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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, 2018

☐ **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.)**
4131 ParkLake Avenue, Suite #225 Raleigh, NC	**27612**
(Address of principal executive offices)	**(Zip Code)**

Registrant'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 every Interactive Data File required to be submitted 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 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. ☐

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	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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 29, 2018 was approximately $113,670,574 based on the closing sale price of the company's common stock on such date of $2.95 per share, as reported by the NASDAQ Capital Market.

As of March 14, 2019, there were 70,968,435 shares of company common stock issued and 70,952,944 shares of company common stock outstanding.

BioDelivery Sciences International, Inc.

Annual Report on Form 10-K

For the fiscal year ended December 31, 2018

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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.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Report and the documents we have filed with the Securities and Exchange Commission (which we refer to herein as the SEC) that are incorporated by reference herein contain forward-looking statements, within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), 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 development, commercialization, manufacturing, marketing and distribution efforts relating to our BEMA® (as defined below) drug delivery technology platform and any of our approved products or product candidates;
- 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;
- our ability, or the ability of our commercial partners, to actually develop, commercialize, manufacture or distribute our products and product candidates, including for BELBUCA® and BUNAVAIL®, which we are self-commercializing;
- 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, inter partes reexaminations and "Paragraph IV" litigations) or other claims or disputes relating to our business, technologies, patents, 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 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.

PART I

ITEM 1. Description of Business

Overview

BioDelivery Sciences International, Inc., (NASDAQ: BDSI), is a rapidly growing commercial-stage specialty pharmaceutical company dedicated to patients living with chronic pain. At our core is a shared passion to make every day a little bit easier for patients and help improve the lives of people living with chronic conditions so they can experience life to the fullest. We have built a portfolio of products utilizing our novel and proprietary BioErodible MucoAdhesive (BEMA) drug-delivery technology, and other drug-delivery technologies to develop and commercialize new applications of proven therapies aimed at addressing important unmet medical needs. We now commercialize in the United States using our own sales force while working in partnership with third parties to commercialize our products outside the United States. We have made it a point to deeply understand the patients' journeys and are driven by recognizing the full impact of their condition so we can deliver life-altering solutions.

Our Strategy

Our strategy is evolving with the establishment of our commercial footprint in the management of chronic pain; we seek to build a well-balanced, diversified, high-growth specialty pharmaceutical company. Through our industry-leading commercialization infrastructure, BDSI is executing the commercialization of our existing products. As part of our corporate growth strategy, we have licensed, and will continue to explore opportunities to acquire or license additional products that meet the needs of patients living with debilitating chronic conditions and treated primarily by therapeutic specialists. As we gain access to these drugs and technologies, we will employ our commercialization experience to bring them to the marketplace. With a strong commitment to patient access and a focused business-development approach for transformative acquisitions or licensing opportunities, we will leverage our experience and apply it to developing new partnerships that enable us to commercialize novel products that can change the lives of people suffering from debilitating chronic conditions.

Our historical clinical and regulatory development strategy has focused primarily on our ability to use the U.S. Food and Drug Administration, or 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, with less regulatory approval risk than other FDA-approval approaches.

An overview of our products and their therapeutic areas is set out below.

Our Company

We are a publicly listed company. Our common stock is listed on The Nasdaq Capital Market under the symbol "BDSI." We were incorporated in the state of Indiana in 1997 and reincorporated as a Delaware-based corporation in 2002.

Chronic Pain

Chronic pain is often defined as any pain lasting more than 12 weeks. Whereas acute pain is a normal sensation that alerts us to possible injury, chronic pain persists – often for months or even longer. Chronic pain may arise from an initial injury, such as back sprain, or there may be an ongoing cause, such as an illness. Sometimes there is no clear cause. According to results from the National Health Interview Survey there are over 25 million American adults experiencing daily chronic pain, with over 10 million of these experiencing severe pain.

Treatment Landscape for Chronic Pain

The pain market is well established, with many pharmaceutical companies marketing new formulations of existing molecules, as well as generic versions of older, non-patent protected products. In 2018, according to data from Symphony Health, the market for extended release opioids in the U.S. totaled nearly $4.7 billion in annual sales with 13.8 million prescriptions dispensed. However, prescription volume of long acting opioids declined over 13% in 2018 compared to 2017 amidst wide-ranging efforts to curb misuse, abuse and over use of opioids in order to address the current opioid crisis.

A number of products are competitors to BELBUCA, including BuTrans®, a transdermal formulation of buprenorphine which also has a generic equivalent available. Other competitors are U.S. Drug Enforcement Agency, or the DEA, Schedule II opioids such as OxyContin® from Purdue Pharma L.P., or Purdue, and Nucynta® ER from Depomed, Inc./ Collegium Pharmaceutical, Inc., or Collegium, and multiple generic Schedule II oral opioid formulations, such as morphine, hydrocodone, and fentanyl containing products. Approximately 75% of the retail/mail order prescriptions for long-acting opioids are dispensed as a generic product.

Some manufacturers have also formulated Schedule II opioids in abuse deterrent formulations (or ADF). Embeda® from Pfizer Inc., Hysingla® ER from Purdue, Zohydro® ER from Pernix Therapeutics Holdings Inc., MorphaBond™ ER from Daiichi Sankyo Company, Xtampza® ER from Collegium and Arymo™ ER from Egalet Corporation, as well as new formulations of OxyContin®, use a variety of technologies that aim to minimize the potential for abuse and misuse. Select abuse deterrent products are playing an increasingly important role in treating patients with chronic pain, while others are experiencing slower than anticipated adoption, leading some manufacturers to reconsider launching an ADF product into the current market.

Other manufacturers are working to develop alternative buprenorphine formulations for treatment of acute or chronic pain. In July 2018, the FDA issued a complete response letter for sublingual buprenorphine spray for the treatment of moderate-to-severe acute pain being developed by Insys Therapeutics, Inc., or Insys. Relmada Therapeutics, Inc., or Relmada, is developing an oral, enteric-coated buprenorphine (BuTab) for chronic pain and opioid dependence indications. In December 2015, Relmada announced topline results of a proof-of-concept pharmacokinetic study in healthy volunteers which showed that the product can be delivered at therapeutic levels through the gastrointestinal route, though the bioavailability remained low. No further development is noted.

In addition to product competition, there are other factors that have impacted the market for pain products in general. Opioids continue to garner increased scrutiny based on the growing problem of prescription drug abuse and addiction. There have been an increasing number of actions the FDA and other government agencies have taken to address the problem of opioid abuse and addiction.

- In July 2012 the FDA approved a class-wide REMS program for the extended release and long-acting opioids. 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. BELBUCA falls within the existing class-wide REMS program.
- In August 2014, the DEA published in the Federal Register its final ruling moving hydrocodone combination products (such as Vicodin, Lortab, Norco, etc.) from Schedule III to the more-restrictive Schedule II, as recommended by the Assistant Secretary for Health of HHS and as supported by the DEA's own evaluation of relevant data. As a result of the ruling, hydrocodone containing products are now classified in the same category (Schedule II) as morphine and oxycodone.
- In March 2016, HHS's Centers for Disease Control and Prevention ,or the CDC, issued guidelines for prescribing opioids for chronic pain. CDC developed and published the *CDC Guideline for Prescribing Opioids for Chronic Pain* to provide recommendations for the prescribing of opioid pain medication for patients 18 and older in primary care settings. Recommendations focus on the use of opioids in treating chronic pain. The guidelines advocate use of nonpharmacologic therapy and nonopioid pharmacologic therapy as first line therapy for chronic pain. When starting opioid therapy for chronic pain, clinicians are advised to prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids and to prescribe the lowest effective dosage. Clinicians were directed to reassess patient's medication needs when considering doses of 50 morphine milligram equivalents (MME) or greater and should avoid increasing total daily doses to 90 MME or greater. The availability of the guidelines has resulted in confusion and cautiousness, particularly among primary care physicians, and a reduced willingness to treat patients for chronic pain. A sharp reduction in prescriptions among Primary Care Physicians and an increase among Pain Specialists are evidence of the shift in prescribing and in the dynamics of pain treatment.
- In June 2017, the FDA requested that Endo Pharmaceuticals, Inc. remove Opana ER (oxymorphone), from the market based on concerns that the benefits of the drug may no longer outweigh its risks. This is the first time the agency has taken steps to remove a currently marketed opioid pain medication from sale due to the public health consequences of abuse. The FDA's decision was based on a review of all available post-marketing data, which demonstrated a significant shift in the route of abuse of Opana ER from nasal to injection following the product's reformulation. It is anticipated that other steps will be taken to further limit the use, duration dose or availability of certain opioids – particularly those with Schedule II designation.
- In September 2017, the CDC removed the MME conversion factors for buprenorphine from its online oral MME data file. And in 2018 it included a statement in the MME data file noting "Buprenorphine doses are not expected to be associated with overdose risk in the same dose-dependent manner as doses for full agonist opioids".
- In December 2018 the Health and Human Services Pain Management Best Practices Inter-Agency Task Force issued a Draft Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations. The report identifies that one of the barriers in pain management best practices is "lack of coverage and reimbursement and understanding of proper usage, limit access to buprenorphine treatment for chronic pain." The draft report then makes

recommendations that third-party payors should provide coverage and reimbursement for buprenorphine treatment approaches.

- For 2019, The Centers for Medicare and Medicaid Services adopted a soft edit of 90 morphine milligram equivalents per day for patients, aligning with the 2016 CDC Guideline recommendation.

Opioid Dependence

Opioid dependence is a medical diagnosis that is characterized by the inability of an individual to stop using opioids, either prescription opioids such as morphine, hydrocodone and oxycodone, or illicit opioids such as heroin, even when it is in the best interest of the individual to do so. Opioid dependence is a complex medical condition that often requires long-term treatment and care. The treatment of opioid dependence is important to reduce both the associated health and social consequences and to improve the well-being and social functioning of people affected. According to the 2016 National Survey on Drug Use and Health, 2.1 million people in the United States had an opioid use disorder.

Treatment Landscape for Opioid Dependence

Treatment with buprenorphine reduces the typical cravings and withdrawal symptoms associated with coming off opioid prescription painkillers and heroin. This allows the individual suffering from an addiction to opioids –along with counseling and support – to work toward recovery. On average, treatment lasts a couple months, reflecting relatively high dropout rates, but a significant number of people remain on buprenorphine treatment chronically, with nearly one-quarter of patients still on therapy after nine months.

The total U.S. market for buprenorphine containing products for opioid dependence exceeded $3.5 billion in 2018, an increase of 13% over 2017 according to Symphony Health. The market has grown steadily as a result of the rapidly escalating problem of prescription opioid misuse and abuse, a recent resurgence of heroin use, the growing number of physicians treating opioid dependence, and the inclusion of addiction treatment as an essential benefit in the Affordable Care Act.

The buprenorphine products currently marketed for the treatment of opioid dependence include Suboxone®, a sublingual film formulation of buprenorphine and naloxone, Zubsolv®, a sublingual tablet of buprenorphine and naloxone, and multiple generic formulations of both buprenorphine and buprenorphine/naloxone tablets. Suboxone® film, the market leader with approximately 65% of total buprenorphine/naloxone prescriptions, achieved sales of over $2 billion in the U.S. in 2018 per Symphony Health data.

