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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2013

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission file number 001-31361

BioDelivery Sciences International, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**35-2089858**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
801 Corporate Center Drive, Suite #210 Raleigh, NC	**27607**
(Address of principal executive offices)	**(Zip Code)**

Issuer's telephone number: 919-582-9050

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Name of exchange on which registered**
Common stock, par value $.001	**Nasdaq Capital Market**

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files) Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. Yes ☐ No ☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer or a smaller reporting company. See definition of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐ Accelerated filer ☒

Non-accelerated filer ☐ (Do not check if a smaller reporting company) Smaller reporting company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates as of June 28, 2013 was approximately

$134,206,938 based on the closing sale price of the company's common stock on such date of $4.06 per share, as reported by the NASDAQ Capital Market.

As of March 11, 2014, there were 47,947,817 shares of company common stock issued and 47,932,326 shares of company common stock outstanding.

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BioDelivery Sciences International, Inc.

Annual Report on Form 10-K

For the fiscal year ended December 31, 2013

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Unless we have indicated otherwise, or the context otherwise requires, references in this Report to "BDSI," the "Company," "we," "us" and "our" or similar terms refer to BioDelivery Sciences International, Inc., a Delaware corporation and its consolidated subsidiaries.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Report and the documents we have filed with the SEC that are incorporated by reference herein contain forward-looking statements, within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, that involve significant risks and uncertainties. Any statements contained, or incorporated by reference, in this Report that are not statements of historical fact may be forward-looking statements. When we use the words "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "predict,"

"project," "will" and other similar terms and phrases, including references to assumptions, we are identifying forward-looking statements. Forward-looking statements involve risks and uncertainties which may cause our actual results, performance or achievements to be materially different from those expressed or implied by forward-looking statements.

A variety of factors, some of which are outside our control, may cause our operating results to fluctuate significantly. They include:

- our plans and expectations regarding the timing and outcome of research, development, commercialization, manufacturing, marketing and distribution efforts relating to our BEMA® drug delivery technology platform and any proposed products, product candidates, including our sole approved product, ONSOLIS®, our partnered product candidate, BEMA® Buprenorphine and our other lead product candidates, BUNAVAIL™ and Clonidine Topical Gel;
- the domestic and international regulatory process and related laws, rules and regulations governing our technologies and our approved and proposed products and formulations, including: (i) the timing, status and results of our or our commercial partners' filings with the U.S. Food and Drug Administration and its foreign equivalents, (ii) the timing, status and results of non-clinical work and clinical studies, including regulatory review thereof and (ii) the heavily regulated industry in which we operate our business generally;
- our ability to enter into strategic partnerships for the development, commercialization, manufacturing and distribution of our products and product candidates, including for BUNAVAIL™, which we are intending to self-commercialize;
- our ability, or the ability of our commercial partners to actually develop, commercialize, manufacture or distribute our products and product candidates;
- our ability to generate commercially viable products and the market acceptance of our BEMA® technology platform and our proposed products and product candidates;
- our ability to finance our operations on acceptable terms, either through the raising of capital, the incurrence of convertible or other indebtedness or through strategic financing or commercialization partnerships;
- our expectations about the potential market sizes and market participation potential for our approved or proposed products;
- the protection and control afforded by our patents or other intellectual property, and any interest patents or other intellectual property that we license, of our or our partners' ability to enforce our rights under such owned or licensed patents or other intellectual property;
- the outcome of ongoing or potential future litigation (and related activities, including inter partes reviews and inter partes reexaminations) or other claims or disputes relating to our business, technologies, products or processes;
- our expected revenues (including sales, milestone payments and royalty revenues) from our products or product candidates and any related commercial agreements of ours;
- the ability of our manufacturing partners to supply us or our commercial partners with clinical or commercial supplies of our products in a safe, timely and regulatory compliant manner and the ability of such partners to address any regulatory issues that have arisen or may in the future arise;
- our ability to retain members of our management team and our employees; and
- competition existing today or that will likely arise in the future.

The foregoing does not represent an exhaustive list of risks that may impact upon the forward-looking statements used herein or in the documents incorporated by reference herein. Please see "Risk Factors" for additional risks which could adversely impact our business and financial performance and related forward-looking statements.

Moreover, new risks regularly emerge and it is not possible for our management to predict all risks, nor can we assess the impact of all risks on our business or the extent to which any risk, or combination of risks, may cause actual results to differ from those contained in any forward-looking statements. All forward-looking statements included in this Report are based on information available to us on the date hereof. Except to the extent required by applicable laws or rules, we undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise. All subsequent written and oral forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by the cautionary statements contained throughout this Report and the documents we have filed with the SEC.

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PART I

Item 1. Description of Business.

