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EQUITY RESEARCH
Company Report

November 26, 2013

BioDelivery Sciences International (BDSI - $ 4.66)

Initiating Coverage with BUY Rating

Healthcare / Specialty Pharma

Ticker:	**BDSI**
Rating:	**Buy**
Price Target:	**$ 9.00**

We are initiating coverage on BioDelivery with a BUY rating and a price target of $9. We believe that BioDelivery has a robust near-term drug pipeline that is not fully appreciated by investors.

- **Initiating Coverage with a BUY Rating.** Our price target for BioDelivery Sciences International is $9, which is based on the NPV of our probability-adjusted forecasts for Bunavail, BEMA Buprenorphine, Onsolis and Topical Clonidine Gel. We considered revenues generated by these products through direct sales, royalty payments and milestone payments. We believe both Bunavail and BEMA Buprenorphine have significant sales potential and we believe that BEMA Buprenorphine will ultimately hit all milestone and threshold payment targets under the agreement with Endo Health Solutions.

- **Many Potential Catalysts in 2014.** BioDelivery announced on October 9, 2013 that its New Drug Application (NDA) for Bunavail was accepted by the FDA. The Prescription Drug User Fee Act (PDUFA) date is June 7, 2014. We believe if approved, the drug will be launched in September 2014. In 1Q14, we expect the company will start a Phase IIb study for Topical Clonidine Gel. In that quarter, we should also see data from the BEMA Buprenorphine opioid naïve Phase III study. The data lock from that trial could trigger a $15 million milestone payment from Endo. By the end of the year, we could see data released from the Phase IIb Clonidine trial and BEMA Buprenorphine could be submitted to the FDA for approval, potentially triggering another $15 million milestone payment from Endo.

- **Solid Drug Delivery Technology.** BioErodible MucoAdhesive (BEMA) drug delivery technology consists of a small, bi-layered erodible polymer film for application to the buccal mucosa (the lining inside the cheek). BEMA films have the capability to deliver a rapid, reliable dose of drug across the buccal mucosa for time-critical conditions or in situations where gastrointestinal absorption of an oral drug is not practical or reliable, or in facilitating the administration of drugs with poor oral bioavailability. The company expects to use BEMA to deliver previously approved drugs utilizing the 505(b)(2) approval process to obtain more timely and efficient approvals. Two potential BEMA products, one at the FDA and the other in Phase III, could address markets that are over $1 billion combined.

Trading Data:

Last Price (11/25/2013)	$ 4.66
52–Week High (10/2/2013)	$ 5.92
52–Week Low (3/1/2013)	$ 3.52
Market Cap. (MM)	$ 177
Shares Out. (MM)	38

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY_15E	NA	NA	NA	NA	-0.09	NM
FY_14E	-0.33	-0.06	-0.30	0.00	-0.69	NM
FY_13E	-0.37A	-0.36A	-0.46A	-0.26	-1.45	NM
FY_12A	0.29	0.23	-0.46	0.17	0.24	19.8

Source: Laidlaw & Company estimates

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Investment Conclusions

Our price target for BioDelivery Sciences is $9, which is based on the NPV of our probability-adjusted forecasts for the company's products

- **Initiating Coverage With a BUY Rating.** Our price target for BioDelivery Sciences International is $9, which is based on the NPV of our probability-adjusted forecasts for Bunavail, BEMA Buprenorphine, Onsolis and Topical Clonidine Gel. We considered revenues generated by these products through direct sales, royalty payments and milestone payments. For our valuation, we assume that BioDelivery will not partner Bunavail in the U.S., but it will partner the product outside the U.S. We believe both Bunavail and BEMA Buprenorphine have significant sales potential and we believe that BEMA Buprenorphine will ultimately hit all milestone and threshold payment targets under the agreement with Endo Health Solutions. We estimate peak sales of Bunavail, BEMA Buprenorphine and Topical Clonidine Gel, in the U.S., will be $238 million, $500 million and $300 million, respectively. Our $9 price target implies 93% upside potential.

- **Many Potential Catalysts in 2014.** There could potentially be a lot of positive news flow for BioDelivery in 2014. BioDelivery announced on October 9, 2013 that its New Drug Application (NDA) for Bunavail was accepted by the FDA. The Prescription Drug User Fee Act (PDUFA) date is June 7, 2014. We believe if approved, the drug will be launched in September 2014. In 1Q14, we expect the company will start a Phase IIb study for Topical Clonidine Gel. In that quarter, we should also see data from the BEMA Buprenorphine opioid naïve Phase III study. The data lock from that trial could trigger a $15 million milestone payment from Endo. By the end of the year, we could see data released from the Phase IIb Clonidine trial and BEMA Buprenorphine could be submitted to the FDA for approval, potentially triggering another $15 million milestone payment from Endo.

Figure 1: BioDelivery Sciences Key Upcoming Events/Developments

Late 4Q13/Early 1Q14	Potential announcement of Bunavail strategy (partner or not)
1Q14	Expected start of Clonidine Topical Gel Phase IIb study
1Q14	Data from opioid naïve Phase III study with BEMA Buprenorphine expected
1Q14	Estimated $15M milestone payment from Endo at data lock of opioid naïve Phase III study
June 7, 2014	Projected FDA approval for Bunavail
September 2014	Potential launch of Bunavail
2Q14	Expected results from Phase III BEMA Buprenorphine opioid experienced study
4Q14	Clonidine Topical Gel Phase IIb data could be released
4Q14	Projected BEMA Buprenorphine NDA submission
4Q14	Estimated $15M milestone payment from Endo upon submission of NDA
Late 2015	Potential BEMA Buprenorphine FDA approval
Late 2015	Estimated $50M milestone payment from Endo upon FDA approval

Source: Company reports, Laidlaw & Company estimates

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BioErodible MucoAdhesive (BEMA) drug delivery technology consists of a small, bi-layered erodible polymer film for application to the buccal mucosa

- **Impressive Drug Delivery Technology.** BioErodible MucoAdhesive (BEMA) drug delivery technology consists of a small, bi-layered erodible polymer film for application to the buccal mucosa (the lining inside the cheek). BEMA films have the capability to deliver a rapid, reliable dose of drug across the buccal mucosa for time-critical conditions or in situations where gastrointestinal absorption of an oral drug is not practical or reliable, or in facilitating the administration of drugs with poor oral bioavailability. The film adheres to the oral mucosa in less than five seconds and drugs can be absorbed within minutes. The BEMA technology permits absorption without patients being required to move the product around in the mouth, thus avoiding variable patient conditions. The film dissolves completely, leaving no residual product or waste, thus avoiding patient removal, and the possibility for diversion or disposal of partially used product. The film also has built-in taste masking. We believe the BEMA technology will be a strong entrant in the highly competitive drug delivery market. BioDelivery targets delivering previously approved drugs through its BEMA technology utilizing the FDA's 505(b)(2) approval process to obtain more timely and efficient approvals.

- **Bunavail Submitted to FDA.** BioDelivery is developing Bunavail to treat opioid addiction. Bunavail utilizes BioDelivery's BEMA technology to deliver a high dose of buprenorphine for the maintenance treatment of opioid dependence, along with the opioid antagonist naloxone. Following completion of two studies assessing the pharmacokinetics of Bunavail, a meeting was held with FDA in early February 2012. BioDelivery reached an agreement with the FDA on the development plan for Bunavail, which included a pivotal pharmacokinetic study comparing Bunavail to Reckitt Benckiser's Suboxone in normal volunteers and a supporting safety study in opioid dependent patients. Suboxone is an FDA approved product for opioid dependence containing both buprenorphine and naloxone. In 2012, U.S. sales approached $1.5 billion. In July 2013, the company filed a NDA for Bunavail with the FDA for the maintenance treatment of opioid dependence. BioDelivery announced on October 9, 2013 its NDA was accepted. The PDUFA date is June 7, 2014. While we anticipate that the market for buprenorphine/naloxone products for the treatment of opioid dependence will get increasingly more competitive, Bunavail has significant appeal given its greater bioavailability of buprenorphine, convenience, fast dissolution time in the oral cavity and lack of taste issues. BioDelivery has yet to announce whether it will sign a partner for the commercialization of the drug in the U.S. or go it alone. This drug could be attractive for a first solo commercial entry by BioDelivery. As 5,000 doctors are responsible for about 90% of the prescriptions written for opioid dependence in the U.S., we believe only 40 - 50 sale reps are needed to sufficiently address this market. Therefore, we believe it is possible that BioDelivery may use a contracted sales force to market Bunavail in the U.S. if it can't find a suitable partner that offers attractive economics for the commercialization of the drug. We estimate annual peak U.S. sales of Bunavail for the maintenance treatment of opioid dependence will be in the range of $225 million - $250 million.

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- **BEMA Buprenorphine Provides Large Opportunity with Well Known Partner.** BEMA Buprenorphine utilizes the BEMA technology to deliver a low dose of the opioid analgesic buprenorphine for the treatment of moderate to severe chronic pain. It has comparable efficacy to morphine but with a lower propensity for abuse and addiction and fewer typical opioid side effects. Buprenorphine is a Schedule III controlled substance versus the majority of the other potent opioids, such as morphine and oxycodone, which are Schedule II, due to the lower potential for abuse and addiction. Though the primary endpoint, overall pain intensity difference between BEMA Buprenorphine and placebo, was not achieved in a first Phase III trial, a high placebo response in the opioid naïve segment of the patient population, particularly at the starting dose, likely accounted for the lack of statistically significant efficacy that was observed. The study results did favor BEMA Buprenorphine, with a near statistically significant difference between BEMA Buprenorphine and placebo in the opioid experienced group of patients in the trial (p=0.067). This trial provided beneficial knowledge in the design of two additional Phase III clinical studies, which were initiated in 2H12 under BioDelivery's agreement with Endo Health Solutions. Endo is one of the premier companies in the area of pain management. The financial terms of the agreement with Endo include: a $30 million upfront license fee; $95 million in potential milestone payments; $55 million in potential sales threshold payments upon achievement of designated sales levels; and a tiered, mid- to upper-teen royalty on net sales of BEMA Buprenorphine in the U.S. and a mid- to high-single digit royalty on net sales of BEMA Buprenorphine outside the U.S. Because of the safety advantage associated with it, we believe BEMA Buprenorphine has the potential to achieve greater than a 5% share of the $10 billion U.S. market for opioid analgesics. We estimate BEMA Buprenorphine will be submitted to the FDA in late 2014 and will be launched in the U.S. in late 2015. We expect U.S. sales will hit $250 million in 2020, generating about $42.5 million in royalties.

We estimate BEMA Buprenorphine will be submitted to the FDA in late 2014 and will be launched in the U.S. in late 2015

We believe BEMA Buprenorphine has the potential to achieve greater than a 5% share of the $10 billion U.S. market for opioid analgesics

- **Recent Acquisition Offers Opportunity Outside of BEMA.** In March 2013, BioDelivery in-licensed clonidine for topical administration for the treatment of painful diabetic neuropathy (PDN) and potentially other indications from Arcion Therapeutics, a private company. This product acquisition allows BioDelivery to build its pipeline, while applying its expertise in pain product development, utilizing the FDA's 505(b)(2) regulatory process, and diversifying outside of opioid therapy and its BEMA technology. The PDN market is under-served by existing products, in our opinion, and there is a strong scientific rationale for developing a topical treatment for PDN that delivers analgesia in a way that avoids systemic side effects. Arcion conducted a double-blind, placebo-controlled, Phase II trial to study its effectiveness in reducing pain in PDN. The primary study endpoint was the change in pain intensity over a three month treatment period in diabetic foot pain. In the overall population that included patients without functioning nerve receptors, there was a trend favoring Topical Clonidine Gel ($p = 0.069$, $n = 179$), though the overall results did not reach statistical significance. A significant treatment difference was seen in the planned subset analysis of diabetic patients who had documented evidence of functioning pain receptors in the skin of the lower leg. BioDelivery was

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We believe the market potential for Topical Clonidine Gel for the treatment of PDN patients with functional nerve receptors is greater than $280 million annually

granted a Type C meeting with the FDA for Topical Clonidine Gel in December 2013. The company plans a confirmatory Phase IIb study in 1Q14, which would potentially lead to data availability before the end of 2014. If the study meets its endpoint, the company plans to proceed with a Phase III placebo-controlled study in the same population. The neuropathic pain market is expected to reach peak sales of $3.6 billion by 2020. We expect the Phase IIb Topical Clonidine Gel study will begin in early 2014 and have results in late 2014. We believe the market potential for Topical Clonidine Gel for the treatment of PDN patients with functional nerve receptors is greater than $280 million annually and we estimate annual sales could reach $100 million by 2020.

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Company Description

BioDelivery Sciences International is a specialty pharmaceutical company that is developing and commercializing new applications of proven therapeutics to address important unmet medical needs using both proven and new drug delivery technologies. The company's primary products focus on the areas of pain management and drug addiction. BioDelivery was incorporated in Indiana in 1997 and was reincorporated as a Delaware corporation in 2002. The company is headquartered in Raleigh, NC and has 22 full-time employees, 12 of which are involved in the clinical development program and operations and 10 are involved in administration, strategy, legal and accounting.

BioDelivery primarily focuses on the areas of pain management and drug addiction

BioDelivery utilizes its novel, patent protected and proprietary BioErodible MucoAdhesive (BEMA) drug delivery technology to develop its products. BEMA is a small, erodible polymer film for application to the buccal mucosa, the lining inside the cheek. BEMA films have the capability to deliver a rapid, reliable dose of drug across the buccal mucosa for time-critical conditions. BioDelivery's current development strategy focuses primarily on its ability to utilize the FDA's 505(b)(2) approval process to obtain more timely and efficient approval of new formulations of previously approved drugs incorporated into its delivery technology. The 505(b)(2) approval process is designed specifically to address new formulations of previously approved drugs, thus it has the potential to be more cost efficient and expeditious and have less regulatory approval risk than other FDA approval approaches, in our opinion.

BEMA is a small, erodible polymer film for application to the buccal mucosa, the lining inside the cheek

The company received its first FDA approval on July 16, 2009 when Onsolis was approved in the U.S. for the treatment of breakthrough pain (i.e., pain that "breaks through" the effects of other medications being used to control persistent pain) in opioid tolerant patients with underlying persistent pain due to cancer. However, in December 2011, the FDA approved a class-wide Transmucosal Immediate Release Fentanyl (TIRF) Risk Evaluation and Mitigation Strategy (REMS) Access Program that was implemented in March 2012, which has greatly hampered sales. BioDelivery markets Onsolis with its commercial partner Meda AB, a Swedish based specialty pharmaceutical company. In May 2010, regulatory approvals were granted for Canada, and in October 2010, approval was obtained in the European Union through the EU's Decentralized Procedure, with Germany acting as the reference member state. Onsolis is marketed in Europe under the trade-name Breakyl. Onsolis is also approved for use in Taiwan.