While limited information is available, a sublingual spray formulation of buprenorphine/naloxone is in development from Insys and is currently in Phase I development studies.

Breakthrough Cancer Pain

According to the National Cancer Institute, there are approximately 14.5 million people in the United States diagnosed with or living with cancer. Cancer patients often suffer from a variety of symptoms including pain as a result of their cancer or cancer treatment. Pain is a widely prevalent symptom in cancer patients, and an estimated 50% to 90% of those with cancer also suffer from what is referred to as breakthrough cancer pain (or BTCP). BTCP episodes have a rapid onset that peaks in three to five minutes and can last several minutes to an hour, and usually occur several times per day.

Treatment Landscape for Breakthrough Cancer Pain

BTCP can be difficult to treat due to its severity, rapid onset and the often unpredictable nature. Physicians typically treat BTCP with a variety of short-acting opioid medications, including morphine and fentanyl. The breakthrough cancer pain market has become increasingly crowded and more competitive in recent years.

A number of formulations of fentanyl are available employing a variety of drug delivery technologies, all which provide rapid onset and relatively short duration of action to address the fast onset and short duration of BTCP. The principal competitors had traditionally been Actiq® (fentanyl citrate) oral transmucosal lozenge and Fentora® (fentanyl buccal tablet). In recent years, newer product entries, particularly Subsys® (fentanyl sublingual spray) from Insys, have gained significant market share. Additional

competitors include the sublingual tablet formulation of fentanyl (Abstral®) and a nasal spray formulation of fentanyl (Lazanda®). In addition, multiple generic formulations of Actiq® are currently available. All of the fentanyl based products are subject to the Transmucosal Immediate Release Fentanyl (TIRF) REMS Access Program, which was designed to ensure informed risk-benefit decisions before initiating treatment with a transmucosal fentanyl product, and while patients are on treatment, to ensure appropriate use.

Despite the increased number of fentanyl-based products approved for the treatment of BTCP, the market has contracted significantly since peaking at almost 120,000 prescriptions in 2014, to less than 30,000 prescriptions in 2018, according to Symphony Health in January 2019.

The BEMA Drug Delivery Technology

Our 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 such as "breakthrough" cancer pain 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.

We believe that the BEMA technology permits control of two critical factors allowing for better dose-to-dose reproducibility: (i) the contact area for mucosal drug delivery, and (ii) the time the drug is in contact with that area, known as residence time. In contrast to competing transmucosal delivery systems such as 1) lozenges, 2) buccal tablets and 3) matrix-based delivery systems placed under the tongue or sprayed in the oral cavity, BEMA products are designed to:

- adhere to buccal mucosa in seconds and dissolve in minutes;
- permit absorption without patients being required to move the product around in the mouth for absorption, thus avoiding patient intervariability;
- allow for unidirectional drug flow into the mucosa as a result of a backing layer on the side of the BEMA film facing into the patient's mouth
- provide a reproducible delivery rate, not susceptible to varying or intermittent contact with oral membranes; and
- dissolve completely, leaving no residual product or waste and avoiding patient removal, and the possibility for diversion or disposal of partially used product.

We currently own the BEMA drug delivery technology.

Sales and Market Overview of our Products

The following table summarizes the status of our marketed products and our current product candidates:

Product/Formulation	Indication	Development Status	Commercial Status
BELBUCA	Management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate	Approval: U.S. in October 2015; Canada in June 2017	BDSI markets in U.S.
BUNAVAIL	Treatment of opioid dependence	Approval: U.S. in June 2014	BDSI markets in U.S.
ONSOLIS/BREAKYL /PAINKYL (U.S./E.U./Taiwan trade names, respectively)	Breakthrough cancer pain in opioid tolerant patients	Approval: U.S. in July 2009; Canada in May 2010; E.U. in October 2010 and Taiwan in July 2013	Partnership with Mylan in all regions except North America, Taiwan and South Korea; partnership with TTY in Taiwan; exploring options for U.S. commercialization
Buprenorphine ER Injection	Opioid dependence and chronic pain	IND submitted December 2016	Not yet approved for marketing

The pharmaceutical industry and the therapeutic areas in which we compete are highly competitive and subject to rapid and substantial regulatory and technological changes. Developments by others may render our BEMA technology, our marketed products

and any proposed drug products and formulations under development noncompetitive or obsolete, or we may be unable to keep pace with technological developments or other market factors. Technological competition in the industry from pharmaceutical and biotechnology companies, universities, governmental entities and others diversifying into the field is intense and is expected to increase.

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. Among the products to receive FDA approval are BELBUCA, BUNAVAIL, and ONSOLI (BDSI), Suboxone film (Indivior PLC) and Zuplenz (Midatech Pharma PLC). Companies in the development and manufacture of thin film technologies include LTS, Lohmann Therapie-Systeme AG, ARx, LLC and Aquestive Therapeutics, Inc. (formerly known as MonoSol Rx LLC, or Aquestive). In addition, a number of companies are developing improved versions of existing products using oral dissolving, nasal spray, aerosol, sustained release injection and other drug delivery technologies. We believe that potential competitors are seeking to develop and commercialize technologies for buccal, sublingual or mucosal delivery of various therapeutics or groups of therapeutics. While our information concerning these competitors and their development strategy is limited, we believe our technology can be differentiated because the BEMA technology provides for a rapid and consistent delivery, high drug bioavailability and convenient use based on how the BEMA technology adheres to the buccal membrane and dissolves. Our clinical trials across a number of BEMA products have demonstrated that the technology is an effective means of drug delivery that is well tolerated and offers convenience to patients.

In 2016, we converted our contract sales force into one employed by us to provide greater flexibility to accommodate future strategic options. Using our own sales force provides us with significantly more control over commercialization efforts and makes us capable of selling our own products in specialty pharmaceutical markets while leaving promotional responsibilities for large primary care audiences and ex-U.S. markets with partners. In 2017 we expanded the sales force territories and further expanded in January and September 2018 to support the commercialization efforts. BELBUCA and BUNAVAIL are currently supported by a field force of approximately 113 sales representatives, thirteen regional sales managers and two area directors.

BELBUCA (buprenorphine buccal film), CIII, for Chronic Pain

BELBUCA was approved by the FDA on October 26, 2015 for use in patients with pain severe enough to require daily, around-the-clock, long-term opioid treatment for which alternative options are inadequate. BELBUCA is differentiated from other opioids and has the potential to address some of the most critical issues facing healthcare providers treating chronic pain with prescription opioids – abuse, misuse, addiction and the risk of overdose. As a Schedule III opioid, buprenorphine has less abuse and addiction potential compared to Schedule II opioids such as oxycodone, hydrocodone and morphine. Compared to currently marketed products and products under development, we believe that BELBUCA is differentiated based on the following features:

- Strong and durable efficacy in both opioid naïve and opioid experienced patients;
- Schedule III designation by DEA, which indicates less abuse and addiction potential compared Schedule II opioids, which include oxycodone, hydrocodone and morphine;
- Published studies have shown that buprenorphine's physiologic effects reach a plateau, and this ceiling effect may result in a lower risk of overdose related respiratory depression;
- Favorable tolerability with a low incidence of constipation and low discontinuation rate;
- Flexible dosing options with 7 available strengths
- Buccal administration to optimize buprenorphine delivery.
- As prescribers are increasingly being guided to monitor total daily morphine milligram equivalents for their patients taking opioids, the CDC has indicated that "buprenorphine doses are not expected to be associated with overdose risk in the same dose-dependent manner as doses for full agonist opioids."

Because of the safety, tolerability and efficacy benefits associated with buprenorphine, we believe that BELBUCA is a clear first-line long-acting opioid for patients with pain severe enough to require daily, around-the-clock, long-term opioid treatment for which alternative treatments, such as non-opioids or immediate release opioids, are inadequate.

In January 2012, we announced the signing of a worldwide licensing and development agreement for BELBUCA (with Endo, which we refer to herein as the Endo Agreement), under which we granted to Endo the exclusive, worldwide rights to develop and commercialize BELBUCA for the treatment of chronic pain. On October 26, 2015, we and Endo announced the FDA approval of BELBUCA. BELBUCA became commercially available from Endo in February 2016. Endo reported favorable early healthcare provider feedback and positive patient experience with regards to efficacy, tolerability and the buccal film formulation.

On December 8, 2016, we announced an agreement with Endo terminating Endo's licensing of rights for BELBUCA. This announcement followed a strategic decision made by Endo to discontinue commercial efforts of its branded pain business. Pursuant to the Endo Termination Agreement, we reacquired BELBUCA, which transition became effective on January 6, 2017.

Given the greater long-term growth opportunities with BELBUCA, we have transitioned our primary commercial emphasis to BELBUCA. We revised our BUNAVAIL-focused commercial efforts, initially leveraging our existing sales force to capitalize on commercial synergies with BELBUCA.

Our sales force is focused on current BELBUCA prescribers and clinicians we believe have the greatest opportunity to be adopters of BELBUCA, such as high prescribers of long-acting opioids, BuTrans and/or HCPs who prescribe short acting opioids around-the-clock for patients with chronic pain. In parallel, we are heavily focused on increasing market access for BELBUCA. As of January 2019, BELBUCA had formulary coverage for more than 88% of commercial lives. Approval rates within the commercial channel remained favorable throughout 2018 at about 80%. In 2018 BELBUCA attained preferred access for over 7.5 million Medicare lives within Humana. BELBUCA continues to have favorable approval rates within other Medicare plans, as we pursue improved access to BELBUCA for the senior population suffering with chronic pain.

In 2018, we also made significant improvements in patient access for BELBUCA, resulting in over 100 million commercial lives having preferred access to BELBUCA. BELBUCA total prescriptions in 2018, according to Symphony Health, totaled over 160,000, an increase of 91% over 2017. BELBUCA share of total buprenorphine prescriptions (products for the treatment of chronic pain only) for 2018 totaled 23% versus 12% for the prior year, ending 2018 with a 31% share in December. In addition to a steady increase in BELBUCA prescription volume through 2018, there was also an increase in the use of higher doses of BELBUCA as healthcare providers continued to gain comfort titrating patients to higher optimal doses. In 2018, 36% of BELBUCA prescriptions were for doses of 450 mcg or greater, compared to 33% in 2017. Therefore, the weighted average price per prescription continued to increase in 2018.

Canada

On July 12, 2017 we announced the signing of a licensing agreement under which we granted the exclusive rights to distribute, market and sell BELBUCA in Canada to Purdue Pharma (Canada). Under terms of the agreement, we were to receive upfront and potential milestones of up to $4.5 million CAD as well as royalties on net sales from Purdue. In January 2018, BELBUCA became commercially available in Canada. In June 2018, Health Canada requested pharmaceutical manufacturers discontinue actively marketing opioids. On January 8, 2019, Purdue terminated the license agreement with us, citing market conditions in Canada. The termination was effective as of March 11, 2019. Given these developments, we are taking steps to discontinue the sale of BELBUCA in Canada.