Overview

We are a specialty pharmaceutical company that is developing and commercializing, either on our own or in partnerships with third parties, new applications of proven therapeutics to address important unmet medical needs using both proven and new drug delivery technologies. We have developed and are continuing to develop pharmaceutical products aimed principally in the areas of pain management and addiction. We were incorporated in the State of Indiana in 1997 and were reincorporated as a Delaware corporation in 2002.

In formulating our products and product candidates, we utilize the novel, patent protected and proprietary *BioErodible MucoAdhesive ("BEMA®")* drug delivery technology, a small, erodible polymer film for application to the buccal mucosa (the lining inside the cheek). Our first U.S. Food and Drug Administration (which we refer to as the FDA) approved product, ONSOLIS® (fentanyl buccal soluble film), as well as other product candidates, including BUNAVAIL™, utilize our BEMA® technology.

We have worked with other delivery technologies in the past, and as part of our corporate growth strategy, we may seek to acquire or license additional drug delivery technologies or drugs utilizing the delivery or other technologies of other companies. Clonidine Topical Gel, which was licensed from Arcion Therapeutics (or Arcion) in 2013, does not utilize the BEMA® technology and allowed us to diversify our portfolio while maintaining a focus in pain and addiction. As we gain access to such technologies, we seek to formulate these technologies with proven, FDA approved therapeutics and utilize our development and commercialization experience to, either by ourselves or through partnerships, navigate the resulting products through the regulatory review process and ultimately bring them to the marketplace.

Our current development strategy focuses primarily on our ability to utilize the FDA's 505(b)(2) approval process to obtain more timely and efficient approval of new formulations of previously approved, active therapeutics incorporated into our drug delivery technology. Because the 505(b)(2) approval process is designed to address new formulations of previously approved drugs, we believe it has the potential to be more cost efficient and expeditious and have less regulatory approval risk than other FDA approval approaches.

BEMA® Buprenorphine for Chronic Pain

BEMA® Buprenorphine is a partial mu-opioid agonist and a potential treatment for moderate to severe chronic pain. In December 2009, we announced that the primary efficacy endpoint was achieved in a Phase 2 clinical study evaluating the safety and efficacy of a range of doses of BEMA® Buprenorphine. Completion of this Phase 2 study led to the initiation of a Phase 3 double-blind, randomized, placebo-controlled clinical study which was initiated in the fourth quarter of 2010. On September 28, 2011, we announced the preliminary findings of our randomized, placebo-controlled, Phase 3 clinical study of BEMA® Buprenorphine for the treatment of moderate to severe chronic pain in a mixed opioid naïve and opioid experienced population. The primary endpoint of the study, overall pain intensity difference between BEMA® Buprenorphine and placebo, was not achieved. Following full analysis of the data, we concluded that we encountered a high placebo response in the opioid naïve segment of the patient population, particularly at our starting dose, which we believe 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. We believe the totality of the study results favored BEMA® Buprenorphine, including a near statistically significant difference between BEMA® Buprenorphine and placebo in the opioid experienced group of patients in the trial (p=0.067). In addition, when eliminating the group of patients that did not titrate beyond the starting dose, a statistically significant difference between BEMA® Buprenorphine and placebo (p=0.025) was identified. Neither of these subgroups was sufficiently large enough to be powered to show a statistical difference. Overall, the trial, though not successful, provided a wealth of knowledge beneficial in the design of two additional Phase 3 clinical studies, which were initiated in the second half of 2012 under our agreement with Endo Pharmaceuticals, Inc. (or Endo), as described below.

In January 2012, we announced the signing of a worldwide licensing and development agreement for BEMA® Buprenorphine (which we refer to herein as the Endo Agreement) with Endo under which we granted to Endo the exclusive, worldwide rights to develop and commercialize BEMA® Buprenorphine for the treatment of chronic pain. The financial terms of our agreement with Endo include: (i) a $30 million upfront license fee, which we received in January 2012; (ii) $95 million in potential milestone payments based on achievement of pre-defined intellectual property, clinical development and regulatory events (some of which we received in 2012); (iii) $55 million in potential sales threshold payments upon achievement of designated sales levels; and (iv) a tiered, mid- to upper-teen royalty on net sales of BEMA® Buprenorphine in the United States and a mid- to high-single digit royalty on net sales of BEMA® Buprenorphine outside the United States. Endo is one of the premier companies in the area of pain management and has demonstrated significant achievements in the pain space, particularly with the development, launch and commercialization of a portfolio of pain therapeutics including Opana® ER, Lidoderm® and Voltaren® Gel. We believe BEMA® Buprenorphine is an excellent fit with Endo's pain portfolio and will, if approved, add a Schedule III opioid to their branded pain franchise. BEMA® Buprenorphine would complement Endo's pain therapeutics portfolio providing the company with an opportunity to offer a "ladder" of pain products, aligned with pain severity and opioid scheduling. In particular, 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 (e.g., NSAIDs).