The company has three products in active development

The company has three products in active development. BioDelivery's lead product candidate is BEMA Buprenorphine, a partial mu-opioid agonist and a potential treatment for moderate to severe chronic pain. Buprenorphine is also used for the treatment of opioid dependence. BioDelivery's BEMA Buprenorphine/Naloxone (Bunavail) product combines a high dose of buprenorphine along with an abuse deterrent agent, naloxone. Bunavail provides the company with an opportunity to compete in the growing opioid dependence market which, according to Symphony Health, exceeded $1.5 billion in sales in

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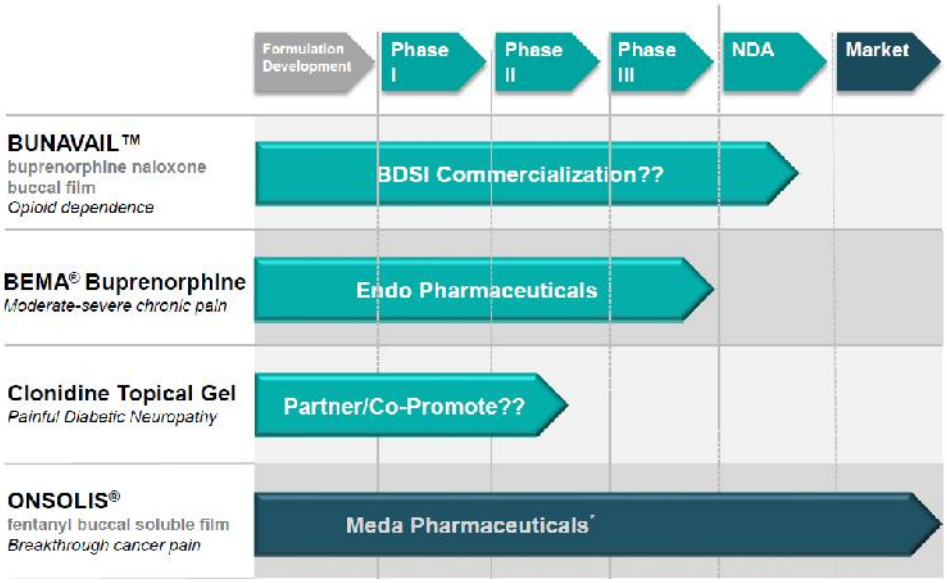
the U.S. in 2012. The company's third product in active development is Topical Clonidine Gel for painful diabetic neuropathy (PDN) and potentially other indications. This product was licensed from Arcion Therapeutics on March 26, 2013. BEMA Granisetron is a fourth pipeline product, although it is not in active development. The company filed an IND in February 2011 for the prevention of nausea and vomiting associated with cancer therapies. This product candidate utilizes the BEMA technology to deliver the 5-HT3 receptor antagonist Granisetron (marketed as Kytril), an FDA approved antiemetic to prevent the nausea and vomiting often encountered following cancer chemotherapy and radiation. The development of this drug was put on the backburner due to the company's focus on progressing more advanced pipeline products and that despite the drug addressing a potential $4 billion market, the market is crowded with other drugs. There has been no recent development activity on this product and we will not discuss it further in this report.

Figure 2: BioDelivery Product Portfolio and Commercialization Strategy



**Licensed to Meda for all territories worldwide except Taiwan (TTY BioPharm) and South Korea (Kunwah Pharmaceutical Co.)*
Source: Company reports

BioDelivery aims to develop its products on its own or in partnership with third parties

It is reviewing its options for marketing Bunavail

BioDelivery aims to develop its products on its own or in partnership with third parties. It has an agreement with Meda for Onsolis. The company has licensing deals in place for the same drug with Kunwha in South Korea and TTY in Taiwan. BioDelivery also has a worldwide licensing and development agreement with Endo Health Solutions for BEMA Buprenorphine. Thus far, Bunavail has not been partnered. BioDelivery is reviewing its options for marketing Bunavail. It may decide to go it alone or it may partner the drug. As 5,000 doctors are responsible for about 90% of the prescriptions written for opioid dependence, we believe only 40-50 sale reps are needed to sufficiently address this market. Therefore, we believe it is possible that BioDelivery may build its own sales force or use a contracted sales force to market Bunavail in the U.S. if it can't find a suitable partner that offers attractive economics for the commercialization of the drug.

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As it showed with the Topical Clonidine Gel agreement, BioDelivery may seek to acquire or license additional drug delivery technologies or drugs utilizing the delivery or other technologies of other companies. The company would seek to formulate these technologies with approved therapeutics and develop them either by itself or through commercial partnerships to bring them to the commercial marketplace.

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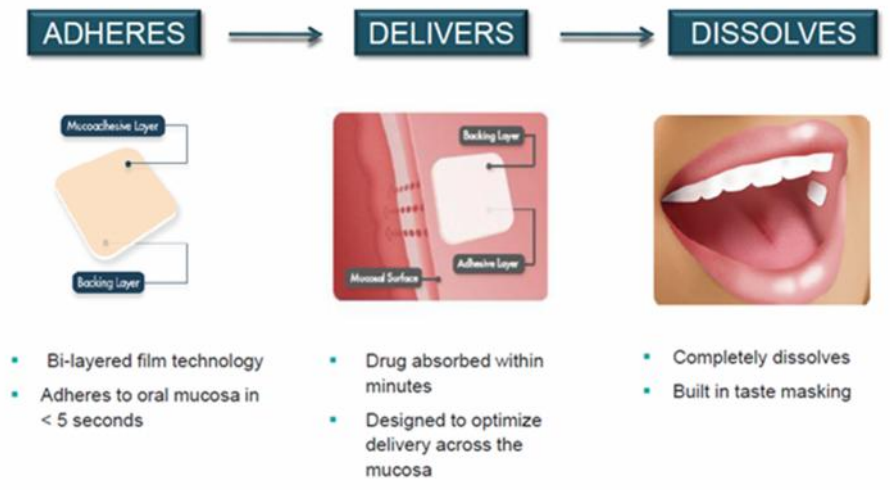
BEMA Drug Delivery Technology

BioErodible MucoAdhesive (BEMA) drug delivery technology consists of a small, bi-layered erodible polymer film for application to the buccal mucosa (the lining inside the cheek). BEMA films have the capability to deliver a rapid, reliable dose of drug across the buccal mucosa for time-critical conditions or in situations where gastrointestinal absorption of an oral drug is not practical or reliable, or in facilitating the administration of drugs with poor oral bioavailability.

BEMA technology permits control of two factors allowing for better dose-to-dose reproducibility: (1) the contact area for mucosal drug delivery, and (2) residence time, the time the drug is in contact with that area. In contrast to competing transmucosal delivery systems like lozenges, buccal tablets and matrix-based delivery systems placed under the tongue or sprayed in the oral cavity, BEMA products are designed to adhere to mucosa in less than five seconds and dissolve in minutes and permit absorption without patients being required to move the product around in the mouth for absorption, thus avoiding variable patient conditions. BEMA also provides a reproducible delivery rate, not susceptible to varying or intermittent contact with oral membranes and it dissolves completely, leaving no residual product or waste and avoiding patient removal, and the possibility for diversion or disposal of partially used product. This is critical with treatments for pain and opioid dependence, in our opinion.

BEMA dissolves completely, leaving no residual product or waste and avoiding patient removal

Figure 3: BioErodible MucoAdhesive (BEMA) Advantages



Source: Company reports

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Previously, BioDelivery licensed the BEMA drug delivery technology on an exclusive basis from Atrix Laboratories (now known as TOLMAR Therapeutics, Inc.). In September 2007, it purchased all North American assets related to the BEMA drug delivery technology from Tolmar and made the final payment on January 6, 2012. From that point, the company fully owned the BEMA technology.

We believe the BEMA technology is impressive and could gain share in several markets including breakthrough pain and opioid addiction

The drug delivery technology market is highly competitive. There have been a growing number of companies developing products utilizing various thin film drug delivery technologies. While numerous over-the-counter pharmaceutical products have been brought to market in thin film formulations, few containing prescription products have been introduced in the U.S. We believe the BEMA technology is impressive and could gain share in several markets including breakthrough pain and opioid addiction. We do not believe that the BEMA technology infringes on any external patents. However, BioDelivery is involved in litigation with MonoSol Rx LLC, which we will discuss later in this report. MonoSol is one of the leading companies in the development and manufacture of thin film technologies. It has been focused on oral dissolvable thin films, and not mucoadhesive films such as BEMA, which are designed to facilitate more rapid and consistent transmucosal drug delivery. Other companies in this space include IntelGenX Corporation, a drug delivery company focusing on the development of oral controlled release and rapidly disintegrating products and delivery systems such as VersaFilm; and ULURU Inc., which utilizes their OraDisc mucoadhesive film technology to deliver drugs transmucosally. Other leading companies in the development and manufacture of thin film technologies include LTS Lohmann Therapie-Systeme AG and ARx LLC. We believe BEMA technology can be differentiated because the it provides for a rapid and consistent delivery of each dose based on how the BEMA adheres to the buccal membrane and dissolves at a predetermined rate. Clinical trials have demonstrated that the BEMA technology is an effective means of drug delivery that is well tolerated and offers convenience to patients. We expect BEMA will be a successful entrant in the drug delivery market.

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The Pain Market

Opioids are used to treat both acute and chronic pain. Acute pain occurs suddenly, often as a result of an illness, injury, or surgery. Acute pain can be short-term but may also last a few days or even weeks. For example, following major surgery, a patient may need strong pain relief for a week or two until healed. One characteristic of acute pain is that once the injury is healed, the pain usually goes away. In contrast, chronic pain often persists long after an injury has healed. Chronic pain can also mysteriously occur when no specific injury, wound, illness, or disease is identified. Such cases can often be linked to nervous system problems. Chronic pain is often defined as any pain that lasts longer than three to six months. Thus, acute pain can become chronic just by virtue of how long it lasts. Chronic pain is common among people who have osteoarthritis, rheumatoid arthritis, fibromyalgia, injuries to their back, injuries to their limbs and muscles, and damage to their nerves or nervous system from diseases such as diabetes or after an episode of shingles.

Chronic pain is often defined as any pain that lasts longer than three to six months

A national survey conducted by ABC News, USA Today and the Stanford University Medical Center reported that just under 50% of surveyed adults experienced pain during the two weeks prior to the survey. This translates into approximately 113 million adults in the U.S. Pain was reported to be acute in 44% (about 45 million adults) and recurrent or chronic in the rest. The CDC estimates that 76.5 million Americans (about 26% of the population) are affected by chronic pain. Based on these statistics, pain affects more people than diabetes, heart disease and cancer combined. Pain is an enormous burden on society. It is the most common complaint in primary care physicians' offices. Unrelieved pain can result in increased outpatient visits, longer hospital stays, increased rates of re-hospitalization, and decreased ability to function, leading to lost income and insurance coverage. About 42% of patients with chronic pain felt that prescription drug regimens they were on did not effectively relieve their pain, according to a survey conducted by Peter D. Hart Research Associates in 2003. It has been reported by the American Pain Association and the CDC that health care expenses, lost work time, and reduced productivity due to pain costs around $100 billion annually. Of course, chronic pain has a negative impact on quality of life as well. The treatment of pain is a well-established market, with many pharmaceutical companies marketing innovative products as well as generic versions of older products. In 2012, the U.S. opioid market exceeded $10 billion in annual sales. As shown in the figure below, retail prescriptions for opioids have been growing steadily. We believe that due to the Patient Protection and Affordable Care Act (PPACA) more Americans will be covered by healthcare insurance and that the growth of prescription medication for pain may accelerate.

The CDC estimates that 76.5 million Americans are affected by chronic pain

In 2012, the U.S. opioid market exceeded $10 billion in annual sales

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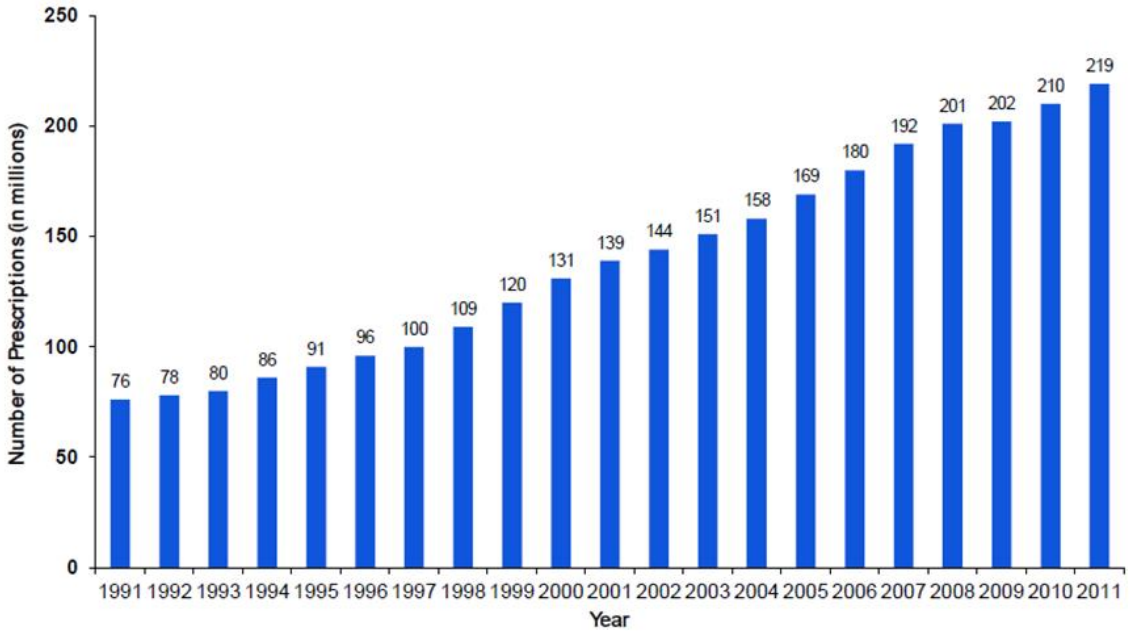
Figure 4: Opioid Prescriptions Dispensed by U.S. Retail Pharmacies 1991-2011



Source: CDC, IMS Vector One

Buprenorphine is a partial opioid agonist

Buprenorphine is a partial opioid agonist. This means that, although buprenorphine is an opioid, and thus can produce typical opioid agonist effects and side effects such as euphoria and respiratory depression, its maximal effects are less than those of full agonists like heroin and methadone. At low doses buprenorphine produces sufficient agonist effect to enable opioid-addicted individuals to discontinue the misuse of opioids without experiencing withdrawal symptoms. The agonist effects of buprenorphine increase linearly with increasing doses of the drug until at moderate doses the effects reach a plateau and no longer continue to increase with further increases in dose—the "ceiling effect." Thus, buprenorphine carries a lower risk of abuse, addiction, and side effects compared to full opioid agonists. In fact, in high doses and under certain circumstances, buprenorphine can block the effects of full opioid agonists and can precipitate withdrawal symptoms if administered to an opioid-addicted individual while a full agonist is in the bloodstream. Buprenorphine has poor oral bioavailability and moderate sublingual bioavailability, according to the U.S. Department of Health and Human Services.

Buprenorphine carries a lower risk of abuse, addiction, and side effects compared to full opioid agonists

Buprenorphine is highly bound to plasma proteins. It is metabolized by the liver via the cytochrome P4503A4 enzyme system into norbuprenorphine and other metabolites. The half-life of buprenorphine is 24–60 hours.