Other Regions

For commercialization of BELBUCA in other regions outside the U.S. and Canada, we are currently seeking partners with commercial reach and experience in pain management in their respective regions.

BUNAVAIL(buprenorphine and naloxone buccal film), CIII, for Opioid Dependence

In June 2014, BUNAVAIL was approved by the FDA for the maintenance treatment of opioid dependence as part of a complete treatment plan to include counseling and psychosocial support, and on November 3, 2014, we announced the availability of BUNAVAIL in the U.S. It was initially supported by a 60-person field sales force and a full marketing effort targeting the nearly 5,000 physicians who are responsible for approximately ninety percent of prescriptions for buprenorphine products for the treatment of opioid dependence. The launch was also supported by a complete marketing effort aimed at increasing product awareness including advertising and promotion, direct mail and email, a speakers' program and a number of other initiatives to minimize patient access issues, including robust contracting with various payers.

In May 2017 we announced that the FDA had approved a Supplemental New Drug Application (known as an sNDA) for BUNAVAIL revising the BUNAVAIL indication to include induction, or the initial process undertaken when a patient is transitioned from the abused opioid responsible for their addiction. BUNAVAIL contains the partial opioid agonist buprenorphine, which binds to the same receptors as opiate drugs but has a higher affinity. Naloone, an opioid antagonist, is included as an abuse deterrent.

BUNAVAIL provides an alternative treatment utilizing the advanced BEMA drug delivery technology. BUNAVAIL provides the highest bioavailability of any buprenorphine-containing product for opioid dependence, allowing for effective treatment with half the dose compared to Suboxone® film. Additionally, BUNAVAIL offers convenient and discrete buccal administration and avoids the need for patients to avoid talking and swallowing during administration. BUNAVAIL has demonstrated an excellent tolerability

profile with a 68% reduction at the end of 12 weeks in the incidence of constipation in a Phase 3 trial in patients converted from Suboxone® sublingual tablets or film to BUNAVAIL.

As noted above, in January 2017 with the reacquisition of BELBUCA, we transitioned our primary commercial emphasis from BUNAVAIL to BELBUCA. Our BUNAVAIL efforts are now focused on current BUNAVAIL prescribers and on increasing prescriptions related to current, upcoming and future managed care contracts where BUNAVAIL is placed in a favorable formulary position. We believe that in this structure, and with the increases in our sales force size, we can maintain an appropriate share of voice.

ONSOLIS (fentanyl buccal soluble film) for Breakthrough Cancer Pain

In July 2009, ONSOLIS was approved for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. ONSOLIS is indicated 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 cancer, or BTCP. ONSOLIS provides significant reduction in pain for patients suffering from BTCP in a convenient formulation with a range of doses to allow patients to titrate to an adequate level of pain control.

North America

In September 2007, we secured an exclusive licensing and supply agreement with Mylan Pharmaceuticals, Inc, for the commercialization rights for ONSOLIS, under which Mylan was responsible for the sales, marketing and distribution of ONSOLIS in the U.S., Canada and Mexico. ONSOLIS was commercially launched in the United States in October 2009. ONSOLIS was approved by the Canadian regulatory authorities in May 2010 and was the first product approved in Canada for the management of breakthrough cancer pain. Mylan Valeant Pharma Canada Inc., a joint venture between Mylan and Valeant Canada Limited was responsible for promotion of ONSOLIS in Canada. ONSOLIS was launched in Canada in the third quarter of 2011

On January 27, 2015, we announced that we had entered into the Assignment Agreement with Mylan to return to us the marketing authorizations for ONSOLIS for the U.S. and the right to seek marketing authorizations for ONSOLIS in Canada and Mexico. On May 11, 2016, we announced the signing of a licensing agreement under which we granted the exclusive rights to develop and commercialize ONSOLIS in the U.S. to Collegium. On December 8, 2017, we received a 90-day notice from Collegium regarding the return of the U.S. rights to ONSOLIS from Collegium; which transition went into effect on March 8, 2018.

Although we have generated licensing-related and other revenue to date from the commercial sales of ONSOLIS, BREAKYL and PAINKYL, such revenue has been limited to date due to multiple factors, including a highly restrictive Risk Evaluation and Mitigation Strategy, or REMS, imposed by the FDA.

On December 29, 2011, the FDA approved a "class-wide" REMS program covering all transmucosal fentanyl products under a single risk management program. The program, which is referred to as the Transmucosal Immediate Release Fentanyl, or TIRF, REMS Access Program, was designed to ensure informed risk-benefit decisions before initiating treatment with a transmucosal fentanyl product, and while patients are on treatment, to ensure appropriate use. The TIRF REMS program was implemented in March 2012. The approved program covers all marketed transmucosal fentanyl products under a single program which will enhance patient safety while limiting the potential administrative burden on prescribers and their patients. Having one common program also ended the disparity in prescribing requirements for ONSOLIS compared to similar products and provided ONSOLIS with the opportunity for retail and inpatient facility access.

We are assessing options for U.S. commercialization of ONSOLIS, including the use of our current sales force, or potentially out-licensing the product. Regulatory documentation to qualify an alternate manufacturer was submitted to FDA in June 2018. In October 2018, BDSI received notification of FDA's approval of Tapemark as the new ONSOLIS manufacturer.

Europe

We initially granted commercialization and distribution rights for ONSOLIS on a worldwide basis (except in South Korea and Taiwan) to Meda AB, a leading international specialty pharmaceutical company based in Sweden that was subsequently acquired by Mylan N.V. (which we refer to herein as Mylan). Mylan secured access to additional markets through acquisition of European businesses from Valeant Pharmaceuticals International. Since September 2006, we secured an exclusive licensing and supply agreement with Mylan for the commercialization rights for BEMA Fentanyl in the European Union, or E.U., which is being marketed in Europe under the trade name BREAKYL. BREAKYL received marketing authorization from the European regulatory authorities in October 2010 and has been launched in over thirteen European countries including Germany, France and the U.K. . The sales royalties to be received by us will be the same for all Mylan territories as agreed to for Europe. In Europe, multiple formulations of fentanyl have been approved and launched for the treatment of BTCP, including ONSOLIS/BREAKYL, as well as Abstral®, Effentora®, and Instanyl® (intranasal fentanyl spray).

Additional Territories

In 2010, we licensed commercialization rights for ONSOLIS for South Korea and TTY Biopharm Co., Ltd., or TTY, for Taiwan where the product is marketed as PAINKYL.

In May 2010, we announced a commercial partnership with Kunwha Pharmaceutical Co. Ltd. for the exclusive rights to develop and commercialize ONSOLIS in the Republic of Korea known as the Kunwha License Agreement. Those rights were subsequently returned to us due to changes in the market dynamics and the Kunwha License Agreement was terminated on August 31, 2015.

In October 2010, a commercial partnership with TTY was announced, providing commercialization rights for Taiwan. This agreement resulted in potential milestone payments of up to $1.3 million (including an upfront payment of $0.3 million) along with royalties based on sales. Milestones were achieved in November 2011 and July 2013 relating to the NDA submission and regulatory approval, respectively, in Taiwan, where the product is marketed under the brand name PAINKYL. TTY launched PAINKYL in Taiwan in 2015.

Buprenorphine Extended Release Injection Product Candidate

In 2014, we entered into an exclusive agreement with Evonik Corporation (or Evonik) to develop and commercialize a proprietary, injectable microparticle formulation of buprenorphine potentially capable of providing 30 days of continuous therapy following a single subcutaneous injection. Microsphere-based, long acting buprenorphine injection has the ability to change the treatment paradigm in opioid dependence. Such a dosage form has the opportunity to improve therapy compliance through continuous delivery of drug for up to 30 days and addresses challenges regarding patient adherence to long-term buprenorphine treatment, which is critical to successfully manage opioid dependence and the potential for misuse and diversion.

As part of the agreement, we had the right to license the product(s) following the attainment of Phase 1 ready formulations. At that point, Evonik could receive downstream payments for milestones related to regulatory filings and subsequent NDA approvals as well as product royalties. Evonik has the exclusive rights to develop the formulation and manufacture the product(s).

In 2015, we completed initial development work and preclinical studies which have resulted in the identification of a formulation we believe is capable of providing 30 days of continuous buprenorphine treatment. During a pre-IND meeting with the FDA in November 2015, the FDA requested an additional study to assess the fate of the polymers used in the formulation. In 2016, we completed this study as well as additional preclinical work and other activities to support a planned Phase 1 clinical study. We submitted an Investigational New Drug application (or IND) for this product candidate to the FDA in December 2016 and have completed steps necessary to initiate a Phase 1 clinical study. Subsequently, the agreement has terminated and the options granted therein have expired. We continue to evaluate whether or not to advance this particular program.

In terms of potential competition for Buprenorphine ER Injection, there are two products that have recently become commercially available and one that has received tentative approval from the FDA.

In May 2016, Probuphine®, a subcutaneous implantable rod containing buprenorphine from Braeburn Pharmaceuticals, Inc., or Braeburn was approved. In December 2012, Titan Pharmaceuticals, or Titan, announced the signing of a license agreement with Braeburn. In May 2018 Braeburn returned the rights to Titan and Titan has subsequently initiated the commercialization of Probuphine® through internal efforts.

In November 2017, Sublocade™, a buprenorphine extended release injection for subcutaneous use from Indivior was approved. Sublocade™ is the first once-monthly injectable buprenorphine formulation and was approved for the treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a transmucosal buprenorphine-containing product followed by dose adjustment for a minimum of seven days. Indivior announced commercial availability of Sublocade™ March 1, 2018.

In December 2018, Brixadi™, an extended-release buprenorphine injection from Braeburn was granted tentative approval by the FDA. Brixadi™ can be dosed weekly or monthly depending upon the dose administered.

Additional Overview Information

From our inception through December 31, 2018, we have recorded accumulated losses totaling approximately $351.3 million. Our historical operating losses have resulted principally from our research and development activities, including clinical trial activities for our product candidates, sales, and general and administrative expenses. Ultimately, if we secure additional approvals from the FDA and other regulatory bodies throughout the world for our product candidates or other products or product candidates that we may acquire or in-license in the future, our goal will be to augment our current sources of revenue and, as applicable, deferred revenue (principally licensing fees), with sales of such products or royalties from such sales, on which we may pay royalties or other fees to our licensors and/or third-party collaborators as applicable.

We intend to finance our commercialization and distribution efforts and our working capital needs primarily through:

- commercializing our approved products such as BELBUCA and BUNAVAIL;
- partnering with other pharmaceutical companies , to assist in the distribution and commercialization of our products, for which we could expect to receive an upfront payment, milestones and/or royalty payments; and
- securing proceeds from public and private financings and other potential strategic transactions.