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One of the key intellectual property milestones under our Endo Agreement was achieved in February 2012, when the U.S. Patent and

Trademark Office (or USPTO) issued a Notice of Allowance regarding one of our patent applications (No. 13/184306) which, once the patent was granted in April 2012, will extend the exclusivity of the BEMA® drug delivery technology for BEMA® Buprenorphine (as well as BUNAVAIL™, as discussed below) from 2020 to 2027. As a result, we received a milestone payment in the amount of $15 million in May 2012, and also related to the issuance of the patent, will receive an additional milestone payment of $20 million at the time of approval of a New Drug Application (or NDA) by the FDA for BEMA® Buprenorphine for the treatment of chronic pain. Such amounts are included in the aforementioned $95 million in potential milestone payments based on intellectual property and clinical development and regulatory events.

In May 2012, in close collaboration with Endo, we initiated two Phase 3 clinical studies – one in an opioid naïve and one in opioid experienced populations. The Phase 3 clinical trials were enriched-enrollment, double-blind, randomized withdrawal studies to evaluate the efficacy and safety of BEMA® Buprenorphine in the treatment of chronic lower back pain in opioid naive patients and a population of patients who were opioid experienced. The studies were designed to address some of the issues encountered in the initial Phase 3 study and included sample size increases, the use of higher doses and multiple adjustments to inclusion/exclusion criteria. Patients titrated to a well-tolerated, effective dose were randomized to either continue on that dose of BEMA® Buprenorphine, or receive placebo (BEMA® film with no active drug), with treatment continuing for 12 weeks. The primary efficacy endpoint was the mean change in the daily average pain numerical rating scale (NRS-Pain) scores from baseline (just prior to randomization) to week twelve of the double-blind treatment period. Pain was self-reported daily on an 11-point numeric rating scale (daily NRS; 0=no pain, 10=worst possible pain).

Interim analyses were conducted as part of the Phase III protocol in both the opioid naïve and opioid experienced studies to allow for adjustments to the sample size in order to maintain appropriate study power to detect statistically significant differences between BEMA® Buprenorphine and placebo. The analyses were conducted by an independent biostatistician. We and Endo announced in September 2013 that, as a result of the interim analyses, no sample size adjustment would be necessary to the opioid naïve study and that additional patients would be added to the ongoing opioid experienced. The outcomes of the interim analyses were significant because they utilized actual study data to confirm or adjust sample sizes, and importantly, maintain probability of a successful outcome.

On January 23, 2014, we announced with Endo positive top-line results from the Phase 3 efficacy study of BEMA® buprenorphine in opioid-“naïve” subjects. The trial successfully met its primary efficacy endpoint in demonstrating that BEMA® Buprenorphine resulted in significantly ($p<0.005$) improved chronic pain relief compared to placebo. Additional secondary endpoints were supportive of the efficacy of BEMA® Buprenorphine compared to placebo. The most commonly reported adverse events in patients treated with buprenorphine compared to placebo were nausea (10% vs. 8%), vomiting (4% vs. 2%) and constipation (4% vs. 2%). The locking of the database for the opioid naïve study triggered a $10 million milestone payment from Endo per the terms of the license agreement, which we received in February 2014. Results from the Phase 3 study in opioid experienced patients is anticipated in mid-2014.

BUNAVAIL™ (buprenorphine and naloxone buccal film)

In addition, we believe that the widespread use of buprenorphine for the treatment of opioid dependence presents an additional commercial opportunity, and we developed a formulation of BEMA® Buprenorphine specifically for the treatment of opioid dependence. The product combines a “high dose” of buprenorphine along with an abuse deterrent agent, naloxone. BUNAVAIL™ provides us with an opportunity to compete in the growing opioid dependence market which, according to Wolters Kluwer, exceeded $1.7 billion in sales in the U.S in 2013.

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, and following the meeting, we announced that we had reached an agreement with the FDA on the development plan for BUNAVAIL™, which includes a pivotal pharmacokinetic study comparing BUNAVAIL™ to Suboxone® in normal volunteers and a supporting safety study in opioid dependent patients. The FDA concurred with our strategy.

In September 2012, we announced the positive outcome of the pivotal pharmacokinetic study comparing BUNAVAIL™ to Suboxone®. The study was designed to compare the relative bioavailability of buprenorphine and naloxone between BUNAVAIL™ and the reference product, Suboxone® tablets. The results demonstrated 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 FDA, assessing the safety and tolerability of BUNAVAIL™ in patients converted from a stable dose of Suboxone® (buprenorphine/naloxone) sublingual tablets or films. A total of 249 patients were enrolled in the study, (191 patients completed) which completed in December

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2012. Results of the study showed a very favorable safety and tolerability profile along with strong study subject retention and high dose form acceptability ratings. Data showed that over 91% of patients who switched from Suboxone® film or tablets considered the taste of BUNAVAIL™ to be very pleasant, pleasant or neutral and over 82% rated the ease of use of BUNAVAIL™ as very easy, easy or neutral.

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