Depending on the application form, buprenorphine is indicated for the palliation of moderate to severe acute or chronic pain with no neuralgic component

Depending on the application form, buprenorphine is indicated for the palliation of moderate to severe acute or chronic pain with no neuralgic component (or when the neuralgia is otherwise treated, such as with pregabalin), or for peri-operative analgesia. For the treatment of chronic pain, the transdermal formulations (which were released in the United States in January 2011, but were available in Australia and many European countries years beforehand) are preferred. In 1978 buprenorphine was first launched in the UK as an injection to treat severe pain, with a sublingual formulation released in 1982. Buprenorphine was first marketed in the U.S. in 1985 as a schedule V narcotic analgesic. On October 7, 2002 the DEA rescheduled buprenorphine and all products containing buprenorphine from Schedule V to a Schedule III narcotic under the

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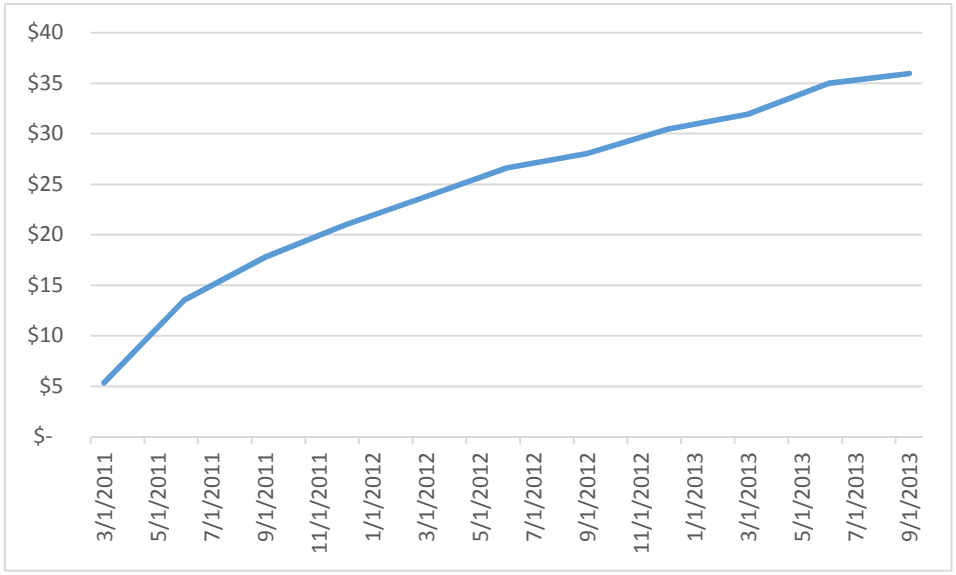
Controlled Substances Act. Initially, the only available buprenorphine product in the U.S. had been a low-dose (0.3 mg/ml) injectable formulation under the brand name, Buprenex. The first extended release transdermal buprenorphine film for the treatment of chronic pain in the U.S. was approved in June 2010. Purdue Pharmaceuticals received FDA approval for Butrans (buprenorphine transdermal system) for the management of moderate to severe chronic pain in patients requiring a continuous, extended period, around-the-clock opioid analgesic. Butrans delivers buprenorphine transdermally (through the skin) over a period of seven days. Butrans was launched in early 2011.

IMS Health National Prescription Audit Plus indicates that 9.3 million buprenorphine prescriptions were dispensed in the U.S. in 2012

IMS Health National Prescription Audit Plus indicates that 9.3 million buprenorphine prescriptions were dispensed in the U.S. in 2012. From January to March 2013, 2.5 million buprenorphine prescriptions were dispensed. Sales of Butrans in 2012 totaled $109 million and continue to steadily grow, according to data from Symphony Health Solutions (see Figure 5). At launch, the price of Butrans was about $11 - $12 per day, which is about where we believe BioDelivery's BEMA Buprenorphine will be priced if approved.

Figure 5: Butrans Quarterly Sales (Millions)



Source: Symphony Health

BioDelivery is using its BEMA technology to deliver buprenorphine in two different products, one for chronic pain and the other as a treatment for opioid addiction, which we will discuss later in this report.

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BEMA Buprenorphine

BioDelivery's lead product candidate, BEMA Buprenorphine, is a partial mu-opioid agonist. This drug candidate utilizes the BEMA technology to deliver a low dose of the opioid analgesic buprenorphine for the treatment of moderate to severe chronic pain. As mentioned previously in this report, buprenorphine is a marketed opioid analgesic which has comparable efficacy to morphine but with a lower propensity for abuse and addiction and fewer typical opioid side effects. Buprenorphine is a Schedule III controlled substance versus the majority of the other potent opioids, such as morphine and oxycodone, which are Schedule II, due to the lower potential for abuse and addiction. We believe that these attributes will help create a broader market opportunity for BEMA Buprenorphine as many doctors are reluctant to prescribe narcotics, particularly on a chronic basis. Also, since buprenorphine is a Schedule III controlled substance, physicians will be able to phone, fax or electronically deliver the prescription to the pharmacy with refills permitted for up to six months, making chronic therapy easier for both the patient and the physician. Refills are not permitted for Schedule II controlled substances. Those require the patient to obtain a new prescription from the doctor's office and take such prescription to the pharmacy each time the medication is needed.

Buprenorphine is a Schedule III controlled substance versus the majority of the other potent opioids, such as morphine and oxycodone, which are Schedule II

In December 2009, BioDelivery announced that the primary efficacy endpoint was achieved in a Phase II clinical study evaluating the safety and efficacy of a range of doses of BEMA Buprenorphine. Completion of this Phase II study led to the initiation of a Phase III double-blind, randomized, placebo-controlled clinical study for the treatment of moderate to severe chronic pain in a mixed opioid naïve and opioid experienced population that was initiated in 4Q10. On September 28, 2011, the company announced disappointing preliminary findings of the Phase III study. The primary endpoint, overall pain intensity difference between BEMA Buprenorphine and placebo, was not achieved. Following full analysis of the data, the company concluded that it encountered a high placebo response in the opioid naïve segment of the patient population, particularly at the starting dose, which BioDelivery believes accounted for the lack of statistically significant efficacy that was observed in the trial overall. We believe this is an occurrence typical of many pain trials. The study results did favor BEMA Buprenorphine, with a near statistically significant difference between BEMA Buprenorphine and placebo in the opioid experienced group of patients in the trial (p=0.067). When the group of patients that did not titrate beyond the starting dose is eliminated, a statistically significant difference between BEMA Buprenorphine and placebo (p=0.025) was identified. However, neither of these subgroups was large enough to be powered to show a statistical difference. Overall, the trial, while not successful, did provide beneficial knowledge in the design of two additional Phase III clinical studies, which were initiated in 2H12 under BioDelivery's agreement with Endo Health Solutions, Inc.

On September 28, 2011, BioDelivery announced disappointing preliminary findings of the Phase III study

Overall, the trial, while not successful, did provide beneficial knowledge in the design of two additional Phase III clinical studies, which were initiated in 2H12

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In January 2012, BioDelivery announced the signing of a worldwide licensing and development agreement for BEMA Buprenorphine with Endo Health Solutions

In January 2012, BioDelivery announced the signing of a worldwide licensing and development agreement for BEMA Buprenorphine with Endo under which BioDelivery granted to Endo the exclusive, worldwide rights to develop and commercialize BEMA Buprenorphine for the treatment of chronic pain. Endo will be responsible for the manufacturing, distribution, marketing and sales of BEMA Buprenorphine on a worldwide basis. It will commercialize BEMA Buprenorphine outside the U.S. through its own efforts or through regional partnerships. Both companies collaborated on the planning and finalization of the Phase III clinical development program and regulatory strategy for BEMA Buprenorphine for chronic pain. BioDelivery will maintain responsibility for the conduct of planned clinical studies leading up to the submission of the NDA. Endo will have the responsibility of submitting the NDA and managing the interactions with the FDA. In aggregate, the agreement is worth up to $180 million if all milestones or thresholds are met.

$80 million in potential milestone payments remaining from Endo

The financial terms of the agreement with Endo include: (A) a $30 million upfront license fee, which BioDelivery received in January 2012; (B) $95 million in potential milestone payments based on achievement of pre-defined intellectual property, clinical development and regulatory events ($15 million of which BioDelivery received in May 2012 following the approval of a U.S. patent that extends patent protection of BEMA products into 2027); (C) $55 million in potential sales threshold payments upon achievement of designated sales levels; and (D) a tiered, mid- to upper-teen royalty on net sales of BEMA Buprenorphine in the U.S. and a mid- to high-single digit royalty on net sales of BEMA Buprenorphine outside the U.S. Of the $80 million in potential milestone payments remaining, we believe one payment of $15 million will be paid upon the Phase III data lock and a second potential milestone payment of $15 million will come on filing with the FDA. We expect the final $50 million potential milestone payment will come upon FDA approval.

Endo is one of the premier companies in the area of pain management and has demonstrated its ability to launch and commercialize pain therapeutics including opioids

Endo is one of the premier companies in the area of pain management and has demonstrated its ability to launch and commercialize pain therapeutics including opioids. Endo currently has approximately 500 sales representatives covering pain specialty and primary care physicians. Endo's current branded pain portfolio generated slightly over $1.5 billion in sales in 2012 and includes products such as Opana ER, Lidoderm, Percocet, Frova and Voltaren Gel and almost $990 million in sales year-to-date. Endo has strong sales and marketing capability in pain therapeutics, and a managed care organization that has established solid formulary positioning for the company's products. We believe BEMA Buprenorphine is an excellent fit to Endo's pain portfolio and will, if approved, add a Schedule III opioid to their branded pain franchise. BEMA Buprenorphine would potentially be aligned with the needs of pain specialists and primary care physicians who seek an alternative to Schedule II opioids for the treatment of moderate to severe chronic pain that is not adequately controlled with commonly prescribed first-line therapies.

In August 2012, BioDelivery initiated the first of two Phase III pivotal studies for BEMA Buprenorphine for the treatment of moderate to severe chronic pain…

In August 2012, BioDelivery initiated the first of two Phase III pivotal studies for BEMA Buprenorphine for the treatment of moderate to severe chronic pain in conjunction with Endo. The first study is being conducted in patients who are naïve to opioid therapy. The study is a double-blind, placebo-controlled, randomized enriched enrollment withdrawal trial assessing the efficacy and safety of BEMA Buprenorphine in opioid naïve subjects with moderate to severe chronic low back pain requiring constant opioid analgesia. A total of 740 patients will be enrolled in the study, with the primary study endpoint being the change from baseline to week 12 in the mean average daily pain intensity scores

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…the company expects data from this trial in 1Q14

A second Phase III pivotal study is also underway with data expected mid-2014

(using an 11-point scale) at twelve weeks compared to placebo. The company expects data from this trial in 1Q14. A second Phase III pivotal study is also underway. It also is a double-blind, placebo-controlled, randomized enriched enrollment withdrawal study. However, this trial will assess the safety and efficacy of BEMA Buprenorphine in opioid experienced patients already receiving chronic opioid treatment. The study will enroll approximately 475 subjects in the open-label titration phase. The company expects data from this trial in mid-2014.

Both studies were designed based on findings from the prior Phase III clinical study with adjustments made in the patient population, study criteria, starting dose and sample size. To address the high placebo response seen in the opioid naïve patient population in the previously conducted study, modifications in study design included:

- Inclusion of patients with more profound and longer duration of pain
- Separation of opioid naïve and opioid experienced patients into two separate studies,
- An increased sample size
- The requirement for a more robust response to BEMA Buprenorphine prior to randomization

In order to address the lack of response to the starting dose in the previous study, the starting dose and overall dosing range was increased. Additionally, naïve patients are required to titrate beyond the starting dose in order to be eligible for randomization. We believe these modifications have resulted in two studies with an improved likelihood of achieving their endpoints.

Figure 6: BEMA Buprenorphine Phase III Clinical Program

	BUP-307 "Opioid Experienced" Study	BUP-308 "Opioid Naïve" Study
Study Design	• "Enriched enrollment" randomized withdrawal • BEMA Buprenorphine vs BEMA Placebo • Moderate to severe chronic low back pain	
Primary Endpoint	Change in average daily pain intensity scores (using 11 point scale) from titration to end of 3 months randomization	
Patient Population	Opioid Experienced (30 – 160 mg MSE)	Opioid Naïve (Up to 10 mg MSE)
Number of subjects enrolled	475 (284 randomized)*	740 (444 randomized)
Dosing	2X, 4X, 6X, 8X, 10X, 12X Twice daily	X, 2X, 4X, 6X Twice daily
Statistics	Power: 90% Delta: 1.0 Standard Deviation: 2.6	Power: 90% Delta: 0.8 Standard Deviation: 2.6
Estimated Completion	Data mid-2014	Enrollment complete Data early 1Q 2014

Source: Company reports

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Upon completion of database lock and the acceptance of the filing with the FDA, BioDelivery is expected to receive milestone payments totaling $30 million

BioDelivery and Endo expect data from the opioid naïve Phase III study to report out in 1Q14 with the opioid experienced trial to report out in mid-2014. Upon completion of study enrollment and database lock for each trial and the acceptance of the filing of the NDA with the FDA, BioDelivery is expected to receive milestone payments from Endo totaling $30 million, which we believe will occur in two equal payments of $15 million. We have modeled the database lock payment in 2Q14 and the FDA filing payment in 4Q14.

A number of products may be competitors to BEMA Buprenorphine for the treatment of chronic pain, including Butrans (as discussed earlier, a buprenorphine transdermal film used for chronic pain). A potential focus will be to position BEMA Buprenorphine as a step up from NSAIDs instead of, or prior to, prescribing more addictive Schedule II narcotics. Indications for such use include pain associated with lower back and severe arthritis conditions. Marketed competitors for these indications include Tramadol (a weak μ-opioid receptor agonist marketed as Ultram ER and Ryzolt) and the potent opioids such as OxyContin, Avinza, Kadian, and Duragesic and others. Other potential competition could come from multiple new chemical entities in clinical development with different mechanisms of action as well as various combination formulations. There are other companies developing buprenorphine in other delivery technologies including Titan Pharmaceuticals and Relmada Therapeutics.

If approved, BEMA Buprenorphine could be one of the few severe pain medications that would allow refills. On October 24, 2013, the FDA announced that after careful evaluation it will be recommending to the U.S. Department of Health and Human Services (HHS) that hydrocodone combination products (e.g., Vicodin, Lortab, hydrocodone/APAP) be reclassified as Schedule II controlled substances. By early December, the FDA plans to submit its formal recommendation package to HHS to reclassify hydrocodone combination products into Schedule II. The FDA anticipates that the National Institute on Drug Abuse (NIDA) will concur with its recommendation. This will begin a process that will lead to a final decision by the DEA on the appropriate scheduling of these products. This rescheduling will tighten restrictions around the use of hydrocodone combination products, which in 2012 alone accounted for nearly 131 million prescriptions. Unlike Schedule II products, Schedule III products such as buprenorphine do not require a written prescription and can be prescribed with refills. On February 23, 2013, New York State rescheduled hydrocodone combination products to Schedule II. Pure hydrocodone products are already classified as Schedule II.

Unlike Schedule II products, Schedule III products such as buprenorphine do not require a written prescription and can be prescribed with refills

As we mentioned earlier in this report, we believe BEMA Buprenorphine will be priced at parity to Butrans at about $11 - $12 per day. Because of the safety advantage associated with it, we believe BEMA Buprenorphine has the potential to achieve greater than a 5% share of the $10 billion U.S. market for opioid analgesics. BEMA Buprenorphine could be an ideal next step product for patients with incomplete pain relief on non-narcotic analgesics. We estimate that BEMA Buprenorphine for chronic pain could generate $500 million in annual peak sales. The drug's sales could be even higher if oxycodone combination products are moved from Schedule III to Schedule II. If the drug achieves about 1% of Hydrocodone sales that could account for $300 million in annual sales alone.