We have based our estimates of market size estimates, peak annual sales projections, development costs and similar matters described below and elsewhere in this Report on our market research, third party reports and publicly available information which we consider reliable. However, readers are advised that the projected dates for filing and approval of our INDs or NDAs with the FDA or other regulatory authorities, our estimates of development costs, our projected sales and similar metrics regarding BELBUCA, BUNAVAIL, ONSOLIS, Buprenorphine Extended Release Injection or any other product candidates discussed below and elsewhere in this Report are merely estimates and subject to many factors, many of which may be beyond our control, which will likely cause us to revise such estimates. Readers are also advised that our projected sales figures do not consider the royalties and other payments we will need to make to our licensors and strategic partners. Our estimates are based upon our management's reasonable judgments given the information available and their previous experiences, although such estimates may not prove to be accurate.

Key Commercial Licensing Agreements

Endo Licensing Agreement for BELBUCA and its Termination

On January 6, 2012, we entered into a world-wide licensing and development agreement for BELBUCA with Endo, which was subsequently terminated. Under terms of the agreement, Endo was responsible for the manufacturing, distribution, marketing and sales of BELBUCA on a worldwide basis. The agreement called for Endo to commercialize BELBUCA outside the U.S. through its own efforts or through regional partnerships.

The FDA's approval of BELBUCA triggered a milestone payment to us from Endo of $50 million, of which $20 million had been deferred for future revenue recognition as the payment was contingently refundable in the event a generic product was commercially launched during the patent extension period. As mentioned below, the obligations of this milestone were extinguished upon the closing of the termination agreement. This $20 million was recognized as revenue in January 2017.

On December 8, 2016 we announced we had entered into a termination agreement with Endo ("the Endo Termination Agreement") terminating Endo's licensing of rights for BELBUCA, which transaction closed on January 6, 2017. As a result of the agreement, the world-wide rights to BELBUCA were transferred back to us.

At the closing of the transactions by the Endo Termination Agreement we purchased from Endo the following assets (the "Assets"): (i) BELBUCA product inventory and work-in-progress, (ii) material manufacturing contracts related to BELBUCA, (iii) BELBUCA-related domain names and trademarks (including the BELBUCA trademark), (iv) BELBUCA-related manufacturing equipment, and (v) all pre-approval regulatory submissions, including any INDs and NDAs, regulatory approvals and post-approval regulatory submissions concerning BELBUCA. The purchase price for the Assets (which we refer to as the Asset Purchase Price) was equal to the sum of: (i) the aggregate book value of the portion of the transferred product inventory forecasted to be used or sold by the Company, (ii) the aggregate book value of work-in-progress inventory, and (iii) the assumption of any assumed liabilities. Upon Closing, we accepted transfer of the Assets and assumed and agreed to discharge when due all applicable liabilities assumed by us, which consisted of post-closing obligations for liabilities and payments associated with the Assets, the assumed contracts related to the Assets and applicable taxes (with the obligation for pre-closing and other certain liabilities resulting from the acts or omissions of Endo being retained by Endo).

In conjunction with the Endo Termination Agreement, we also entered into a distribution agreement (the "Distribution Agreement") with Par Pharmaceuticals, Inc. (or "Par") for the distribution of an authorized generic BELBUCA product after the launch of a generic BELBUCA product by a third party. The Distribution Agreement covers distribution within the entire United States, has an initial term of three years after the launch of a generic BELBUCA product by a third party, an initial automatic renewal period of two years, and additional automatic one-year renewal periods thereafter, which will occur unless either party provides written notice of termination an agreed upon period of time prior to the expiration of the initial term or any renewal term. In exchange for distribution rights of the generic product, Par will pay us an agreed upon base purchase price and a deferred purchase price equal to a percentage of profit (as such term is specifically agreed to in the Distribution Agreement) with respect to units of each dosage strength of generic product. During the term of the Distribution Agreement, Par is precluded from manufacturing for sale in the United States, or distributing in the United States, any equivalent product, provided that nothing prohibits Par from continuing or undertaking to develop any equivalent product or selling such equivalent product outside of the U.S. The Distribution Agreement contains customary termination provisions for bankruptcy, withdrawal of product from the market, and regulatory and legislative changes, as

well as a termination right for insufficient profits or Par's acquisition by or of a party challenging our patents with respect to BELBUCA.

Mylan Licensing Agreements for ONSOLIS

North American Agreement. On September 5, 2007, we entered into a definitive License and Development Agreement with Mylan and our subsidiary Arius pursuant to which we and Arius agreed to grant to Mylan an exclusive commercial license to market, sell, and, following regulatory approval, continue development of ONSOLIS in the United States, Mexico and Canada (which we refer to as the Mylan North American License).

Pursuant to such license agreement, we are to receive the following future milestones:

- sales milestones equaling an aggregate of $30 million will be payable at:
  - $10.0 million when and if annual sales meet or exceed $75.0 million;
  - $10.0 million when and if annual sales meet or exceed $125.0 million; and
  - $10.0 million when and if annual sales meet or exceed $175.0 million.

European Agreement. In 2006, we announced collaboration with Mylan to develop and commercialize BEMA Fentanyl (marketed as BREAKYL™ in Europe). Under terms of the agreement, we granted Mylan rights to the European development and commercialization of BREAKYL, in exchange for an upfront fee of $2.5 million and a $2.5 million milestone payment (received in 2008) for completion of Phase 3 clinical trials. Mylan managed the regulatory submission in Europe that led to approval in October 2010. Mylan exclusively commercializes BREAKYL in Europe.

In 2009, we received a $3 million payment in exchange for amending the European agreement to provide Mylan the worldwide rights to ONSOLIS, except for South Korea and Taiwan. The sales royalties to be received by us will be the same for all territories as agreed to for Europe. In addition, various terms of the European agreements have been modified to reflect the rights and obligations of both us and Mylan in recognition of the expansion of the scope of the European agreements.

On January 27, 2015, we entered into an assignment and revenue sharing agreement with Mylan (which we refer to as the ARS Agreement) to return to us the marketing authorization for ONSOLIS in the U.S. and the right to seek marketing authorizations for ONSOLIS in Canada and Mexico. Under the ARS Agreement, financial terms were established that enable Mylan to share a significant portion of the proceeds of milestone and royalty payments received by us from any new North American partnership for ONSOLIS that may be executed by us. Following the return of the U.S. marketing authorization from Mylan, we submitted a prior approval supplement for the new formulation to the FDA in March 2015, which was approved in August 2016.

Collegium License and Development Agreement for ONSOLIS and its Termination

On May 11, 2016, we entered into a definitive License and Development Agreement (which we refer to as the Collegium Agreement) with Collegium under which we granted Collegium the exclusive rights to develop and commercialize ONSOLIS in the U.S. Under the terms of the Collegium Agreement, Collegium was to be responsible for the manufacturing, distribution, marketing and sales of ONSOLIS in the U.S. We were obligated to use commercially reasonable efforts to continue the transfer of manufacturing to the anticipated manufacturer for ONSOLIS and to submit a corresponding Prior Approval Supplement (the "Supplement") to the FDA with respect to the current NDA for ONSOLIS. Following approval of the Supplement, the NDA and manufacturing responsibility for ONSOLIS (including the manufacturing relationship with our manufacturer, subject to our entering into an appropriate agreement with such manufacturer that is acceptable and assignable to Collegium) was to be transferred to Collegium.

Pursuant to such license agreement, we received:

- $2.5 million upfront non-refundable payment, (received in June 2016); and
- reimbursement to us for a pre-determined amount of the remaining expenses associated with the ongoing transfer of the manufacturing of ONSOLIS;

The execution of the Collegium Agreement also required the execution of a definitive termination agreement between us and Mylan embodying royalty-sharing terms, returning ONSOLIS-related assets and rights in the U.S., Canada, and Mexico to us, and including certain other provisions. In addition, our royalty obligations to CDC IV, LLC (or CDC IV), an entity that originally provided funding for the development of ONSOLIS, and its assignees will remain in effect. CDC IV provided funding for the development of ONSOLIS in the past.

On December 8, 2017, Collegium provided us the required 90-day notice regarding termination of the license and development agreement for ONSOLIS between us and Collegium. Collegium's decision to terminate the license involved their execution of a

license agreement to commercialize Nucynta® (tapentadol) Immediate Release and Nucynta® ER (tapentadol). The license and development agreement for ONSOLIS between us and Collegium formally ended on March 8, 2018 and we received our assets back from Collegium.

Key Collaborative, Supply and Manufacturing Agreements

We are and have been a party to collaborative agreements with corporate partners, contractors, universities and government agencies. Our collaboration arrangements are intended to provide us with access to greater resources and scientific expertise in addition to our in-house capabilities. We also have supply arrangements with several of the key component producers of our delivery technology and we rely on third-party manufacturers and packagers to produce commercial product. Our collaborative, supply and manufacturing agreements include:

- *Mylan.* For a description of our agreements with Mylan, please see "Mylan Licensing Agreements for ONSOLIS" above.
- *Collegium.* For a description of our agreements with Collegium, please see "Collegium License and Development Agreement for ONSOLIS" above.
- *LTS Lohmann Therapie-Systeme AG.* Effective December 15, 2006, we entered into a Process Development Agreement with LTS Lohmann Therapie-Systeme AG (which we refer to herein as LTS). Under the agreement, LTS has granted us a license under European Patent No. 0 949 925, regarding BREAKYL in the E.U. Our BREAKYL agreement is renewable for successive terms of two-year terms and shall continue until terminated under the following conditions: i) bankruptcy/insolvency, ii) intellectual property loss, iii) breach of contract iv) supply failure, and v) mutual agreement. LTS manufactures BREAKYL for sale in the E.U. and PAINKYL for sale in the Republic of China (Taiwan). In accordance with the supply agreement executed by us with LTS in April 2012, LTS is the exclusive manufacturer of BEMA Fentanyl for all countries with exception of the United States and Canada. The current term extends to December 31, 2019.
- *ARx.* Effective July 30, 2014, we entered into an agreement with ARx, LLC. Pursuant to which ARx acts as a supplier of BUNAVAIL laminate (bulk product) for the United States. Our supply agreement with ARx was then amended July 14, 2017 and now the agreement runs until December 31, 2023. The agreement can be further renewed for additional terms by mutual agreement.

  Effective January 6, 2017, we assumed Endo's agreement with ARx to supply BELBUCA laminate (bulk product). This agreement automatically renews for successive terms of one year each and currently covers minimum annual commitments for supply of bulk product through 2023.
- *Sharp*. Effective March 6, 2014, we entered into an exclusive agreement with Sharp Corporation, or Sharp, to convert the BUNAVAIL laminate (bulk product) into individual dosage units and package them to supply BUNAVAIL finished product. Our supply agreement with Sharp ran for an initial term from March 6, 2014 until December 31, 2016 and continues to be extended by mutual agreement for subsequent one-year terms. The current term extends to December 31, 2019.

  Effective January 6, 2017, we assumed Endo's agreement with Sharp which covers exclusive annual commitments for supply of packaged BELBUCA finished product through 2022.
- *Tapemark*. Effective January 6, 2017, we assumed Endo's agreement with The Tapemark Company, or Tapemark, to convert the BELBUCA laminate (bulk product) into individual dosage units which were then transferred to Sharp for secondary packaging and supply of BELBUCA finished product. Tapemark continued to provide such services for BELBUCA through 1st quarter of 2018 as we transitioned the converting and primary packaging operations for BELBUCA over to an alternate packaging site in 2018. Tapemark remains qualified to conduct converting and primary packaging of BELBUCA and we continue to explore other opportunities to utilize Tapemark's contract manufacturing services going forward.

