/razor blade component to the DR-70 test kit?
**Mr. MacLellan:** "We have the ability to do that. Currently however, we make a test kit that runs 96 wells and it runs on a number of open platforms. DR-70 can be sold in two ways. Number one, it can be sold in the 96 well format specifically for the detection of colorectal cancer. We also offer a separate test kit for CLIA-labs that would like to run it as a general cancer screen. We do believe that that may become a market for us. Clearly, this is focused on the US in addition to other global markets. Could we just sell reagents so that laboratories could use those to make their own kits? The answer is yes."

**CEOCFO:** You run a huge operation with three distinctive divisions; please give us an idea of your sales and marketing process and the size of the markets?
**Mr. MacLellan:** "Our largest division and market is China-based pharmaceuticals. Today there are approximately 205 cities with over a million people in China. For marketing purposes for our Chinese operations, we primarily target those markets. Today, we are in approximately 35-37 of Chinese markets serving 1 million or more people, and by year-end, we expect to double that footprint and be somewhere in the 75 market range. That is the biggest driver for us as far as sales are concerned and to accomplish this we really just need to add a few products this year, which are already in the pipeline and expand our distribution.

We exclusively use third party distributors to sell our products in China today. It is a very effective way of getting to our core buyers, which are hospitals, spa markets, and drugstores. We may eventually acquire one or more distribution companies to help add additional margin to our bottom line and aid in getting us a slightly better expansion. We continue to look for opportunities in that area. Our Chinese operations today have approximately 500 people, of which approximately 70 people are associated with the marketing and sales in support of our distributors. Currently, we have a total of approximately 25-30 distributors in China at our JPI facility, which is a primarily facility there. We expect to probably double those to 50 or 60 this year. That is the approach in our China operations.

In the case of DR-70, which is our key product within AMDL's IVD division – or AMDL diagnostics, we have approximately 10 employees located in Tustin, California. We have begun commercializing this product just this year and anticipate solid sales through the second half of the year, which are incremental to our stated guidance figures.

We have a strong scientific advisory board for this division, which run by Dr.Andrea Small-Howard. She is a very effective professional in the diagnostic field. We also have a gentleman named Chris Gee, who is the head of marketing and sales for AMDL diagnostics and his focus, is to strictly build third party distribution relationships in our targeted markets. With this team in place, we are well positioned to successfully execute on our FY 2009 commercialization plan for our IVD division. We do not need a huge marketing staff to sell DR-70 because our model is outlined where our distributors hold that responsibility. As far as that distribution model, they provide all sorts of sales and marketing support and commitments to AMDL. We are in the process of negotiating various global contracts and we expect to complete the majority of these during the second quarter, which is really the driving force behind initiating substantial sales of DR-70. Lastly, we plan to sell our high-end skin care products initially in China through existing distribution relationships; and we also developing third party distribution relationships in the same regions we currently sell our China-based pharmaceutical products. We also plan to expand sales to select international markets and are aggressively working on that plan."

**CEOCFO:** Are your products developed through R&D, brought in through acquisitions or both?
**Mr. MacLellan:** "DR-70 was a product that we built internally, so in that case, DR-70 was developed and is owned by us. In the case of our various products in China, for the most part, we collaborate with several different research and development groups who develop product for us and get them approved by the SFDA as part of the acquisition price."

**CEOCFO:** In closing, why should investors be interested in AMDL?
**Mr. MacLellan:** "We have three unique lines of business, each with significant growth opportunity. Our In vitro diagnostics division is part of an estimated $228 billion industry with significantly high PE ratios. Next, we have our Chinese pharmaceuticals division, which has traditionally lower industry PE values compared to let's say, IBD Diagnostics. It is still however, a very strong and growing business for AMDL. We've seen over 100% year-over-year growth in the division for the last three years and expect comparable growth in FY 2009. Lastly, we expect our new high-end skin care division to deliver substantively high margins, high growth. This division is in a market that we think is somewhat recession proof. If we can effectively compete in this market and gain market share we believe we will have a very high success rate with the products in our pipeline.

We believe that because we have three different divisions we offer an investment opportunity that actually lowers the risk from an investor's standpoint. Each division is unique, competing in very different industry categories, and seeking customers in three different distinct areas. All divisions are also high growth industry segments, which we think are pretty exciting. We think that we have a very compelling story to share with Wall Street. Part of my job is to communicate this unique story to the street and get people interested in following us and ac-

tively participating as shareholders. We're not a pure play China pharmaceutical company, or a pure play in vitro diagnostic company, nor a pure play cosmetic company. In that sense, sometimes it's harder to define what we are and it's difficult to pigeon hole us into one particular industry segment. At the end of the day, we are just trying to be a very high growth and profitable pharmaceutical company, and we think that should merit people taking a serious look at us."


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