We believe BEMA Buprenorphine has the potential to achieve greater than a 5% share of the $10 billion U.S. market for opioids

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We expect sales will hit $250 million in 2020, generating about $42.5 million in royalties

We estimate BEMA Buprenorphine will be submitted to the FDA in late 2014 and will be launched in the U.S. in late 2015. We expect sales will hit $250 million in 2020, generating about $42.5 million in royalties.

The FDA has implemented a class-wide REMS covering the extended release and long acting opioid class. The class-wide REMS program consists of a REMS-compliant educational program offered by an accredited provider of continuing medical education, patient counseling materials and a medication guide. BEMA Buprenorphine is anticipated to fall within the existing class-wide REMS program. The cost and implementation of the extended release and long-acting opioid REMS is shared among multiple companies in the category.

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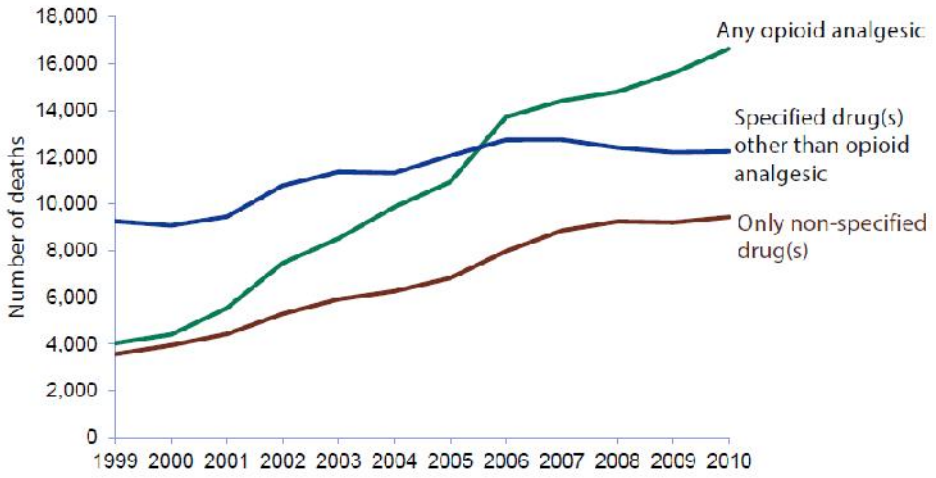
The Opioid Addiction Market

Opioid addiction is a problem that affects nearly 5 million people in the U.S. and leads to about 17,000 deaths in the U.S. annually

Non-medical use and abuse of prescription opioids costs the U.S. approximately $53.4 billion dollars annually

Over the past decade, opioid dependence has become an epidemic in the U.S. Between 1999 and 2008, the rate of prescription opioid overdose-related deaths in the U.S. quadrupled, according to the CDC. Opioid addiction is a problem that affects nearly 5 million people in the U.S. and leads to about 17,000 deaths in the U.S. annually. Of those nearly 5 million people, approximately 2 million people are dependent on prescription opioids according to the 2010 National Survey on Drug Use and Health, conducted by the U.S. Department of Health and Human Services. Only about 20% of people addicted to the painkillers get any treatment. Opioid dependence greatly impacts the U.S. economy, with the non-medical use of prescription painkillers, including opioids, costing health insurers up to $72.5 billion annually in direct health care costs with about $56 billion spent on opioid dependence alone each year. In addition, the average healthcare cost per patient with opioid dependence is eight times higher compared to nondependent patients. Non-medical use and abuse of prescription opioids costs the U.S. approximately $53.4 billion dollars annually, of which $42 billion is attributed to lost productivity, $8.2 billion to criminal justice costs and $2.2 billion to drug abuse treatment, according to a 2011 article in The Clinical Journal of Pain. Buprenorphine, like methadone, is a chosen method for opioid dependence therapy because of its long half-life, which provides a milder withdrawal. Buprenorphine is available alone or in combination with the opioid antagonist, naloxone, to deter its abuse by intravenous injection.

Figure 7: Number of U.S. Drug Overdose Deaths Involving Opioid Pain Relievers and Other Drugs 1999-2010



Source: CDC, National Center for Health Statistics, National Vital Statistics System

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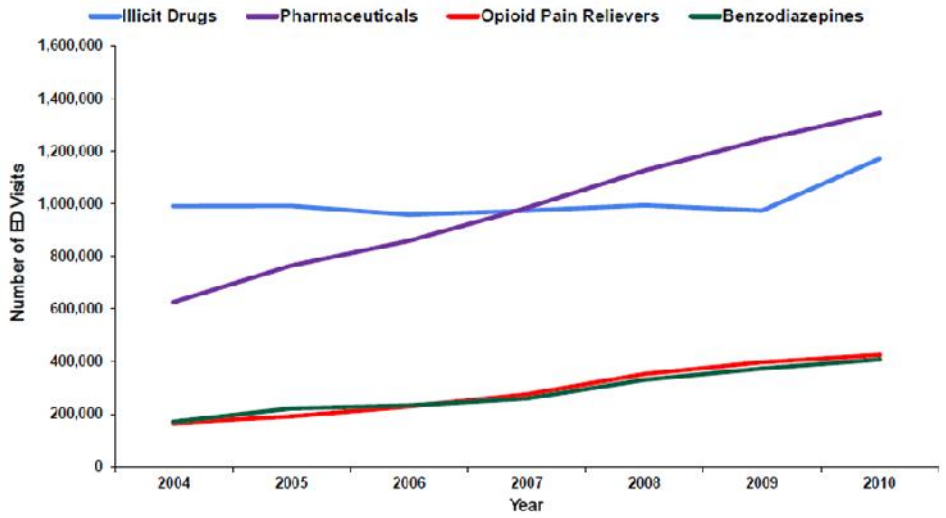
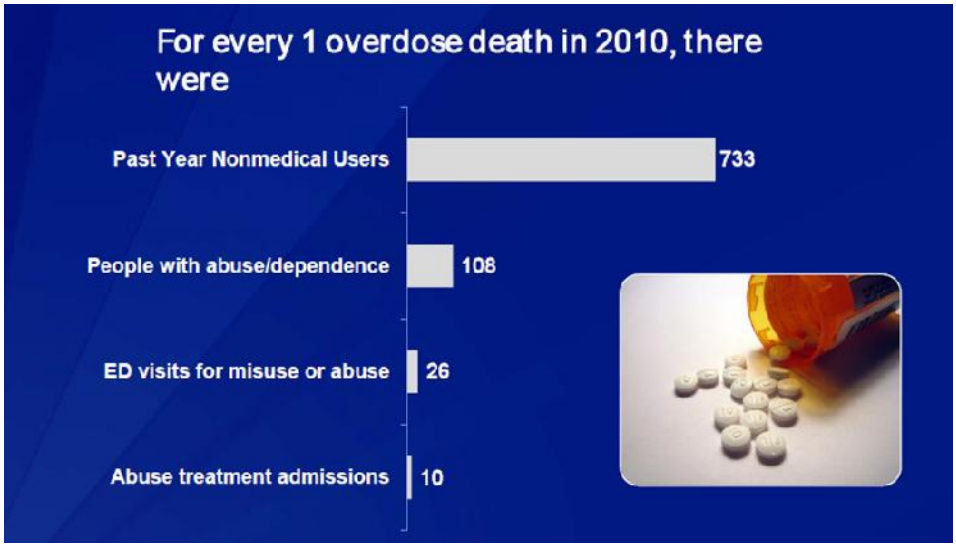
Figure 8: U.S. Emergency Department Visits Related to Drug Misuse or Abuse 2004-2010



Source: SAMHSA, Highlights of the 2010 Drug Abuse Warning Network (DAWN) Findings on Drug-Related ED Visits, 2011

Figure 9: Public Health Impact of Opioid Use 2010



Source: CDC, National Survey on Drug Use and Health

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BEMA Buprenorphine/Naloxone Bunavail (Bunavail)

Buprenorphine attaches to empty opioid receptors and suppresses withdrawal symptoms and reduces cravings for opiates

BioDelivery is developing Bunavail to treat opioid addiction. Bunavail utilizes BioDelivery's proprietary BioErodible MucoAdhesive (BEMA) technology to deliver a high dose of buprenorphine for the maintenance treatment of opioid dependence, along with the opioid antagonist naloxone, which is intended to serve as an abuse deterrent. Buprenorphine attaches to empty opioid receptors and suppresses withdrawal symptoms and reduces cravings for opiates. Buprenorphine is poorly absorbed orally from the gastrointestinal tract. With Bunavail, however, drug is absorbed within the oral cavity transmucosally (across the cheek or under the tongue). Buprenorphine reduces the craving and withdrawal effects from the dependent opioid, and the opioid antagonist, naloxone, deters abuse. Naloxone blocks the effect of narcotics and can cause severe narcotic withdrawal if injected, thus deterring abuse by intravenous injection. Bunavail was designed to efficiently and conveniently deliver buprenorphine while potentially overcoming some of the challenges with other dosage forms.

Suboxone is an FDA approved product for opioid dependence containing both buprenorphine and naloxone

Pharmacokinetic studies have demonstrated the ability of the BEMA technology to deliver the high doses of buprenorphine necessary for the treatment of opioid dependence. Following completion of two studies assessing the pharmacokinetics of Bunavail, a meeting was held with FDA in early February 2012. BioDelivery reached an agreement with the FDA on the development plan for Bunavail, which included a pivotal pharmacokinetic study comparing Bunavail to Reckitt Benckiser's Suboxone in normal volunteers and a supporting safety study in opioid dependent patients. Suboxone is an FDA approved product for opioid dependence containing both buprenorphine and naloxone. In 2012, U.S. sales approached $1.5 billion, which is an increase of 20% over 2011. Most Suboxone now sold in the U.S. is an orange film strip form of Suboxone with a lime flavor. More than 71% of patients gave Suboxone film a "favorable" or "neutral" taste rating, according to the company, however, a poster by Jonsson et. al. presented at the 44th Annual Conference of the American Society of Addiction Medicine in April 2013 found that 92.6% of 27 people surveyed stated that Suboxone had an unpleasant taste. In the same poster, 42.3% of 28 people stated that Zubsolv, a sublingual tablet containing buprenorphine and naloxone, had an unpleasant taste. Suboxone, available only by prescription, is a Schedule III narcotic medication.

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Figure 10: Bunavail Bioavailability Versus Suboxone

Parameter	BUNAVAIL™	Suboxone®
Relative Bioavailability	50%	25%
Equivalent buprenorphine dose	4 mg	8 mg
Amount absorbed through buccal mucosa	2 mg	2 mg
Amount delivered to GI tract	2 mg	6 mg (300% of BUNAVAIL)

Source: Company reports

In September 2012, BioDelivery announced the positive outcome of the pivotal pharmacokinetic study comparing Bunavial to Suboxone

In September 2012, BioDelivery announced the positive outcome of the pivotal pharmacokinetic study comparing Bunavial to Suboxone. The study was designed to compare the relative bioavailability of the drugs. The results verified that the two key pharmacokinetic parameters, maximum drug plasma concentration (Cmax) and total drug exposure (AUC), for buprenorphine were comparable to Suboxone, and that the same parameters for naloxone were similar or less than Suboxone. This was followed by initiation of the safety study requested by the FDA, assessing the safety and tolerability of Bunavail in patients converted from a stable dose of Suboxone sublingual tablets or films. A total of 249 patients were enrolled in the study, which was completed in December 2012. A total of 191 patients completed the study. In July 2013, the company filed a New Drug Application for Bunavail with the FDA for the maintenance treatment of opioid dependence. BioDelivery announced on October 9, 2013 its New Drug Application (NDA) for Bunavail was accepted by the FDA. The Prescription Drug User Fee Act (PDUFA) date is June 7, 2014.

BioDelivery announced on October 9, 2013 its NDA for Bunavail was accepted by the FDA. The PDUFA date is June 7, 2014

Suboxone and other buprenorphine-containing products for opioid dependence generate annual sales of more than $1.5 billion

Suboxone, which was approved for the treatment of opioid dependence in 2002, has been shown to be a highly effective treatment option and, as a result, Suboxone and other buprenorphine-containing products for opioid dependence generate annual sales of more than $1.5 billion according to data from Symphony Health. In September 2012, Reckitt Benckiser announced that it had notified the FDA that it would be voluntarily discontinuing the distribution of Suboxone tablets in the U.S. and would halt further shipments in March 2013. The decision made by Reckitt Benckiser was reportedly due to accumulating data demonstrating significantly lower rates of accidental pediatric exposure with Suboxone films compared with the tablet formulation due to the child-resistant, unit-dose packaging of the film versus a multi-dose bottle for the tablets. Data from poison control centers consistently found significantly higher rates (7.8 – 8.5 times greater) of accidental pediatric exposure with Suboxone tablets as compared with Suboxone Film. Children who take buprenorphine/naloxone can have severe, possibly fatal, respiratory depression.

There is an increasing rate of young children being accidentally exposed to buprenorphine. From 2009 to 1Q12, there were a total of 2,380 unique cases of

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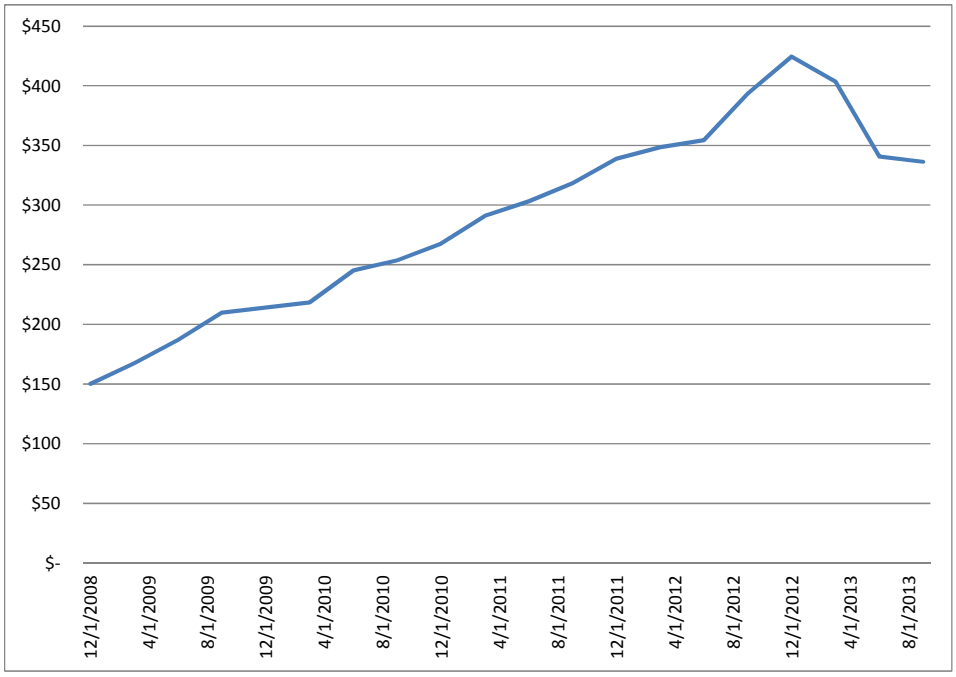
pediatric exposure in children younger than 6 years, with 536 being serious adverse events, according to a study by Venebio Group. Reckitt Benckiser states that the film discourages misuse and abuse, as the paper-thin film is more difficult to crush and snort. Also, a ten-digit code is printed on each pouch, which helps facilitate medication counts and, therefore, serves to deter diversion into the illegal drug market. Reckitt issued a Citizens Petition to request that the FDA require all manufacturers of buprenorphine-containing products for the treatment of opioid dependence to implement public health safeguards including child-resistant, unit-dose packaging to reduce the risk of pediatric exposure. FDA subsequently rejected the Citizens Petition in February 2013, which allowed for the approval of the first generic formulations of Suboxone tablets. However, the actions taken by Reckitt Benckiser as well as patient preference for a film formulation of Suboxone have resulted in significant conversion of the Suboxone market to the branded film formulation. In January 2013, the sublingual film formulation of Suboxone accounted for over 80% of volume sales, which helps to preserve the branded market for future buprenorphine/naloxone film products including Bunavail, in our opinion.