  We initiated a program to qualify Tapemark as an alternate commercial manufacturing site for ONSOLIS. This program was necessary since previous efforts to extend a supply agreement with the original ONSOLIS manufacturer Aveva Drug Delivery Systems, Inc. (subsequently acquired by Apotex) were unsuccessful and the agreement expired. In October 2018, we received notification of FDA's approval of Tapemark as the new ONSOLIS manufacturer.

Relationship with CDC IV, LLC

On July 14, 2005, we entered into a Clinical Development and License Agreement (the "CDLA"), with the predecessor of CDC IV, which provided funds to us for the development of ONSOLIS. Under the CDLA, as amended, CDC IV is entitled to receive a low-double digit royalty based on net sales of ONSOLIS. The CDLA includes minimum royalties of $375,000 per quarter beginning in the second full year following commercial launch which came into effect in 2011. The royalty term and minimum payments end upon the latter of expiration of the patent or generic entry into any particular country, or the CDLA is terminated.

We and CDC IV entered into a Royalty Purchase and Amendment Agreement, dated September 5, 2007 (the "RPAA") pursuant to which we granted CDC IV a 1% royalty on sales of the next BEMA product, which was BUNAVAIL, including an active pharmaceutical ingredient other than fentanyl, to receive FDA approval. In connection with the 1% royalty grant: (i) CDC IV shall have the option to exchange its royalty rights to BUNAVAIL in favor of royalty rights to a substitute BEMA product, (which CDC subsequently exchanged for BELBUCA) (ii) we shall have the right, no earlier than six (6) months prior to the initial commercial launch of BUNAVAIL or BELBUCA, to propose in writing and negotiate the key terms pursuant to which it would repurchase the royalty from CDC IV, (iii) CDC IV's right to the royalty shall immediately terminate at any time if annual net sales of BUNAVAIL or BELBUCA equal less than $7.5 million in any calendar year following the third (3rd) anniversary of initial launch of the product and CDC IV receives $18,750 in three (3) consecutive quarters as payment for CDC IV's 1% royalty during such calendar year and (iv) CDC IV shall have certain information rights with respect to BUNAVAIL or BELBUCA.

In April 2016, CDC IV exercised its right pursuant to the RPAA to exchange its royalty rights to the next BEMA product which was BUNAVAIL, in favor of royalty rights to the Substitute BEMA product which was BELBUCA (the CDC IV Option).

On November 21, 2016 we entered into an Amended and Restated CDLA with CDC IV and Athyrium LLC that did not materially change the rights of the parties under the CDLA, but merely clarified and memorialized in a single agreement the rights and obligations of our company, CDC IV and Athyrium under the CDLA and its various amendments as described above.

Licenses, Intellectual Property and Proprietary Information

Our intellectual property strategy is intended to maximize protection of our proprietary technologies and know-how and to further expand targeted opportunities by extension of our patents, trademarks, license agreements and trade secrets portfolio. In addition, an element of our strategic focus provides for varying specific royalty or other payment obligations by our commercial partners as our applicable intellectual property portfolio changes or business activity reaches certain thresholds.

However, patent positions of biotechnology and pharmaceutical organizations are uncertain and involve complex legal and technical issues. There is considerable uncertainty regarding the breadth of claims in patent cases which results in varied degrees of protection. While we believe that our intellectual property position is sound, it may be that our pending patent applications will not be granted or that our awarded claims may be too narrow to protect the products against competitors. It is also possible that our intellectual property positions will be challenged or that patents issued to others prior to our patent issuance may preclude us from commercializing our products. It is also possible that other parties could have or could obtain patent rights which may cover or block our products or otherwise dominate our patent position.

BEMA Technology

The drug delivery technology space is congested, although we do not believe that our BEMA products conflict with, are dominated by, or infringe any external patents and we do not believe that we require licenses under external patents for our BEMA based products in the United States. It is possible, however, that a court of law in the United States or elsewhere might determine otherwise. If a court were to determine that we were infringing other patents and that those patents were valid, we might be required to seek one or more licenses to commercialize our products or technologies and we may be unable to obtain such licenses from the patent holders. If we were unable to obtain a license, or if the terms of the license were onerous, there may be a material adverse effect upon our business plan to commercialize these products.

On March 1, 2011, we were granted a patent extending the exclusivity of the BEMA drug delivery technology in Canada to 2027. The Canadian Patent No. 2,658,585 provides additional patent protection for ONSOLIS and BELBUCA. In April 2012, the USPTO granted US Patent No. 8,147,866, which will extend the exclusivity of the BEMA drug delivery technology for BELBUCA and BUNAVAIL in the United States from 2020 to 2027. In April 2014, the USPTO granted US Patent No. 8,703,177 (issued from US Patent Application No. 13/590,094), which will extend the exclusivity of the BEMA drug delivery technology for BUNAVAIL in the United States to at least 2032. In February 2018, we were granted US Patent No. 9,901,539, which will extend the exclusivity of the BEMA technology for BELBUCA in the United States to December 21, 2032.

We own various patents and patent applications relating to the BEMA technology. US Patent No. 6,159,498 (expiration date October 2016), US Patent No. 7,579,019 (expiration date January 22, 2020), US Patent No. 8,147,866 (expiration date July 23, 2027), US Patent 8,703,177 (expiration date August 20, 2032), US Patent 9,522,188 (expiration date April 24, 2035), US Patent 9,597,288 (expiration date July 23, 2027), US Patent 9,655,843 (expiration date July 23, 2027), US Patent 9,901,539 (expiration date December 21, 2032, Canadian Patent No. 2,658,585 (expiration date July 2027), EP2054031 (expiration date July 2027) and EP 0 973 497 (expiration date October 2017) are of particular value to our business and technology platform relating to the BEMA delivery technology. On February 16, 2010, we filed a complaint with the United States Federal District Court for the District of Columbia, requesting the USPTO be required to further extend the patent term for US 7,579,019 from 835 days to 1,191 days. In March 2011, we

prevailed in this case, and the patent expiration date of US Patent No. 7,579,019 is now extended from January 31, 2019 to January 22, 2020.

On January 22, 2014, Aquestive filed a Petition for Inter Partes Review, or IPR, on US Patent No. 7,579,019 with the USPTO. In the Petition, Aquestive is requesting an inter partes review because it is asserting that the claims of US Patent No. 7,579,019 are alleged to be unpatentable over certain prior art references. The USPTO instituted the IPR on the US Patent No. 7,579,019 (which we refer to as the '019 Patent). The USPTO found all claims patentable and Aquestive filed a Request for Rehearing. On December 19, 2016, the PTAB issued a final decision denying Aquestive's request for rehearing. Aquestive did not appeal this final decision.

With respect to trademarks, "BDSI®," "BEMA®", "BELBUCA®" and "BUNAVAIL®" are registered trademarks of BioDelivery Sciences International, Inc. ONSOLIS® and BREAKYL are also trademarks owned by BioDelivery Sciences International, Inc. PAINKYL™ is a trademark owned by TTY Biopharm.

Government Regulation

The nonclinical and clinical development, manufacturing and marketing of any drug product is subject to significant regulation by governmental authorities in the United States and other countries. Complying with these regulations involves considerable time, expense and uncertainty.

In the United States, drugs are subject to rigorous federal regulation and, to a lesser extent, state regulation. The Federal Food, Drug and Cosmetic Act, as amended, and the regulations promulgated thereunder, and other federal and state statutes and regulations govern, among other things, the testing, manufacture, safety, efficacy, labeling, storage, record keeping, approval, advertising and promotion of our drugs. Drug development and approval within this regulatory framework is difficult to predict, requires several years and involves the expenditure of substantial resources. Moreover, ongoing legislation by Congress and rulemaking by the FDA presents an ever-changing landscape where we could be required to undertake additional activities before any governmental approval to market our products is granted.

The steps required before a pharmaceutical product may be marketed in the United States include:

1. small scale manufacturing of the product;
2. laboratory and nonclinical tests for safety of the product;
3. submission of an IND to the FDA for the product (the IND must become effective before human clinical trials can commence);
4. larger scale manufacturing of the product;
5. clinical trials to characterize the efficacy and safety of the product in the intended patient population;
6. submission of an NDA to the FDA; and
7. approval of the NDA by the FDA.

In addition to obtaining FDA approval for each product, each product-manufacturing establishment must be registered with, and approved by, the FDA. Manufacturing establishments are generally subject to biennial inspections by the FDA and must comply with the FDA's Good Manufacturing Practices and with other federal and local regulations.

Nonclinical Testing

Nonclinical testing includes laboratory evaluations of the active drug substance and formulation, as well as tissue culture and animal studies to assess the safety and potential efficacy of the investigational product. Nonclinical tests must be conducted by laboratories that comply with FDA Good Laboratory Practices regulations. Nonclinical testing is inherently risky, and the results can be unpredictable or difficult to interpret. The results of nonclinical testing are submitted to the FDA as part of an IND and are reviewed by the FDA prior to the commencement of clinical trials. Unless the FDA places a clinical hold on an IND, clinical studies may begin thirty (30) days after the IND is submitted.

We have relied and intend to continue to rely on third party contractors to perform nonclinical trials.

Clinical Research

Clinical research involves administration of the investigational product to healthy volunteers and/or to patients under the supervision of a qualified investigator. Clinical trials must be conducted in accordance with Good Clinical Practices following protocols acceptable to FDA that detail the objectives of the study, the parameters to be used to monitor safety and the efficacy and the planned evaluation of results. Each protocol must be submitted to the FDA prior to its conduct. Further, each clinical study must be conducted under the auspices of an independent institutional review board that protects the rights and welfare of the study subjects. The drug product used in clinical trials must be manufactured according to Good Manufacturing Practices.

Clinical research is typically conducted in three sequential phases, but the phases may overlap and not all phases may be necessary when developing investigational products that will utilize the FDA's 505(b)(2) approval process. Phase 1 studies are typically performed in normal healthy volunteers to assess the safety (adverse side effects), absorption, metabolism, bio-distribution, excretion, and food and drug interactions of the investigational drug product. Additional studies may be performed to assess abuse potential as well as limited measures of pharmacologic effect. Phase 2 is the proof of principle stage and involves studies in a limited number of patients in order to:

- assess the potential efficacy of the product for specific, targeted indications;
- identify the range of doses and dose regimens likely to be effective for the indication; and
- identify possible adverse events and safety risks.

When there is evidence that the product may be effective and has an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to establish the clinical efficacy and safety profile of the product within a larger population at geographically dispersed clinical study sites. Phase 3 frequently involves randomized controlled trials and, whenever possible, studies are conducted in a manner so that neither the patient nor the investigator knows what treatment is being administered. We, or the FDA, may suspend clinical trials at any time if it is believed that the individuals participating in such trials are being exposed to unacceptable health risks.

New Drug Application and FDA Approval Process

The results of the pharmaceutical and manufacturing development work, nonclinical studies and clinical studies are submitted to the FDA in the form of an NDA for approval to market and sell the product. The testing and approval process is likely to require substantial time and effort. In addition to the results of nonclinical and clinical testing, the NDA applicant must submit detailed information about chemistry, manufacturing and controls that will describe how the product is made, packaged, labeled, and tested through the manufacturing process. The manufacturing process continues to develop throughout the period of clinical trials such that, at the time of the NDA, it has been demonstrated that there is control of the process and the product can be made consistently at commercial scale.

The NDA review process involves FDA investigation into the details of the manufacturing process, as well as the design and analysis of each of the nonclinical and clinical studies. This review includes inspection of the manufacturing facility, the data recording process for the clinical studies, the record keeping at a sample of clinical trial sites and a thorough review of the results for each nonclinical and clinical study. Through this review, the FDA reaches a decision about the risk-benefit profile of a product candidate. If the benefit outweighs the risk, the FDA begins negotiation with the company on the content of an acceptable package insert and an associated REMS plan if required.

The NDA review process is affected by many factors, including the severity of the disease, the availability of alternative treatments, and the risks and benefits demonstrated in clinical trials. Consequently, there is a risk that approval may not be granted on a timely basis, if at all. The FDA may deny approval of an NDA if applicable regulatory criteria are not satisfied. Moreover, if regulatory approval of a product is granted, such approval may entail limitations on the indicated uses for which it may be marketed, require additional testing or information, or require post-marketing testing (Phase 4) and surveillance to monitor the safety of a company's product if it does not believe the NDA contains adequate evidence of its safety. Finally, product approvals may be withdrawn if compliance with regulatory standards is not maintained or health problems are identified that would alter the risk-benefit

analysis for the product. Post-approval studies may be conducted to explore the use of the product for new indications or populations such as pediatrics.

Among the conditions for NDA approval is the requirement that any prospective manufacturer's quality control and manufacturing procedures conform to Good Manufacturing Practices and the specifications approved in the NDA. In complying with standards set forth in these regulations, manufacturers must continue to expend time, money and effort in the area of quality control and quality assurance to ensure full technical compliance. Manufacturing establishments, both foreign and domestic, also are subject to inspections by or under the authority of the FDA and by other federal, state or local agencies. Additionally, in the event of non-compliance, the FDA may issue warning letters and/or seek criminal and civil penalties, enjoin manufacture, seize product or revoke approval.

Risk Evaluation and Mitigation Strategy

In March 2008, new legislation designated as the Food and Drug Administration Amendments Act of 2007 (the FDAAA) took effect. This legislation strengthened the FDA's authority over drug safety and directs the FDA to develop systems aimed at managing the risk-benefit ratio of a drug, with a particular focus on post-approval safety. FDAAA authorized the FDA to require and enforce a Risk Evaluation and Mitigation Strategy, or REMS, if the FDA determines that it is necessary to ensure that the benefits of a drug outweigh the potential risks. The legislation also provides the FDA with authority to require a REMS at any point in a drug product's lifecycle based on new safety information.

A REMS is defined by the FDA as a strategy to manage a known or potential serious risk associated with a drug or biological product. The FDA's assessment of whether to require a REMS as a condition for approval considers factors such as the size of the population likely to use the drug, the seriousness of the disease or condition that is to be treated by the drug, the expected benefit, and the seriousness of any known or potential adverse events that may be related to the drug. A REMS may be conveyed through the use of a number of tools including a Medication Guide for distribution when the drug is dispensed, a communication plan to physicians to convey potential risks, and elements to ensure safe use. These elements may include provisions that healthcare providers who prescribe the drug and pharmacists who dispense the drug have particular training, experience or special certifications; that the drug be dispensed only in certain healthcare settings; that the drug be dispensed to patients with evidence of safe-use conditions; and/or that patients must be enrolled in a registry. Under the FDAAA, the FDA has also been granted enforcement authority over violations of the REMS provisions. The FDA may impose civil monetary penalties, the drug or biological product can be deemed misbranded, and/or the FDA may obtain injunctive relief against further distribution of the product.

On December 29, 2011, the FDA approved a "class-wide" REMS program covering all transmucosal fentanyl products under a single risk management program. ONSOLIS is subject to this REMS, which includes a number of Elements to Assure Safe Use (ETASU).

Additionally, FDA has implemented a class-wide REMS covering all opioid analgesic drug products. The class-wide REMS includes a REMS-compliant educational program offered by an accredited provider of continuing medical education, patient counseling materials and a medication guide. BELBUCA is subject to this REMS.

A REMS is also in place for buprenorphine for the treatment of opioid dependence. BUNAVAIL is included in this REMS, which includes a medication guide and healthcare professional and patient education.

The cost and implementation of all of these "shared system" REMS is shared among multiple companies that are required to participate by way of having an approved product that is subject to the particular REMS.

International Approval

Whether or not FDA approval has been obtained, approval of a product by regulatory authorities in foreign countries must be obtained prior to the commencement of commercial sales of the drug in such countries. The requirements governing the conduct of clinical trials and drug approvals vary widely from country to country, and the time required for approval may be longer or shorter than that required for FDA approval. Although there are some procedures for unified filings for certain European countries, in general, each country currently has its own procedures and requirements.

BELBUCA is approved in Canada, and ONSOLIS (under different trade names and with a slightly different formulation) is approved in Europe and in Taiwan.

Other Regulation

In addition to regulations enforced by the FDA, we are also subject to United States regulation under the Controlled Substances Act, the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other present and potential future federal, state, local or similar foreign regulations. Our research

and development may involve the controlled use of hazardous materials, chemicals and radioactive compounds. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of any accident, we could be held liable for any damages that result and any such liability could exceed our resources.

Research and Development

Most of our research and development relating to our BEMA and other technologies has been conducted through third parties in collaboration with us.

Research and development expenses have historically consisted of product development expenses incurred in identifying, developing and testing product candidates. Product development expenses consist primarily of labor, benefits and related employee expenses for personnel directly involved in product development activities; fees paid to professional service providers for monitoring and analyzing clinical trials; regulatory costs; costs of contract research and manufacturing of inventory used in testing and clinical trials. For the years ended December 31, 2018, 2017 and 2016, we spent approximately $4.9 million, $13.0 million and $18.9 million, respectively, on research and development, and such expenses represented approximately 8%, 18% and 28%, respectively, of our total operating expenses for such fiscal years.

Employees

As of March 14, 2019, we have 164 full-time employees. 127 handle our outside sales and training, thirteen are involved in our medical affairs, clinical development program and operations, seventeen handle our administration, accounting, and supply chain management and seven handle our marketing and managed markets. Advanced degrees and certifications of our staff include one Ph.D, one M.D, three PharmDs, two CPAs, eighteen MBAs, seven MSs, five MAs, one JD, one MPA, one MEDU and one RN. None of our employees are covered by collective bargaining agreements. From time to time, we also employ independent contractors on a consulting basis or to support our administrative functions. We consider relations with all our employees to be good. Each of our employees has entered into confidentiality, intellectual property assignment and non-competition agreements with us.

Available Information

Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to reports filed pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended (which we refer to herein as the Exchange Act), are filed with the SEC. Such reports and other information that we file with the SEC are available free of charge on our website at http://ir.bdsi.com/financials/sec-filings when such reports are available on the SEC website. The SEC maintains an Internet site that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC at http://www.sec.gov. The contents of these websites are not incorporated into this filing. Further, the foregoing references to the URLs for these websites are intended to be inactive textual references only.

Item 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. Before purchasing our common stock, you should carefully consider the following risk factors as well as all other information contained in this Report, including our consolidated financial statements and the related notes. The risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties that we are unaware of, or that we currently deem immaterial, also may become important factors that affect us. If any of the following risks occur, our business, financial condition or results of operations could be materially and adversely affected. In that case, the trading price of our common stock could decline, and you may lose some or all of your investment.

Risks Relating to Our Business

We have incurred significant losses since inception and as such, you cannot rely upon our historical operating performance to make an investment decision regarding our company.

From our inception in January 1997 and through December 31, 2018, we have recorded significant losses. Our accumulated deficit at December 31, 2018 was approximately $351.3 million. As of December 31, 2018, we had working capital of approximately $44.5 million, and until our product revenue grows more substantially, we will continue to use our working capital to maintain our operations. Our ability to generate revenue and achieve profitability depends upon our ability, alone or with others, to effectively market and sell our products, secure and maintain payer access and manufacture our products to meet demand. We may be unable to achieve any or all of these goals consistently.

Although we have generated licensing-related and other revenue to date, we have only recently begun to generate revenue from the commercial sales of our approved products — BELBUCA, BUNAVAIL and ONSOLIS. In the case of BELBUCA, our approval has generated milestone revenue from our prior commercial partner Endo. However, in January 2017, we obtained the commercialization rights back to BELBUCA and are utilizing our internal sales force to sell our product. In the case of BUNAVAIL, sales have been challenging since we commenced the commercial launch of the product in November 2014 and are subject to the risks of launching a new product. There is a risk that we will be unable to generate sustained and predictable revenues from product sales. In the case of ONSOLIS, sales have been adversely affected by: (i) the lack of a uniform REMS program at the time of the launch of ONSOLIS, and (ii) certain post-FDA manufacturing issues associated with ONSOLIS which have led to the temporary suspension of manufacturing and marketing of ONSOLIS in the US and Canada.

We have limited experience as a company in self-commercializing pharmaceutical products, which heightens the risks related to our self-commercialization of BELBUCA and BUNAVAIL.

Prior to our decision to commercialize BUNAVAIL, we had relied on third parties to manage sales and marketing efforts for us, including Mylan for ONSOLIS and Endo for BELBUCA until January 2017. We therefore have limited experience as a company in commercializing a product, and our sales, marketing and distribution capabilities are fairly new. As such, we may not achieve success in marketing and promoting BELBUCA and BUNAVAIL, or any other products we develop or acquire in the future or products we may commercialize through the exercise of co-promotion rights. Specifically, to optimize the commercial potential of BELBUCA and BUNAVAIL, we must execute upon our commercialization plan effectively and efficiently. In addition, we must continually assess and modify our commercialization plan to adapt to the promotional response. Further, we must continue to focus and refine our marketing campaign to ensure a clear and understandable physician-patient dialogue around BELBUCA and BUNAVAIL as an appropriate therapies. In addition, we must provide our sales force with the highest quality training, support, guidance and oversight for them to effectively promote BELBUCA and BUNAVAIL. If we fail to perform these commercial functions in the highest quality manner, BELBUCA and BUNAVAIL will not achieve its maximum commercial potential or any level of success at all. The deterioration or loss of our sales force would materially and adversely impact our ability to generate sales revenue, which would hurt our results of operations. Finally, we are competing and expect to compete with other companies that currently have extensive and well-funded marketing and sales operations, and our marketing and sales efforts may be unable to compete against these other companies, which would also hurt our results of operations.