Figure 11: Suboxone Quarterly Sales (*millions*)



Source: Bloomberg LP

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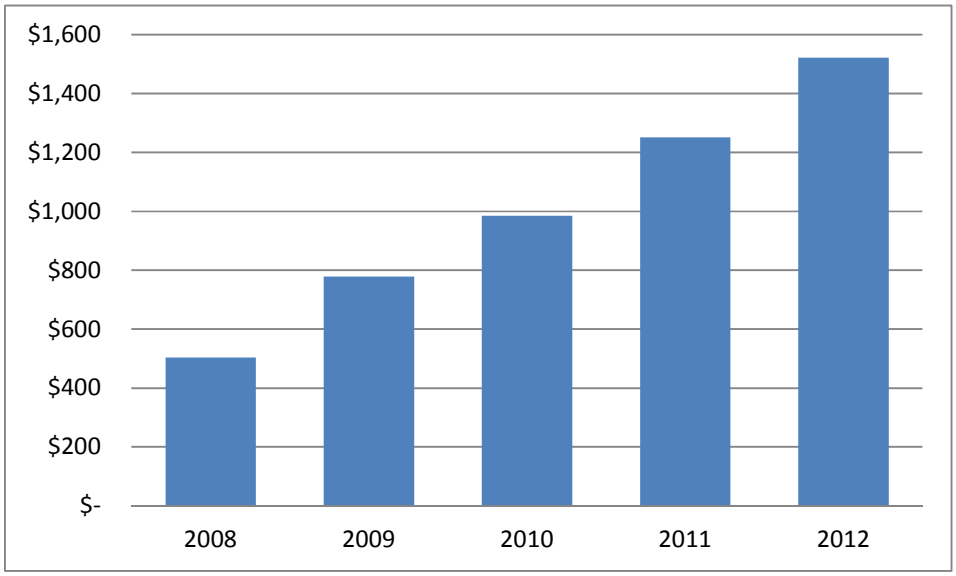
Figure 12: Suboxone Annual Sales (*millions*)



Source: Bloomberg LP

In terms of potential competition for Bunavail, in addition to Suboxone, Titan Pharmaceuticals completed Phase III trials for Probuphine, a subcutaneous depot delivery system containing buprenorphine using a polymer matrix sustained-release technology, in 2011. This novel implantable formulation of buprenorphine has been developed to offer treatment for opioid dependence while minimizing risks of patient noncompliance and illicit diversion. Probuphine was anticipated to address the needs of the subset of patients undergoing treatment for opioid dependence who are unable to maintain compliance with alternative formulations or those who may be at high risk for diversion. In December 2012, Titan announced the signing of a license agreement with Braeburn Pharmaceuticals Sprl. The license grants Braeburn exclusive commercialization rights in the U.S. and Canada. Results of clinical studies demonstrated efficacy and safety, and Probuphine was submitted for FDA review in October 2012. However, the FDA requested additional information about Probuphine in a complete response letter to Titan on April 30, 2013 stating that the FDA could not approve the application in its present form. On September 26, 2013, Titan announced that the FDA has granted its request for a meeting to discuss Probuphine, the Type C meeting is scheduled for November 19, 2013.

On July 4, 2013, Swedish drug developer Orexo announced that the FDA had approved its Zubsolv for the maintenance treatment of opioid dependence. Zubsolv is a once-daily, sublingual tablet with a formulation of buprenorphine and naloxone that fully dissolves within minutes. Zubsolv was launched in September by Orexo US, Inc and its partner Publicis Touchpoint Solutions. Orexo CEO Nikolaj Sørensen stated that the company anticipates a peak market potential of at least $500 million.

Other formulations of buprenorphine may also be in early stages of development for the treatment of opioid dependence, including an oral capsule from Nanotherapeutics, Inc.

While we anticipate that the market for buprenorphine/naloxone products for the treatment of opioid dependence will get increasingly more competitive,

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Bunavail has significant appeal given its enhanced delivery (i.e. greater drug absorption) of buprenorphine, convenience, fast dissolution time in the oral cavity

Bunavail has significant appeal given its enhanced delivery (i.e. greater bioavailability) of buprenorphine, convenience, fast dissolution time in the oral cavity and lack of taste issues. We also believe that the increased number of companies promoting the use of buprenorphine containing-products for opioid dependence has the potential to create greater awareness and help to further expand what is already a significant and growing market.

Figure 13: Potential Bunavail Benefits Over Currently Marketed Products

	Suboxone®	Zubsolv®	BUNAVAIL™	Benefit of BUNAVAIL™
Administration[1]	Sublingual *Avoid swallowing; Avoid talking*	Sublingual *Avoid swallowing; Avoid talking*	Buccal *Adheres to inner cheek in seconds*	**Convenient**
Bioavailability[2]	Low (<25%)	Low (<35%)	2-Fold Greater than Suboxone (~50%)	**Reduces amount of available drug by 50% and potential misuse and diversion** **Potential for fewer side effects (e.g., constipation)**
Taste[3]	Unpleasant taste – 92.6%	Unpleasant taste – 42.3%	Unpleasant taste – 8% (BNX-201 study)	**Pleasant citrus taste**

[1] Product labeling. zubsolv.com - *Do not eat or drink anything until the Zubsolv tablet has completely dissolved. Talking while the tablet is dissolving can affect how well the medicine in Zubsolv is absorbed;* suboxone.com - *While Suboxone film is dissolving, don't chew or swallow—less medication will be absorbed into your bloodstream and you may not get the amount of medicine you need. Talking while the films are dissolving can interfere with how well the medication in Suboxone film is absorbed.*
[2]BUNAVAIL bioavailability based on BUP-117; Suboxone based on published data; Zubsolv based on dosing vs Suboxone.
[3] Jonsson, et al. Poster presented at the 44th Annual Conference of the American Society of Addiction Medicine. April 2013. (Zubsolv n=28, Suboxone n=27). BUNAVAIL data from a separate study, BNX-201, using similar rating scale.

Source: Company presentation

We estimate annual peak sales of Bunavail for the maintenance treatment of opioid dependence will be in the range of $225 million - $250 million

Bunavail, if approved by the FDA, would be the first buccal film formulation of buprenorphine/naloxone to enter the market. BioDelivery's management believes that Bunavail has the potential to generate annual peak U.S. sales up to $250 million. We believe Bunavail has the potential to offer advantages over Suboxone films and the more recently approved generic tablets. Because of its lower propensity for abuse and addiction, Bunavail may serve as a treatment for opioid dependence by preventing opioid addicted patients' withdrawal symptoms while simultaneously maintaining pain control. We believe Bunavail could be priced potentially at parity with Zubsolv and Suboxone, which is priced at $7.04 for the 8mg film and $14.08 for the 16mg daily maintenance dose. We estimate annual peak sales of Bunavail for the maintenance treatment of opioid dependence will be in the range of $225 million - $250 million.

BioDelivery has yet to announce whether it will sign a partner for the commercialization of the drug in the U.S. or go it alone

BioDelivery has yet to announce whether it will sign a partner for the commercialization of the drug in the U.S. or go it alone. This drug could be very attractive for a first solo commercial entry by BioDelivery. As 5,000 doctors are

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responsible for about 90% of the prescriptions written for opioid dependence in the U.S., we believe only 40 - 50 sale reps are needed to sufficiently address this market. Therefore, we believe it is possible that BioDelivery may build its own sales force or use a contracted sales force to market Bunavail in the U.S. if it can't find a suitable partner that offers attractive economics for the commercialization of the drug. We expect the company will announce its U.S. commercialization strategy in late 2013 or early 2014. For modeling purposes only, we are assuming that the company will market Bunavail on its own via a contracted sales force. Outside the U.S., BioDelivery is exploring partners for the commercialization of the drug in Europe, China and Japan. In Europe, the Suboxone patent does not expire until 2016. As such, we believe the company will hold off looking for a partner for a few years as it focuses on other near-term catalysts for the company. We do expect the company will seek to partner Bunavail in China and/or Southeast Asia prior to finding a European partner. We do not expect the drug to be on the market in Europe until 2017. We estimate Bunavail will generate $5 million of sales in 2014 growing to about $150 million by 2020 in the U.S.

For modeling purposes only, we are assuming that the company will market Bunavail on its own

We estimate Bunavail will generate $5 million of sales in 2014 growing to about $150 million by 2020 in the U.S.

There also continues to be a REMS in place for buprenorphine for the treatment of opioid dependence. It is expected that Bunavail will fall within the existing REMS, which is also far less cumbersome and includes a medication guide and healthcare professional and patient education. Given the existence of a REMS in both the extended release and long-acting opioid and opioid dependence markets, we anticipate Bunavail will fit within the existing REMS and will avoid the issues that the company encountered with Onsolis, where a REMS program was yet to be developed when the product was approved.

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Onsolis

BioDelivery's first FDA approved product, Onsolis, is indicated for the treatment of persistent pain in opioid tolerant cancer patients

BioDelivery's first FDA approved product, Onsolis, is indicated for the treatment of persistent pain in opioid tolerant cancer patients. It is a fentanyl buccal soluble film approved in the U.S. on July 16, 2009. The drug later received approval in Europe in May 2010 (marketed as Breakyl), and Canada in October 2010.

BioDelivery markets Onsolis with its commercial partner Meda AB, a Swedish based specialty pharmaceutical company. A $29.8 million milestone was paid for the approval of Onsolis by the FDA and provision of commercial supplies in the U.S. The first commercial sale occurred in October 2009. By that point, an aggregate of $59.7 million in milestone payments and service revenue under the Onsolis North American agreement with Meda had been received. The launch of Breakyl in Europe resulted in the recognition of $17.5 million in 2012 of previously deferred contract revenue. As of September 30, 2013, BioDelivery has recognized $1.8 million in product royalty revenue for EU sales in 2013. BioDelivery receives a double-digit royalty from Meda on the net sales of Onsolis, with certain guaranteed minimum royalties extending through to the seventh year from first commercial sale, which occurred in 4Q09. BioDelivery is also entitled to a potential aggregate of $30 million milestone payments if certain annual sales goals are met. Milestones of $10 million each will be payable when and if annual sales meet or exceed $75.0 million, then when and if annual sales meet or exceed $125.0 million, and when and if annual sales meet or exceed $175.0 million.

BioDelivery receives a double-digit royalty from Meda on the net sales of Onsolis

In 2009, BioDelivery amended its Meda agreement granting worldwide rights to Meda (with the exception of Korea and Taiwan) in exchange for a $3.0 million payment. This change extended the royalty arrangement from its European deal to all global territories with the exception of South Korea and Taiwan. BioDelivery entered into additional arrangements with KUNWHA Pharmaceutical Co. in South Korea and TTY Biopharm Co. in Taiwan. The KUNWHA agreement includes provisions for potential milestone payments of up to $1.3 million with an upfront payment of $0.3 million and royalties based on net sales. The commercial partnership with TTY includes potential milestone payments of up to $1.3 million and similar terms of an upfront payment of $0.3 million and sales based royalties.

In April 2007, BioDelivery announced results of its Onsolis Phase III efficacy study, with data that exhibited statistical significance on its primary efficacy endpoint of the Summary of the Pain Intensity Difference at 30 minutes in patients treated with Onsolis compared to placebo (with p value <0.004). The company submitted Onsolis for NDA under the FDA 505(b)(2) process in October 2007, with approval delayed by additional requirements until July 2009. Approval was delayed due to a required submission of an acceptable Risk Evaluation and Mitigation Strategy (REMS). The company has generated minimal revenue aside from milestone payments due to this initial drug specific REMS which, until March 2012, only affected BioDelivery. Sales of Onsolis

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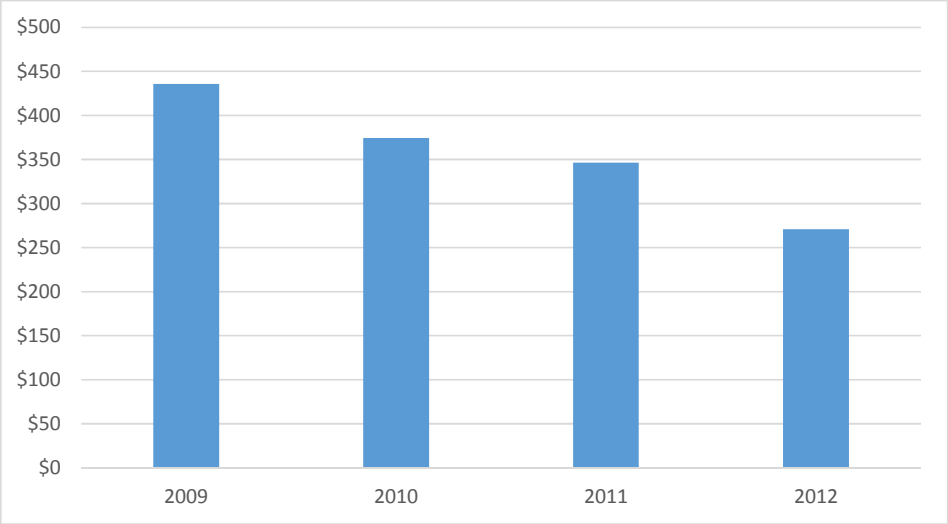
Sales of Onsolis inhibited due to the restrictive policy under the REMS while competitor drugs were not subject to similar programs

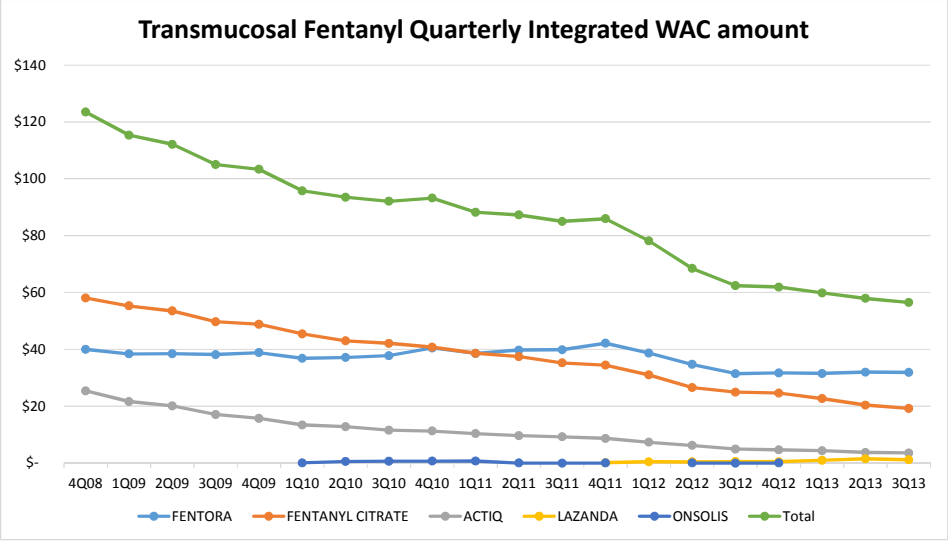
were inhibited due to the restrictive policy under the REMS while competitor drugs, including Teva Pharmaceutical's Actiq, were not subject to similar programs. In December 2011, the FDA approved a class-wide Transmucosal Immediate Release Fentanyl (TIRF) REMS Access Program which was implemented in March 2012. According to Symphony Health data, 2009 sales of transmucosal fentanyl products in the U.S. were $435 million, declining sequentially year-on-year to 2012 sales of $271 million.