If our competitors are successful in obtaining approval for Abbreviated New Drug Applications for products that have the same active ingredients as BELBUCA or BUNAVAIL, sales of BELBUCA or BUNAVAIL may be adversely affected.

Our competitors may submit for approval certain Abbreviated New Drug Applications, or ANDAs, which provide for the marketing of a drug product that has the same active ingredients in the same strengths and dosage form as a drug product already listed with the FDA, and which has been shown to be bioequivalent to such FDA-listed drug. Drugs approved in this way are commonly referred to as generic versions of a listed drug and can often be substituted by pharmacists under prescriptions written for an original listed drug. Any applicant filing an ANDA is required to certify to the FDA that the new product subject to the ANDA will

not infringe an already approved product's listed patents or that such patents are invalid (otherwise known as a Paragraph IV Certification).

In February 2016, we announced that a generic competitor, Teva Pharmaceutical Industries Ltd., or Teva, had filed a Paragraph IV Certification challenging certain of our BUNAVAIL-related patents and we received notices regarding Paragraph IV certifications from Teva in November and December 2016, seeking to find invalid two Orange Book listed patents relating specifically to BELBUCA. The filing of this certification required us to initiate costly litigation against Teva. In addition, a number of our competitor companies have filed Paragraph IV Certifications challenging the patent for Suboxone® film, the market leader in the field in which we are seeking to generate sales of BUNAVAIL. To the extent that any company is successful in challenging the validity of certain patents covering BUNAVAIL or Suboxone® film under a Paragraph IV Certification, it could result in FDA approval of a drug that is lower in price to BUNAVAIL or Suboxone® film. Such a new drug could make it more difficult for BUNAVAIL to gain any significant market share in an increasingly generic marketplace, which would have a material adverse effect on our results of operations, cash flow, reputation and stock price.

In October 2017, we announced that we had entered into a settlement agreement with Teva that resolved our BUNAVAIL patent litigation against Teva pending in the U.S. District Court for the District of Delaware. As part of the Settlement Agreement, which is subject to review by the U.S. Federal Trade Commission and the U.S. Department of Justice, we entered into a non-exclusive license agreement with Teva that permits Teva to first begin selling its generic version of BUNAVAIL in the U.S. on July 23, 2028 or earlier under certain circumstances. Other terms of the agreement are confidential.

In February 2018, we announced that we had entered into a Settlement Agreement with Teva that resolves our previously reported BELBUCA, patent litigation against Teva pending in the United States District Court for the District of Delaware. As part of the settlement agreement, which is subject to review by the U.S. Federal Trade Commission and the U.S. Department of Justice, we entered into a non-exclusive license agreement with Teva that permits Teva to first begin selling its generic version of BELBUCA in the U.S. on January 23, 2027 or earlier under certain circumstances. Other terms of the agreement are confidential.

As such, we have been and may continue to be subject to ANDA-related litigation, which is costly and distracting and has the potential to impair the long-term value of our products.

We may have difficulty raising any needed additional capital.

Our business currently generates a limited amount of revenue from product sales and milestone revenues, and such current sources of revenue may not be sufficient to meet our present and short-term capital requirements. Therefore, given that we plan to continue to spend on commercialization activities (including those relating to BELBUCA and BUNAVAIL) as well as potentially on other strategic initiatives, there is a risk that we may require additional capital to fund these activities. If adequate funds are unavailable, we may be required to delay, reduce the scope of or eliminate one or more of our commercialization programs or marketing efforts, any of which may materially harm our business, financial condition and results of operations.

Our long-term capital requirements are subject to numerous risks.

Our long-term capital requirements are expected to depend on many factors, including, among others:

- time and costs involved in obtaining regulatory (including FDA) clearance and addressing regulatory and other issues that may arise post-approval (such as we have experienced with ONSOLIS and, to a lesser extent, with BELBUCA and BUNAVAIL);
- costs involved in preparing, filing, prosecuting, maintaining and enforcing (through litigation or other means) our patents, trademarks and other intellectual property;
- costs of developing sales, marketing and distribution channels and our ability to sell our products;
- costs involved in establishing manufacturing capabilities for commercial quantities of our products;
- costs we may incur in acquiring new technologies or products;
- competing technological and market developments;
- market acceptance of our products;
- costs for recruiting and retaining employees and consultants;
- costs for training physicians; and
- legal, accounting, insurance and other professional and business-related costs.

We may consume available resources more rapidly than currently anticipated, resulting in the need for additional funding sooner than anticipated. We may seek to raise any necessary additional funds through equity or debt financings, collaborative arrangements with corporate partners or other sources, which may have a material effect on our current or future business prospects.

Our additional financing requirements could result in dilution to existing stockholders.

The additional financings which we have undertaken and which we may in the future require, have and may be obtained through one or more transactions that have diluted or could dilute (either economically or in percentage terms) the ownership interests of our stockholders. Further, we may not be able to secure such additional financing on terms acceptable to us, if at all. We have the authority to issue additional shares of common stock and preferred stock, as well as additional classes or series of ownership interests or debt obligations which may be convertible into any one or more classes or series of ownership interests. We are authorized to issue 125 million shares of common stock and 5 million shares of preferred stock. Such securities may be issued without the approval or other consent of our stockholders.

Our term loan agreement with CRG Servicing LLC (or CRG) and other lenders party thereto contains restrictions that limit our flexibility in operating our business. We may be required to make a prepayment or repay the outstanding indebtedness earlier than we expect under our Credit Agreement if a prepayment event or an event of default occurs, including a material adverse change with respect to us, which could have a materially adverse effect on our business.

Our agreement with CRG contains various covenants that limit our ability to engage in specified types of transactions. These covenants limit our ability to, among other things:

- incur additional indebtedness;
- enter into a merger, consolidation or certain changing of control events without complying with the terms of the loan agreement;
- change the nature of our business;
- change our organizational structure or type;
- amend, modify or waive any of our material agreements or organizational documents;
- grant certain types of liens on our assets;
- make certain investments;
- pay cash dividends;
- enter into material transactions with affiliates; and

The restrictive covenants of the term loan agreement could cause us to be unable to pursue business opportunities that we or our stockholders may consider beneficial. A breach of any of these covenants could result in an event of default under the term loan agreement. An event of default will also occur if, among other things, a material adverse change in our business, operations or condition occurs, or a material impairment of the prospect of our repayment of any portion of the amounts we owe under the term loan agreement occurs. In the case of a continuing event of default under the agreement, CRG could elect to declare all amounts outstanding to be immediately due and payable and terminate all commitments to extend further credit, proceed against the collateral in which we granted CRG a security interest under the term loan agreement and related agreements, or otherwise exercise the rights of a secured creditor. Amounts outstanding under the term loan agreement are secured by all of our existing and future assets (excluding certain intellectual property).

We may not have enough available cash or be able to raise additional funds on satisfactory terms, if at all, through equity or debt financings to make any required prepayment or repay such indebtedness at the time any such prepayment event or event of default occurs. In such an event, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant to others rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Our business, financial condition and results of operations could be materially adversely affected as a result.

Until ONSOLIS returns to the market in North America, we will not receive additional revenues from ONSOLIS.

ONSOLIS was originally licensed to and launched in the U.S. by Mylan. In January 2015, we entered into an assignment and revenue sharing agreement with Mylan under which Mylan transferred the marketing authorizations for ONSOLIS for the U.S. back to us. On May 11, 2016, we and Collegium executed a definitive license and development Agreement under which we granted the exclusive rights to develop and commercialize ONSOLIS in the U.S. to Collegium.

On December 8, 2017, we received the required 90-day notice from Collegium regarding termination of the License Agreement and the effective date of termination is March 8, 2018. We are assessing our commercial options for ONSOLIS. Until such time that we commercialize or license ONSOLIS in the U.S., we will not receive additional revenues from this product.

Social issues around the abuse of opioids, including law enforcement and other legal concerns over diversion of opioids and regulatory efforts to combat abuse, misuse and addiction, could impact the potential market for BELBUCA, BUNAVAIL and any product candidates we may develop that contain opioids.

Opioid abuse in the United States is a significant healthcare issue, and our two currently marketed products (BELBUCA and BUNAVAIL) contain opioids as their active ingredients. Media stories regarding prescription drug abuse and the diversion of opioids and other controlled substances are commonplace. Law enforcement and regulatory agencies have and will likely continue to apply policies and guidelines that seek to limit the availability or use of opioids. In addition, federal, state and local governments have and may enact legislation or executive orders with similar goals. State and local governments have also taken legal action against opioid manufacturers to recoup alleged damages arising out of the opioid crisis. Such efforts have challenged and could inhibit our ability to commercialize BELBUCA and BUNAVAIL and any product candidates we may develop that contain opioids.

Aggressive enforcement and unfavorable publicity regarding, for example, the use or misuse of oxycodone or other opioid drugs; the limitations of abuse-resistant formulations; the ability of drug abusers to discover previously unknown ways to abuse opioid drugs; public inquiries and investigations into prescription drug abuse; litigation; or regulatory activity regarding sales, marketing, distribution or storage of opioid drugs could have a material adverse effect on our business. Additionally, there may be continued reluctance of some regulators and third-party payers to pay a premium for abuse-deterrent formulations of opioids or opioids such as BELBUCA with less abuse and addiction potential compared to Schedule II opioids. These factors could reduce the potential size of the market for BELBUCA, and possibly BUNAVAIL and our product candidates and decrease the revenues we are able to generate from their sale.

Efforts by the FDA and other regulatory bodies to combat abuse of opioids may negatively impact the market for BELBUCA and BUNAVAIL. For example, in February 2016, the FDA released an action plan to address the opioid abuse epidemic and reassess the FDA's approach to opioid medications. The plan identifies FDA's focus on implementing policies to reverse the opioid abuse epidemic, while maintaining access to effective treatments. The actions set forth in the FDA's plan include strengthening post marketing study requirements to evaluate the benefit of long-term opioid use, changing the REMS requirements to provide additional funding for physician education courses, releasing a draft guidance setting forth approval standards for generic-abuse deterrent opioid formulations, and seeking input from the FDA's Scientific Board to broaden the understanding of the public risks of opioid abuse. The FDA's Scientific Advisory Board met to address these issues on March 1, 2016. The FDA's plan is part of a broader initiative led by the HHS to address opioid-related overdose, death and dependence. The HHS initiative's focus is on improving physician's use of opioids through education and resources to address opioid over-prescribing, increasing use and development of improved delivery systems for naloxone, which can reverse overdose from both prescription opioids and heroin, to reduce overdose-related deaths, and expanding the use of Medication-Assisted Treatment, which couples counseling and behavioral therapies with medication to address substance abuse. Also, as part of this initiative, the CDC has launched a state grant program to offer state health departments resources to assist with abuse prevention efforts, including efforts to track opioid prescribing through state-run electronic databases. In March 2016, as part of the HHS initiative, the CDC released a new Guideline for Prescribing Opioids for Chronic Pain. The guideline is intended to assist primary care providers treating adults for chronic pain in outpatient settings. The guideline provides recommendations to improve communications between doctors and patients about the risks and benefits of opioid therapy for chronic pain, improve the safety and effectiveness of pain treatment, and reduce the risks associated with long-term opioid therapy. The guideline does not specifically address the use of buprenorphine for chronic pain or make treatment recommendations about the use of abuse-deterrent opioids.