Figure 14: Annual U.S. Transmucosal Fentanyl Sales (*millions*)



Source: Symphony Health

Figure 15: Quarterly U.S. Transmucosal Fentanyl Integrated WAC Amount (*millions*)



Source: Symphony Health

BioDelivery announced the postponement of its Onsolis re-launch on March 12, 2012, due to FDA cited issues during an inspection of the North American

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BioDelivery announced the postponement of its Onsolis re-launch on March 12, 2012…

…it anticipates submission of the new formulation to the FDA will occur in early 2014, with approval expected for mid-2014 and re-launch in 2H14

manufacturing facility. The largely aesthetic issues included formation of microscopic crystals and fading of the color in the mucoadhesive layer during the 24-month shelf life of the product and required modification of the Onsolis formula. The company anticipates submission of the new formulation to the FDA will occur in early 2014, with approval expected for mid-2014 and re-launch in 2H14. U.S. patent protection for the Onsolis formula will remain in effect until 2020. European Breakyl sales continue to generate immaterial revenue with sales somewhat sporadic and recorded when manufactured and sold to wholesalers with ongoing launches on a country-by-country basis, which began in 4Q12. We do not view Onsolis as a growth driver for the company. We estimate that Onsolis will start generating sales in the U.S. in late 2014. We expect global royalties will remain well under $10 million per year for the next several years.

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Topical Clonidine Gel

On March 26, 2013, BioDelivery entered into a definitive Exclusive License Agreement with Arcion for an exclusive commercial world-wide license

On March 26, 2013, BioDelivery entered into a definitive Exclusive License Agreement with Arcion for an exclusive commercial world-wide license, with rights of sublicense, under certain patent and other intellectual property rights to develop, manufacture, market, and sell gel products containing clonidine (or a derivative thereof), alone or in combination with other active ingredients, for topical administration for the treatment of painful diabetic neuropathy (PDN) and other indications. This product acquisition allows BioDelivery to build its pipeline, while applying its expertise in pain product development, utilizing the FDA's 505(b)(2) regulatory process, and diversifying outside of opioid therapy and its BEMA technology.

Pursuant to the agreement, BioDelivery is responsible for using commercially reasonable efforts to develop and commercialize Arcion Products, including conducting certain clinical trials within certain time frames. Upon execution of the agreement, BioDelivery issued 500,516 unregistered shares of common stock (having a fair market value of $2.1 million) to Arcion. These shares are subject to a nine month lock-up and certain limitations on sale thereafter. Additionally, BioDelivery is required to make the following payments to Arcion: $2.5 million upon filing and acceptance by the FDA of an NDA with respect to an Arcion product, payable at BioDelivery's option, in cash or unregistered shares of common stock; and up to a potential $60 million in cash payments upon achieving certain pre-determined sales thresholds in the U.S., none of which occur prior to achieving at least $200 million in U.S. net sales. BioDelivery must also pay Arcion $35 million in cash on initial FDA approval of an Arcion product, unless BioDelivery does not receive at least $70 million in FDA approval-related milestone payments from its U.S. sublicenses (if any sublicenses are involved) with respect to the Arcion product, in which case the company shall pay Arcion a prorated amount between $17.5 million and $35 million based on the total amount of such milestone payments received by BioDelivery and its affiliates from its sublicenses (if any sublicenses are involved); or if the FDA requires or recommends the performance of a capsaicin challenge test as a precondition or precursor to the prescribing of the Arcion product (as a condition of approval, a labeling requirement, or otherwise), in which case the milestone will be reduced to $17.5 million, but the first and second sales threshold payments described above will each be increased by $8 million. The licensing agreement includes sales milestones and low single-digit royalties on net worldwide sales. The use of equity for initial payment combined with the success-based milestones in this agreement allows BioDelivery to preserve capital for the clinical development program, with the majority of the cost falling in 2014 and beyond.

The PDN market is under-served by existing products, in our opinion

The PDN market is under-served by existing products, in our opinion, and there is a strong scientific rationale for developing a topical treatment for PDN that delivers analgesia in a way that avoids systemic side effects. Evidence has shown that clonidine stimulates an inhibitory receptor in the skin associated with pain fibers. Arcion has developed a patented topical gel formulation of

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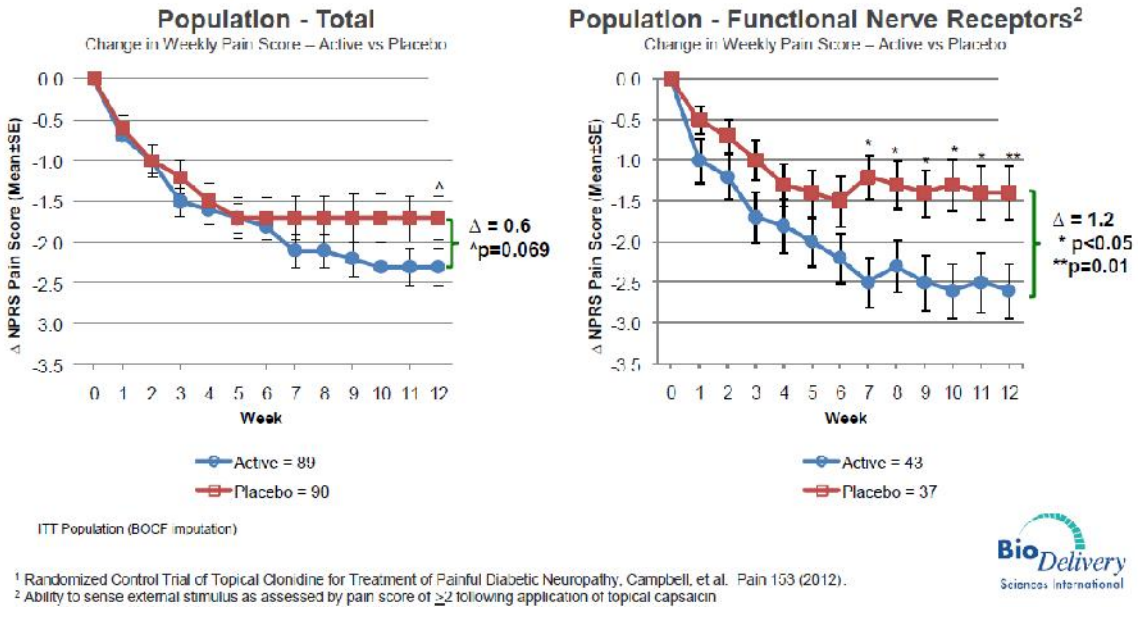
Phase II trial to study its effectiveness in reducing pain in PDN did not reach statistical significance, but…

…a significant treatment difference was seen in the planned subset analysis of diabetic patients who had documented evidence of functioning pain receptors in the skin of the lower leg

clonidine. It conducted a double-blind, placebo-controlled, Phase II trial to study its effectiveness in reducing pain in PDN. The primary study endpoint was the change in pain intensity over a three month treatment period in diabetic foot pain. In the overall population that included patients without functioning nerve receptors, there was a trend favoring Topical Clonidine Gel (p = 0.069, n = 179), though the overall results did not reach statistical significance. A significant treatment difference was seen in the planned subset analysis of diabetic patients who had documented evidence of functioning pain receptors in the skin of the lower leg (p = 0.01, n = 80) thus, at a minimum, supporting the effectiveness of topical clonidine in diabetic patients with functioning pain receptors of the skin. To test for functioning of nociceptors in the skin, topical capsaicin cream 0.1% was applied to the skin above the ankle for 30 minutes at the screening visit. Analgesic efficacy of clonidine over placebo increased with the subjects' response to the capsaicin stimulus. Thus, these data suggest that the analgesic effect of clonidine depends on the presence of functional capsaicin-responsive nociceptors in the skin, and raises the broader issue that neuropathic pain treatments may be guided by results of sensory testing.

Figure 16: Randomized Control Trial of Topical Clonidine Gel for the Treatment of PDN



Source: Campbell, et al. Pain 153 (2012)

The company plans a confirmatory Phase IIb study in 1Q14, which would potentially lead to data before the end of 2014

BioDelivery was granted a Type C meeting with the FDA for Topical Clonidine Gel in December 2013. The company plans a confirmatory Phase IIb study in 1Q14, which would potentially lead to data availability before the end of 2014. If the study meets its endpoint, the company plans to proceed with a Phase III placebo-controlled study in the same population. We expect the Phase IIb study will enroll 160 patients and we estimate the cost of the trial will be approximately $5 million.

About 25.8 million people in the U.S. have diabetes according to the American Diabetes Association. A substantial number of these people have neuropathy as manifested by impaired sensation and pain in the extremities, most commonly

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the feet. Patients with PDN often experience debilitating pain symptoms that affect day-to-day functioning and quality of life. It is unknown how diabetes causes a length-dependent neuropathy.

Approximately 50% of the patients with PDN demonstrated functional nociceptors in the skin in the painful region as revealed by a response to topical capsaicin

In the prior double-blind, randomized, controlled trial approximately 50% of the patients with PDN demonstrated functional nociceptors in the skin in the painful region as revealed by a response to topical capsaicin. Clonidine is thought to relieve pain by decreasing the abnormal excitability of these functional nociceptors. Currently available oral treatments are modestly effective in relieving symptoms and are limited by systemic side effects and drug interactions. There are no topical products approved for the treatment of this condition.

Currently there is no topical product approved to treat this painful condition

Oral medications that are approved for the treatment of painful diabetic neuropathy include anticonvulsants such as Lyrica, the antidepressant Cymbalta and the opioid Nucynta. These treatments are modestly effective in relieving symptoms and their use can be limited by adverse effects and drug interactions. Clonidine has been shown to stimulate an inhibitory receptor in the skin associated with pain fibers. Currently there is no topical product approved to treat this painful condition.

The neuropathic pain market is expected to reach peak sales of $3.6 billion by 2020

According to Datamonitor forecasts, the neuropathic pain market is expected to reach peak sales of $3.6 billion by 2020 and a projected compound annual growth rate of 3.6% for their forecasted period of 2011 – 2020. While the neuropathic pain market is expected to be negatively impacted by patent expirations of marketed brands, including Cymbalta and Lyrica, Datamonitor anticipates that pipeline products will contribute to market growth into 2020. Based on these figures we estimate the current neuropathic pain market size is approximately $2.8 billion as of 2013. BioDelivery believes, and we concur, that a Topical Clonidine Gel offers a novel mechanism of action to the available therapies with an improved safety and tolerability profile. We believe this treatment will find a fairly broad audience in the PDN market. BioDelivery's management estimates annual peak sales potential for this product in excess of $300 million.

We expect the Phase IIb Topical Clonidine Gel study will begin in early 2014 and have results in late 2014

We expect the Phase IIb Topical Clonidine Gel study in patients with functional nerve receptors will begin in early 2014 and have results in late 2014. It is possible that this Phase IIb study could be considered as a Phase III by the FDA. We do believe a Phase III study about the same size or perhaps a bit larger (n = 160 – 200) than the Phase IIb will be required. Ultimately, we believe Topical Clonidine Gel could reach the market in 1H17. We expect the pricing of Topical Clonidine Gel will be modeled after Lidoderm (lidocaine topical patch 5%). A six month course of treatment of Lidoderm costs about $250 - $260. Note that Lidoderm is a local anesthetic indicated to relieve post-shingles pain. According to IMS Health, for the 12-month period ending May 31, 2013, Lidoderm has sales of approximately $1.4 billion in the U.S. Actavis launched a generic version on September 16, 2013. We believe the market potential for Topical Clonidine Gel for the treatment of PDN patients with functional nerve receptors is greater than $280 million annually and we estimate annual sales could reach $100 million by 2020.

We believe the market potential for Topical Clonidine Gel is greater than $280 million annually and we estimate annual sales could reach $100 million by 2020

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Financial Assumptions

We expect BioDelivery's potential revenue will come from three sources: 1) direct sales of Bunavail and Topical Clonidine Gel in the U.S.; 2) royalties from BEMA Buprenorphine sales, Onsolis sales, and royalties on sales of Bunavail and Topical Clonidine Gel outside of the U.S.; and 3) milestone payments from partners. Thus far, Endo Health Solutions is BioDelivery's most important partner in terms of milestone payments and royalties.

The financial terms of the agreement with Endo include: (A) a $30 million upfront license fee, which BioDelivery received in January 2012; (B) $95 million in potential milestone payments based on achievement of pre-defined intellectual property, clinical development and regulatory events ($15 million of which BioDelivery received in May 2012 following the approval of a U.S. patent that extends patent protection of BEMA products into 2027); (C) $55 million in potential sales threshold payments upon achievement of designated sales levels; and (D) a tiered, mid- to upper-teen royalty on net sales of BEMA Buprenorphine in the U.S. and a mid- to high-single digit royalty on net sales of BEMA Buprenorphine outside the U.S. Of the $80 million in potential milestone payments remaining, we believed one payment of $15 million will be paid upon the Phase III data lock in 1Q14 and a second potential milestone payment of $15 million will come on filing with the FDA in 4Q14. We estimate BEMA Buprenorphine will be launched in the U.S. in late 2015. We expect sales will hit $250 million in 2020, generating about $42.5 million in royalties. Ultimately, we believe BEMA Buprenorphine has the potential to achieve greater than a 5% share of the $10 billion U.S. market for opioid analgesics. The drug's sales could be even higher if oxycodone combination products are moved from Schedule III to Schedule II.

We believe Bunavail has the potential to offer advantages over Suboxone films and the more recently approved generic tablets. Because of its lower propensity for abuse and addiction, its ease of use and its bioavailability, Bunavail may serve as a treatment for opioid dependence by preventing opioid addicted patients' withdrawal symptoms while simultaneously maintaining pain control. We believe Bunavail could be priced potentially at parity with Zubsolv and Suboxone, which is priced at $7.04 for the 8mg film and $14.08 for the 16mg daily maintenance dose. We estimate annual peak sales of Bunavail for the maintenance treatment of opioid dependence will be in the range of $225 million - $250 million. We estimate Bunavail will generate $5 million of sales in 2014 growing to about $150 million by 2020 in the U.S.

We estimate annual peak sales of Bunavail for the maintenance treatment of opioid dependence will be in the range of $225 million - $250 million

BioDelivery has yet to announce whether it will sign a partner for the commercialization of Bunavail in the U.S. or go it alone. This drug could be very attractive for a first solo commercial entry by BioDelivery. As 5,000 doctors are responsible for about 90% of the prescriptions written for opioid dependence in the U.S., we believe only 40 - 50 sale reps are needed to sufficiently address this market. We have modeled that BioDelivery will build its own sales force or use a contracted sales force to market Bunavail in the U.S.

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We expect the company will announce its U.S. commercialization strategy in late 2013 or early 2014. For modeling purposes only, we are assuming that the company will market Bunavail on its own. We have modeled for a 45 person sale force to sell the drug in the U.S.

We do not view Onsolis as a growth driver for the company. We estimate that Onsolis will start generating sales in the U.S. in late 2014. We expect global royalties will remain well under $10 million per year for the next several years.

We estimate that research and development spending for 2014 will be about half of what it will be for the full year 2013

The Bunavail clinical program is complete and the BEMA Buprenorphine chronic pain program is winding down, so we estimate that research and development spending for 2014 will be about half of what it will be for the full year 2013. Furthermore, we expect 4Q13 R&D expenses will be reduced substantially. We assume in our model that BioDelivery will hire a contract sales force to sell Bunavail. Our SG&A expenses estimates are $12.0 million in 2013, rising to $30.7 million in 2014 and $32.1 million in 2015.

In July 2013, BioDelivery completed a $20 million debt financing with an affiliate of MidCap Financial. At September 30, 2013, the company had $38.3 million in cash compared to $31.3 million at September 30, 2012. With the R&D spending reduction, along with the Endo milestones, we expect the company will have sufficient cash to reach the potential Bunavail launch in September 2014. However, if, as we expect, BioDelivery decides to go it alone with Bunavail, it may have to revisit the capital markets to fund a proper launch of the drug.

We believe the company will be profitable in 2H15

We estimate BioDelivery will post revenue of $10.2 million in 2013, $46.8 million in 2014 and $77.0 million in 2015. We forecast non-GAAP EPS of a loss of $1.45 in 2013, a loss of $0.69 in 2014 and a loss of $0.09 in 2015. We believe the company will be profitable, on a non-GAAP EPS basis, in late 2015.

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Management Profiles

Mark A. Sirgo, Pharm.D.

President and Chief Executive Officer

Mark A. Sirgo, Pharm.D. has been President and Chief Executive Officer since July 2005. Dr. Sirgo joined BioDelivery in August 2004 as Senior Vice President of Commercialization and Corporate Development upon the acquisition of Arius Pharmaceuticals, of which Dr. Sirgo was a co-founder and Chief Executive Officer. Dr. Sirgo has also served as Executive Vice President, Corporate and Commercial Development, and Chief Operating Officer of the company. Dr. Sirgo has more than 20 years of experience in the pharmaceutical industry, including 16 years in clinical drug development; seven years in marketing, sales, and business development, and five years in executive management. Prior to his involvement with Arius Pharmaceuticals from 2003 to 2004, he spent 16 years in a variety of positions of increasing responsibility in both clinical development and marketing at Glaxo, Glaxo Wellcome, and GlaxoSmithKline, including Vice President of International OTC Development and Vice President of New Product Marketing. Dr. Sirgo was responsible for managing the development and FDA approval of Zantac 75 while at Glaxo Wellcome, among other accomplishments. From 1996 to 1999, Dr. Sirgo was Senior Vice President of Global Sales and Marketing at Pharmaceutical Product Development, Inc. Dr. Sirgo serves on the Board of Salix Pharmaceuticals, a specialty pharmaceutical company specializing in gastrointestinal products. Dr. Sirgo received his Bachelor of Science in Pharmacy from Ohio State University and his Doctorate from the Philadelphia College of Pharmacy and Science.

Andrew L. Finn, Pharm.D.

Executive Vice President of Product Development

Andrew L. Finn, Pharm.D., has been Executive Vice President of Product Development of BioDelivery since January 2007. He joined the company in August 2004 upon the acquisition of Arius Pharmaceuticals, of which he was a co-founder. Dr. Finn has previously served as Senior Vice President of Product Development and Executive Vice President of Clinical Development and Regulatory Affairs. Dr. Finn has nearly 30 years of experience in pharmaceutical product development. Prior to his involvement with Arius, he was, from 2000 to 2003, Executive Vice President of Product Development at Pozen Inc. with responsibilities for formulation development, non-clinical development, clinical research and regulatory affairs. He participated in the Pozen activities leading up to the initial public offering and submitted marketing applications in Europe and the U.S. for two migraine products. From 1996 to 1999, Dr. Finn was Co-Founder and Chief Executive Officer of enVision

Sciences, a regulatory and clinical service company. From 1991 to 1996, he was Vice President of Clinical Research and Biometrics for Solvay Pharmaceuticals, where he oversaw NDA submissions in the areas of inflammatory bowel disease, osteoporosis prevention and treatment of obsessive-compulsive disorder. Prior to this, he spent 10 years in positions of increasing responsibility at Glaxo Inc., where he oversaw a number of NDA submissions, including Zofran for chemotherapy induced nausea and vomiting. Dr. Finn received his Bachelor of Science in Pharmacy from the University of North Carolina and his Doctorate from the University of Michigan.

Ernest De Paolantonio

Chief Financial Officer

Ernest R. De Paolantonio, CPA has been Chief Financial Officer of BioDelivery since October of 2013. He has over 35 years of varied financial and business experience in the pharmaceutical industry. Prior to joining the company, Mr. De Paolantonio served as the Chief Financial Officer of CorePharma LLC, a private specialty generic company, and was directly involved in the financial and commercial strategy to establish Core's proprietary labeled portfolio of products. In addition, he previously served in finance and controllers positions in roles of increasing responsibility at Colombia Laboratories, where he was also responsible for business development and logistics, including supply chain management for the company's first commercial product launch. Mr. De Paolantonio has served in various financial positions in senior management at Taro Pharmaceuticals where he was the Corporate Controller, Watson Pharmaceuticals where he was Executive Director of Finance, Group Controller and responsible for managing the Corporation's supply chain of Active Pharmaceutical Ingredients, and GlaxoSmithKline where began his career in finance and spent over 17 years in areas of increasing responsibility including; Manufacturing, Corporate Finance, R&D and U.S. Pharmaceuticals where he was Group Controller. Mr. De Paolantonio received his Bachelor of Arts Degree from Lycoming College, his MBA in Finance at Saint Joseph's University and is a licensed CPA.

James A. McNulty

Senior Vice President—Finance and Treasurer

James A. McNulty, was Secretary, Treasurer and Chief Financial Officer of BioDelivery from 2000 until October 21, 2013. Mr. McNulty is now in the new role of Senior Vice President—Finance and Treasurer. Mr. McNulty reports to Mr. De Paolantonio. Since 2000, Mr. McNulty has also served as Chief Financial Officer of Hopkins Capital Group, an affiliation of limited liability companies which engage in venture investing activities. Mr. McNulty also serves part-time as the Treasurer and Corporate Secretary of Accentia, a holding company with commercialization assets in specialty pharmaceuticals and biologics, and from 2003 to 2007 as Chief Financial Officer for Biovest, a majority-owned subsidiary of Accentia. He served as CFO of Star Scientific, Inc. from 1998 - 2000. During 2000 - 2002 he served as CFO/COO of American Prescription Providers, Inc. Mr. McNulty has performed accounting and consulting services as a Certified Public Accountant since 1975. He co-founded

Pender McNulty & Newkirk, which became one of Florida's largest regional CPA firms, and was a founder/principal in two other CPA firms, McNulty & Company, and McNulty Garcia & Ortiz. He is a Director of Quantum Technology Sciences, Inc., a private company. He is a published co-author (with Pat Summerall) of Business Golf, the Art of Building Relationships on the Links. Mr. McNulty is a graduate of University of South Florida, a licensed Certified Public Accountant, a member of the American and Florida Institutes of CPA's and is a board member of the Tampa Bay chapter of Financial Executives International.

Albert J. Medwar

Vice President, Marketing and Corporate Development

Albert J. Medwar has served as Vice President of Marketing and Corporate Development since joining BioDelivery in April 2007, with over 20 years of experience in marketing, sales, and marketing research. Prior to joining the company, Mr. Medwar was the Head of Oncology Marketing at EMD Pharmaceuticals, the U.S. subsidiary of Merck KGaA, where he was responsible for developing the global market for a pipeline of oncology products. Mr. Medwar was also the Marketing Director for Triangle Pharmaceuticals, a start-up company focusing on the development and commercialization of compounds for HIV and hepatitis. Mr. Medwar's pharmaceutical career began in sales at Burroughs Wellcome, which later became Glaxo Wellcome. After six years of sales experience, he took on marketing research responsibilities, and then played an important role in the launch of a short acting opioid analgesic, remifentanil, and held increasing marketing responsibility for a number of products including a portfolio of anesthetic/analgesic agents, Zofran, and Wellbutrin SR. Mr. Medwar received a Bachelor of Science degree from Cornell University and a Masters of Business Administration from Bentley College.

Niraj Vasisht, Ph.D.

Senior Vice President, Product Development & Chief Technical Officer

Niraj Vasisht, Ph.D. has been BioDelivery's Senior Vice President of Product Development and Chief Technical Officer since October 2008. He joined the company in February 2005 as the Vice President of Product Development. Dr. Vasisht heads the chemistry, manufacturing and control operations for the company's pipeline products. He directs and oversees the product design, formulation development, quality control, process engineering, validation and stability testing of the drug product and CTM and commercial manufacturing operations at vendor sites worldwide. In addition, he is responsible for creation of relevant intellectual property, provides risk assessment for the development program, and provides technical and strategic leadership to the business development function. He evaluates technical suitability of drug delivery platforms and candidate molecules suitable for the technology. Dr. Vasisht serves as BioDelivery's pharmaceutical development representative for FDA interactions for NDA and MAA filings. From 1994 to 2005, Dr. Vasisht held positions of increasing responsibility at Southwest Research Institute where he ultimately served as the Director of Microencapsulation, Pharmaceutical Development and Nanomaterials and was responsible for leading the group that

provides research and development and product development services to pharmaceutical, consumer health, and nutraceutical companies. Dr. Vasisht is the inventor/co-inventor on multiple patents in drug delivery. Dr. Vasisht received a BTech degree in Chemical Engineering from the Indian Institute of Technology at Kanpur, a Master's of Science from the University of New Hampshire and a Doctorate in Chemical Engineering from Rensselaer Polytechnic Institute.

George K. Ng

Senior Vice President & General Counsel

George K. Ng, J.D. has been BioDelivery's Senior Vice President & General Counsel since joining the company in December 2012, with over 10 years of combined experience in pharmaceuticals and the law. Mr. Ng heads the legal, compliance and intellectual property functions. Prior to joining the company, Mr. Ng held various senior management positions, including Head of Legal, Chief Compliance Officer and Chief Intellectual Property Counsel, with publicly-traded, global biotechnology and pharmaceutical companies, including Spectrum Pharmaceuticals, Inc. (SPPI, HOLD-rated) and Alpharma, Inc., with oversight over legal, intellectual property, litigation and compliance matters. Additionally, Mr. Ng has held responsibility for being the legal lead in due diligence, negotiations, and contract preparation for multiple business development transactions, including U.S. and ex-U.S. licenses, global collaboration agreements and intellectual property and product acquisitions. Previously, in private practice, Mr. Ng was a partner in two AMLAW 200 law firms where he had leadership roles, including establishing the life sciences practice group for one firm and heading it as the national co-chair. In his private practice positions, Mr. Ng's responsibilities included patent and trademark prosecution, licensing and litigation support, with areas of expertise including drug delivery technologies and medical devices. Mr. Ng earned a Juris Doctor (J.D.) degree in law from the University of Notre Dame School of Law and a Bachelor of Arts and Sciences (B.A.S.) dual degree in Biochemistry & Economics from the University of California, Davis.

Valuation

Our valuation for BioDelivery Sciences is based on the NPV of our probability-adjusted forecasts for Bunavail, BEMA Buprenorphine, Onsolis and Topical Clonidine Gel. We considered revenues generated by these products through direct sales, royalty payments and milestone payments. For our valuation, we assume that BioDelivery will not partner Bunavail in the U.S. but will partner the product outside the U.S. We believe both Bunavail and BEMA Buprenorphine have significant sales potential and we believe that BEMA Buprenorphine will ultimately hit all milestone and threshold payment targets under the Endo agreement. We estimate peak sales of Bunavail, BEMA Buprenorphine and Topical Clonidine Gel, in the U.S., will be $238 million, $500 million and $300 million, respectively. We project the company will turn profitable on a non-GAAP EPS basis in late 2015.

Our price target for BioDelivery is $9, which is based on our risk-adjusted values for the company's product pipeline

We are initiating coverage on BioDelivery with a BUY rating and $9 price target.

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Risks to Owning the Stock

There are many standard risks for development stage specialty pharmaceutical companies that hold true for the entire industry. There are development risks associated with preclinical and clinical studies, and potential delays in the start of trials. There is regulatory risk that the company will be unable to receive regulatory approvals for drugs or that regulatory approval may be delayed. Manufacturing risks are associated with relying on third parties to formulate and manufacture products and the upgrading of facilities from clinical study production to commercial production. There is also commercial risk for a company to successfully market and sell its drug or drugs. Other risks include: patent infringement risk, financing risk, currency risk, product liability (both clinical and non-clinical), patent protection risk and potential governmental price controls. The stock of small cap specialty pharmaceutical companies, like all publically traded companies, is subject to market volatility and liquidity risks if there are small trading floats. BioDelivery is susceptible to all of these risks.

Downside risks specific to BioDelivery include the likelihood of the need to sell more stock to raise capital for the continuation of the company's clinical trials and the launch of Bunavail. However, we believe investors already assume that the company will have to raise funds for the continued development of the company's products and the launch. We expect the company will have to raise capital in each of the next two years and have included those assumptions in our models. The value of the stock is hinged on a binary events, including the success of the two Phase III trials for BEMA Buprenorphine and the FDA approval of Bunavail. Longer-term value for the company is based on the ultimate market potential and expectations for the company's drugs, and the successful commercialization of these drugs.

BioDelivery is exposed to litigation by third parties based on claims that its technologies, processes, formulations, methods, or products infringe the intellectual property rights of others or that it has misappropriated the trade secrets of others. On October 29, 2013, Reckitt Benckiser, Inc., RB Pharmaceuticals Limited, and MonoSol RX, LLC filed an action against BioDelivery relating to Bunavail the United States District Court for the Eastern District of North Carolina for alleged patent infringement. The plaintiffs claim that the formulation for Bunavail, which has never been disclosed publicly, infringes its patent (U.S. Patent No. 8,475,832). This action could be in response to a recent decision in which the FDA ruled in favor of BioDelivery's position in two Citizen Petitions filed by the plaintiffs that sought to prevent the FDA from accepting and filing BioDelivery's NDA for Bunavail. The two Citizen Petitions, filed on December 2, 2011 and August 13, 2013, respectively, included requests that the FDA refuse to accept for filing any NDAs submitted using the 505(b)(2) regulatory pathway for buprenorphine/naloxone products consisting of a polymer film for application to the buccal mucosal membranes (such as Bunavail), unless such application references the NDA for Suboxone (buprenorphine/naloxone) sublingual film (and not the Suboxone sublingual tablet NDA).

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Figure 17: Income Statement

BioDelivery Sciences *Income Statement (millions, except per share data)*	FY 2012 Q1_12 Mar	Q2_12 Jun	Q3_12 Sept	Q4_12 Dec	FY 2013E Q1_13 Mar	Q2_13 Jun	Q3_13 Sept	Q4_13E Dec	FY 2014E Q1_14E Mar	Q2_14E Jun	Q3_14 Sept	Q4_14E Dec		FY_11 Dec	FY_12 Dec	FY_13E Dec	FY_14E Dec	FY_15E Dec
Product sales	-	-	-	-	-	-	-	-	-	-	1.0	4.0				-	5.0	14.3
Product royalties	-	-	-	1.1	-	0.9	0.9	1.0	1.1	1.1	1.2	1.3		2.7	1.1	2.8	4.6	5.6
Research revenues	0.0		-	(0.0)	-	-	-	-	-	-	-	-		0.2	0.0	-	-	-
Contract revenues	16.5	16.3	1.9	18.8	1.6	1.9	2.1	1.8	1.8	16.8	1.8	16.7		0.3	53.4	7.4	37.2	57.2
Revenue	**16.5**	**16.3**	**1.9**	**19.9**	**1.6**	**2.8**	**3.0**	**2.8**	**2.9**	**17.9**	**4.0**	**22.0**		**3.3**	**54.5**	**10.2**	**46.8**	**77.0**
Cost of product royalties	0.4	0.4	0.4	0.8	0.4	0.7	0.6	0.7	0.7	0.8	0.8	0.9		1.8	1.9	2.4	3.2	3.9
Cost of sales	-	-	-	-	-	-	-	-	-	-	2.0	6.0			-	-	8.0	10.0
Gross Profit	**16.1**	**15.9**	**1.5**	**19.1**	**1.2**	**2.1**	**2.4**	**2.1**	**2.1**	**17.2**	**1.2**	**15.1**		**1.5**	**52.6**	**7.8**	**35.6**	**63.2**
Operating expenses:																		
Selling, general and administrative	2.8	2.2	3.0	2.1	2.9	3.1	3.0	2.9	4.5	8.3	8.4	9.6		7.6	10.1	12.0	30.7	32.1
Research and development	4.7	6.5	12.5	11.6	12.0	12.8	16.4	9.0	9.1	9.2	4.1	3.4		20.8	35.4	50.2	25.9	26.1
Related party general and administrative, net	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	-	-	-	-		0.1	0.1	0.0	-	-
Other non-GAAP adjustments			-	-	-	-	-	-	-	-	-	-		-	-	-	-	-
Total Operating Expenses (ex-COGS)	**7.6**	**8.8**	**15.6**	**13.7**	**15.0**	**15.9**	**19.4**	**11.9**	**13.6**	**17.5**	**12.5**	**13.0**		**28.5**	**45.6**	**62.2**	**56.6**	**58.2**
Total Operating Expenses (non-GAAP, ex-COGS)	**7.6**	**8.8**	**15.6**	**13.7**	**15.0**	**15.9**	**19.4**	**11.9**	**13.6**	**17.5**	**12.5**	**13.0**		**28.5**	**45.6**	**62.2**	**56.6**	**58.2**
Operating Income/(loss)	**8.6**	**7.1**	**(14.1)**	**5.4**	**(13.7)**	**(13.8)**	**(17.1)**	**(9.8)**	**(11.5)**	**(0.3)**	**(11.3)**	**2.1**		**(27.0)**	**7.1**	**(54.4)**	**(20.9)**	**4.9**
Operating Income/(loss) non-GAAP	**8.6**	**7.1**	**(14.1)**	**5.4**	**(13.7)**	**(13.8)**	**(17.1)**	**(9.8)**	**(11.5)**	**(0.3)**	**(11.3)**	**2.1**		**(27.0)**	**7.1**	**(54.4)**	**(20.9)**	**4.9**
Other Income:																		
Interest income	0.1	0.1	0.1	0.1	0.1	0.1	(0.5)	(0.4)	(1.6)	(2.2)	(2.2)	(2.2)		0.2	0.3	(0.7)	(8.2)	(8.8)
Derivative gain (loss)	(1.9)	(3.5)	(3.5)	3.3	1.0	0.4	(0.9)	-	-	-	-	-		3.5	(5.6)	0.5	0.0	0.0
Other (expense) income, net	(0.0)	0.1	0.0	(0.0)	(0.0)	(0.1)	(0.0)	0.0	0.0	0.0	0.0	0.0		0.0	0.0	(0.2)	0.0	0.0
Income (loss) before provision for income taxes (GAAP)	**6.8**	**3.8**	**(17.5)**	**8.7**	**(12.6)**	**(13.4)**	**(18.5)**	**(10.2)**	**(13.1)**	**(2.5)**	**(13.5)**	**(0.0)**		**(23.3)**	**1.8**	**(54.8)**	**(29.1)**	**(3.9)**
Income (loss) before provision for income taxes (non-GAAP)	**8.6**	**7.3**	**(14.0)**	**5.4**	**(13.7)**	**(13.8)**	**(17.6)**	**(10.2)**	**(13.1)**	**(2.5)**	**(13.5)**	**(0.0)**	**0.0**	**(26.8)**	**7.4**	**(55.3)**	**(29.1)**	**(3.9)**
Tax: (%) non-GAAP	*0.0%*	*0.0%*	*0.0%*	*2.4%*	*NM*	*NM*	*0.0%*	*0.0%*	*NM*	*NM*	*0.0%*	*0.0%*		*0.0%*	*1.8%*	*NM*	*0.0%*	*0.0%*
Income tax provision GAAP	0.0	0.0	0.0	0.1	0.1	0.0	-	-	0.0	0.0	-	-		-	0.1	0.1	0.0	-
Non-GAAP tax adjustments	-	-	-	-	-	-	-	-	-	-	-	-		-	-	-	-	-
Net income (loss) GAAP	**6.8**	**3.8**	**(17.5)**	**8.6**	**(12.7)**	**(13.4)**	**(18.5)**	**(10.2)**	**(13.1)**	**(2.5)**	**(13.5)**	**(0.0)**		**(23.3)**	**1.7**	**(54.8)**	**(29.1)**	**(3.9)**
Net income (loss) non-GAAP	**8.6**	**7.3**	**(14.0)**	**5.3**	**(13.7)**	**(13.8)**	**(17.6)**	**(10.2)**	**(13.1)**	**(2.5)**	**(13.5)**	**(0.0)**		**(26.8)**	**7.2**	**(55.3)**	**(29.1)**	**(3.9)**
EPS (GAAP)	**$0.23**	**$0.12**	**($0.58)**	**$0.28**	**($0.34)**	**($0.35)**	**($0.49)**	**($0.26)**	**($0.33)**	**($0.06)**	**($0.30)**	**($0.00)**		**($0.82)**	**$0.05**	**($1.44)**	**($0.69)**	**($0.09)**
EPS (non-GAAP)	**$0.29**	**$0.23**	**($0.46)**	**$0.17**	**($0.37)**	**($0.36)**	**($0.46)**	**($0.26)**	**($0.33)**	**($0.06)**	**($0.30)**	**($0.00)**		**($0.95)**	**$0.24**	**($1.45)**	**($0.69)**	**($0.09)**
Weighted Diluted Shares outstanding (millions)	29.6	31.1	30.1	30.7	37.5	38.0	38.1	38.8	39.6	40.4	44.8	45.2		28.3	30.7	38.1	42.5	45.2
Weighted Diluted Shares YOY change (%)					*26.8%*	*22.0%*	*26.6%*	*26.6%*	*5.6%*	*6.3%*	*17.6%*	*16.5%*			*8.4%*	*24.2%*	*11.6%*	*6.2%*

Source: Bloomberg LP; Company reports; Laidlaw & Company estimates

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Figure 18: Balance Sheet

BioDelivery Sciences *Balance Sheet ($ millions, except per share data)*	FY 2012 Q1_12 Mar	 Q2_12 Jun	 Q3_12 Sept	 Q4_12 Dec	FY 2013E Q1_13 Mar	 Q2_13 Jun	 Q3_13 Sept	 Q4_13E Dec	 FY_11 Dec	 FY_12 Dec	 FY_13E Dec	 FY_14E Dec	 FY_15E Dec
Assets:													
Cash and cash equivalents	32.1	43.0	31.3	63.2	49.7	37.4	38.3	25.2	10.8	63.2	25.2	12.3	17.5
Accounts receivable, other	0.2	0.0	0.0	0.5	0.2	0.5	0.9	0.8	0.1	0.5	0.8	5.8	8.6
Prepaid expenses and other current assets	0.6	0.1	0.2	0.2	0.5	0.3	0.5	0.4	0.2	0.2	0.4	0.4	0.4
Total Current Assets	**32.9**	**43.2**	**31.6**	**63.9**	**50.4**	**38.2**	**39.6**	**26.4**	**11.1**	**63.9**	**26.4**	**18.5**	**26.6**
Equipment, net	3.2	3.1	2.9	2.8	2.7	2.6	0.2	0.2	3.3	2.8	0.2	0.2	0.2
Goodwill	2.7	2.7	2.7	2.7	2.7	2.7	2.7	2.7	2.7	2.7	2.7	2.7	2.7
Total other intangible assets	6.9	6.7	6.4	6.2	5.9	5.7	2.5	2.5	6.2	6.2	2.5	2.5	2.5
Derivative asset, warrant	0.7	0.4	0.2	0.1	0.0	-	5.4	5.4	0.4	0.1	5.4	5.4	5.4
Other assets	0.0	0.0	0.0	0.0	-	-	0.1	0.1	0.0	0.0	0.1	0.1	0.1
Total Assets	**46.4**	**56.1**	**43.9**	**75.7**	**61.8**	**49.3**	**50.6**	**37.4**	**23.6**	**75.7**	**37.4**	**29.5**	**37.6**
Liabilities & Shareholders' Equity:													
Accounts payable and other accured liabilities	5.0	5.8	7.4	10.8	9.5	12.0	11.1	6.8	5.1	10.8	6.8	6.2	6.4
Notes payable, current	-	-	-	-	-	-	5.3	5.3	-	-	5.3	5.3	5.3
Deferred revenue, current	12.5	15.1	22.7	8.0	7.2	5.6	4.1	3.8	12.5	8.0	3.8	3.6	4.0
Derivative liabilities	2.4	5.6	8.9	4.5	3.5	3.0	3.9	3.9	0.3	4.5	3.9	3.9	3.9
Total Current Liabilities	**20.0**	**26.5**	**39.1**	**23.2**	**20.2**	**20.6**	**24.4**	**19.9**	**17.9**	**23.2**	**19.9**	**19.1**	**19.6**
Note Payable, less current maturities	-	-	-	-	-	-	13.8	13.3	-	-			
Deferred revenue, long-term	1.6	1.5	4.3	2.7	1.9	1.6	1.3	1.3	1.6	2.7	1.3	4.8	4.8
Total Liabilities	**21.5**	**28.0**	**43.3**	**26.0**	**22.1**	**22.2**	**39.5**	**34.5**	**19.5**	**26.0**	**21.2**	**23.8**	**24.4**
Stockholders' Equity	**24.9**	**28.1**	**0.6**	**49.8**	**39.7**	**27.1**	**11.0**	**2.9**	**4.1**	**49.8**	**16.2**	**5.6**	**13.1**
Total Liabilities & Equity	**46.4**	**56.1**	**43.9**	**75.7**	**61.8**	**49.3**	**50.6**	**37.4**	**23.6**	**75.7**	**37.4**	**29.5**	**37.6**

Source: Bloomberg LP; Company reports; Laidlaw & Company estimate

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Figure 19: Cash flow Statement

BioDelivery Sciences *Non-GAAP Cash Flow Cont. Ops.($ millions, except per share data)*	**FY_11** Dec	**FY_12** Dec	**FY_13E** Dec	**FY_14E** Dec	**FY_15E** Dec
Cash flows from operating activities:					
Net income	(23.3)	1.7	(54.8)	(29.1)	(3.9)
Adjustments to reconcile net income to net cash provided by operating activities:					
Depreciation and amortization	1.3	1.5	1.2	1.2	1.2
Accretion of Discount	-	0.1	0.1	-	-
Derivative (gain) loss	(3.5)	5.6	(0.5)	-	-
Purchase of Arcion license with common stock		-	2.1	-	-
Stock-based compensation expense	1.2	1.6	3.6	-	-
Changes in assets and liabilities:					
Accounts receivable	0.5	(0.4)	(0.3)	(5.0)	(2.8)
Prepaid expenses and other assets	0.0	0.0	(0.1)	-	-
Accounts payable and other accrued expenses	0.4	5.6	0.3	0.6	(0.2)
Income tax payable		0.1	(4.2)	-	-
Deferred revenue	0.0	(3.4)	(5.1)	0.2	(0.3)
Net cash provided by (used in) operating activities	(23.3)	12.3	**(57.7)**	**(32.1)**	**(5.9)**
Cash flow from investing activities:					
Purchases of property and equipment	(0.3)	(0.0)	(0.0)	(0.0)	(0.0)
Purchases of intangible assets		(1.1)	-	-	-
Cash provided by investing activities	**(0.3)**	**(1.1)**	**(0.0)**	**(0.0)**	**(0.0)**
Cash flows from financing activities:					
Procees from sale of securities	14.0	38.4	20.0	25.0	20.0
Proceeds from exercise of stock options	0.3	2.1	0.3	-	-
Deferred financing activities	-	-	(0.2)	-	-
Repayment of note	-	-	(0.4)	(8.2)	(8.8)
Change in amounts due to related parties	0.0	(0.0)	(0.1)	-	-
Other	1.7	0.9	-	2.4	-
Cash (used in) provided by financing activities	**16.1**	**41.3**	**19.6**	**19.2**	**11.2**
Effect of exchange rates on cash	-	-	-	-	-
Net (decrease) increase in cash and cash equivalents	(7.5)	52.5	(38.1)	(12.9)	5.3
Cash and cash equivalents at beginning of the period	18.2	10.8	63.3	25.2	12.3
Cash and cash equivanlents at end of period -	**10.8**	**63.3**	**25.2**	**12.3**	**17.5**

Source: Bloomberg LP; Company reports; Laidlaw & Company estimates

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DISCLOSURES:

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Rating and Price Target Change History

3 Year Rating Change History

Date	Rating	Closing Price ($)
11/26/2013	Buy (B)	4.66*

3 Year Price Change History

Date	Target Price ($)	Closing Price, ($)
11/26/2013	9.00	4.66*

** Previous Close11/25/2013*

Source: Laidlaw & Company **Created by: Blue-Compass.net**

Laidlaw & Company Rating System*		% of Companies Under Coverage With This Rating	% of Companies for which Laidlaw & Company has performed services for in the last 12 months	
			Investment Banking	Brokerage
Strong Buy (SB)	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	90.91%	36.36%	9.09%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	9.09%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

ADDITIONAL COMPANIES MENTIONED

Endo Health Solutions Inc. (ENDP, Not Rated)
Meda AB (MEDAA SS SEK, Not Rated)
Orexo AB (ORX SS, Not Rated)
Reckitt Benckiser Group PLC (RB/LN, Not Rated)
Teva Pharmaceutical (TEVA, Not Rated)
Titan Pharmaceuticals, Inc. (TTNP, Not Rated)
TTY BioPharm Co., Ltd. (4105 TT TWD, Not Rated)
ULURU Inc. (ULUR, Not Rated)

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