In addition, at least 41 U.S. states and many cities and counties have filed civil suits or instituted other proceedings against opioid manufacturers and wholesalers of opioid drugs seeking damages under various claims for contributing to the opioid crisis. Such litigations could further damage the market for opioid products like BELBUCA and BUNAVAIL. To the extent our company is named in such lawsuits (such as the lawsuit in Arkansas described under "Legal Proceedings", of which the plaintiffs filed a notice to voluntarily dismiss us from the case in July 2018), we could be required to participate in the settlement of such litigations or the payment of damages, which could divert our management's attention from our business, deplete our financial resources, and damage our reputation.

Government agencies may establish and promulgate usage guidelines that could limit the use of our products and drug candidate.

National and state level government agencies, professional and medical societies, and other groups may establish usage guidelines that apply to our products and drug candidate. These guidelines could address such matters as usage and dose, among other factors. Application of such guidelines could limit the clinical use or commercial appeal of our products or drug candidate.

Acceptance of our technologies, product candidates or products in the marketplace is uncertain and failure to achieve market acceptance will prevent or delay our ability to generate material revenues.

Our future financial performance will depend, to a large extent, upon the introduction and physician and patient acceptance of our technologies, product candidates and products. Even if approved for marketing by the necessary regulatory authorities, our technologies, product candidates and products may not achieve market acceptance.

The degree of market acceptance for our products and product candidates will depend upon a number of factors, including:

- regulatory clearance of marketing claims for the uses that we are developing;
- demonstration of the advantages, safety and efficacy of our products and technologies;
- pricing and reimbursement policies of government and third-party payers such as insurance companies, health maintenance organizations and other health plan administrators;
- ability to attract corporate partners, including pharmaceutical companies, to assist in commercializing our products;
- regulatory programs such as the class-wide REMS for ONSOLIS, BELBUCA and BUNAVAIL or market (including competitive) forces that may make it more difficult for us to penetrate a particular market segment; and
- ability to timely and effectively manufacture and market our products.

Physicians, various other health care providers, patients, payers or the medical community in general may be unwilling to accept, utilize or recommend any of our approved products or product candidates. If we are unable to obtain regulatory approval or are unable (either on our own or through third parties) to manufacture, commercialize and market our proposed formulations or products when planned, we may not achieve any market acceptance or generate revenue.

All these risks are particularly true for BELBUCA and BUNAVAIL, which are our two products that we are commercializing ourselves.

If we are unable to convince physicians as to the benefits of our products or product candidates, we may incur delays or additional expense in our attempt to establish market acceptance.

Use of our products and, if approved, our product candidates will require physicians to be informed regarding the intended benefits of our products and product candidates. The time and cost of such an educational process may be substantial. Inability to carry out this physician education process may adversely affect market acceptance of our proposed formulations or products. We may be unable to timely educate physicians regarding our intended pharmaceutical formulations or products in sufficient numbers to achieve our marketing plans or to achieve product acceptance. Any delay in physician education may materially delay or reduce demand for our formulations or products. In addition, we may expend significant funds toward physician education before any acceptance or demand for our products or product candidates are created, if at all. Nonetheless, even with our best efforts, certain physicians may never prescribe our product.

We have been and expect to be significantly dependent on our collaborative agreements for the manufacturing of our products, which expose us to the risk of reliance on the performance of third parties.

In conducting our operations, we currently rely, and expect to continue to rely, on numerous collaborative agreements with third parties such as manufacturers, commercial partners, governmental agencies and not-for-profit organizations for both strategic and financial resources. Key among these agreements are our manufacturing agreements with LTS relating to BREAKYL and Sharp relating to BELBUCA and BUNAVAIL.

The termination of these relationships, or failure to perform by us or our partners (who are subject to regulatory, competitive and other risks) under their applicable agreements or arrangements with us, or our failure to secure additional agreements for our product candidates, would substantially disrupt or delay our development activities. Any such loss would likely increase our expenses and materially harm our business, financial condition and results of operation.

We depend upon key personnel who may terminate their employment with us at any time.

Our ability to achieve our corporate objectives will depend to a significant degree upon the continued services of key management, particularly our senior executive officers. Our management and other employees may voluntarily terminate their employment with us at any time. The loss of the services of these or other key personnel, or the inability to attract and retain additional qualified personnel, could result in delays to loss of sales and diversion of management resources. In addition, we depend on our ability to attract and retain other highly skilled personnel. Competition for qualified personnel is intense, and the process of hiring and integrating such qualified personnel is often lengthy. We may be unable to recruit such personnel on a timely basis, if at all, which would negatively impact our commercialization programs. Additionally, we do not currently maintain “key person” life insurance on

the lives of our executives or any of our employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals.

We may be unable to manage our growth effectively.

After focusing our efforts for many years on clinical development of products, our business strategy now involves growth and expansion as we continue our evolution into a fully integrated specialty pharmaceutical company. For example, as we in-license or acquire additional product candidates, we will likely have to expand existing operations to increase our contract manufacturing capabilities, hire and train new personnel to handle the marketing and sales of our products and assist patients in obtaining reimbursement for the use of our products. We may also need to grow to support our commercial activities for BELBUCA and BUNAVAIL or other approved products. This growth may place significant strain on our management and financial and operational resources. Successful growth is also dependent upon our ability to implement appropriate financial and management controls, systems and procedures. Our ability to effectively manage growth depends on our success in attracting and retaining highly qualified personnel, for which the competition may be intense. If we fail to manage these challenges effectively, our business could be harmed.

We are exposed to product liability, non-clinical and clinical liability risks which could place a substantial financial burden upon us, should lawsuits be filed against us.

Our business exposes us to potential product liability and other liability risks that are inherent in the testing, manufacturing and marketing of pharmaceutical formulations and products. We expect that such claims could be asserted against us at some point. In addition, the use in our clinical trials of pharmaceutical formulations and products and the subsequent sale of these formulations or products by us or our potential collaborators may cause us to bear a portion of or all product liability risks. A successful liability claim or series of claims brought against us could have a material adverse effect on our business, financial condition and results of operations.

We currently have a general liability/product liability policy which includes coverage for our clinical trials and our commercially marketed products. Annual aggregate limits include $2 million for general liability, with $1 million for each occurrence; product liability is $10 million for aggregate and $10 million per occurrence with excess liability in the amount of an additional $5 million; umbrella liability is $5 million aggregate and $5 million per occurrence. It is possible that this coverage will be insufficient to protect us from future claims. Under our agreements, our partners are required to carry comprehensive general product liability and tort liability insurance, each in amounts not less than $2 million per incident and $2 million annual aggregate and to name us as an additional insured thereon. However, we or our commercial partners may be unable to obtain or maintain adequate product liability insurance on acceptable terms, if at all, and there is a risk that our insurance will not provide adequate coverage against our potential liabilities. Furthermore, our current and potential partners with whom we have collaborative agreements, or our future licensees may not be willing to indemnify us against these types of liabilities and may not themselves be sufficiently insured or have sufficient assets to satisfy any product liability claims. Claims or losses in excess of any product liability insurance coverage that may be obtained by us or our partners could have a material adverse effect on our business, financial condition and results of operations.

Moreover, product liability insurance is costly, and due to the nature of the pharmaceutical products underlying BELBUCA, BUNAVAIL, ONSOLIS and our product candidates, we or our partners may not be able to obtain such insurance, or, if obtained, we or our partners may not be able to maintain such insurance on economically feasible terms. If a product or product candidate related action is brought against us, or liability is found against us prior to our obtaining product liability insurance for any product or product candidate, or should we have liability found against us for any other matter in excess of any insurance coverage we may carry, we could face significant difficulty continuing operations.

We are presently a party to lawsuits by third parties who claim that our products, methods of manufacture or methods of use infringe on their intellectual property rights, and we may be exposed to these types of claims in the future.

We are presently, and may continue to be, exposed to litigation by third parties based on claims that our technologies, processes, formulations, methods, or products infringe the intellectual property rights of others or that we have misappropriated the trade secrets of others. This risk is exacerbated by the fact that the validity and breadth of claims covered in pharmaceutical patents is, in most instances, uncertain and highly complex. Any litigation or claims against us, whether or not valid, would result in substantial costs, could place a significant strain on our financial and human resources and could harm our reputation. Such a situation may force us to do one or more of the following:

- incur significant costs in legal expenses for defending against an intellectual property infringement suit;
- delay the launch of, or cease selling, making, importing, incorporating or using one or more or all of our technologies and/or formulations or products that incorporate the challenged intellectual property, which would adversely affect our revenue;

- obtain a license from the holder of the infringed intellectual property right, which license may be costly or may not be available on reasonable terms, if at all; or
- redesign our formulations or products, which would be costly and time-consuming.

With respect to our BEMA delivery technology, the thin film drug delivery technology space is highly competitive. There is a risk that a court of law in the United States' or elsewhere could determine that one or more of our BEMA based products conflicts with or covered by external patents. This risk presently exists in our litigation with Aquestive which was filed by Aquestive in November 2010, wherein Aquestive claims that our and our partner's trade secret manufacturing process for ONSOLIS is infringing upon Aquestive patented manufacturing process, as well as a similar litigation with Reckitt Benckiser, Inc., RB Pharmaceuticals Limited, and Aquestive relating to our BUNAVAIL product which was filed in October 2013. If the courts in these cases were to rule against us and our partner in that case, we could be forced to license technology from Aquestive or otherwise incur liability for damages, which could have a material adverse effect on our ability for us or our partners to market and sell BUNAVAIL or ONSOLIS.

We have been granted non-exclusive license rights to European Patent No. 949 925, which is controlled by LTS to market BELBUCA and ONSOLIS within the countries of the European Union. We are required to pay a low single digit royalty on sales of products that are covered by this patent in the European Union. We have not conducted freedom to operate searches and analyses for our other proposed products. Moreover, the possibility exists that a patent could issue that would cover one or more of our products, requiring us to defend a patent infringement suit or necessitating a patent validity challenge that would be costly, time consuming and possibly unsuccessful.

Our lawsuits with Aquestive and RB Pharmaceuticals have caused us to incur significant legal costs to defend ourselves, and we would be subject to similar costs if we are a party to similar lawsuits in the future Furthermore, if a court were to determine that we infringe any other patents and that such patents are valid, we might be required to seek one or more licenses to commercialize our BEMA products. We may be unable to obtain such licenses from the patent holders, which could materially and adversely impact our business.

If we are unable to adequately protect or enforce our rights to intellectual property or secure rights to third-party patents, we may lose valuable rights, experience reduced market share, assuming there is any market share, or incur costly litigation to, enforce, maintain or protect such rights.

Our ability to license, enforce and maintain patents, maintain trade secret protection and operate without infringing the proprietary rights of others will be important to our commercializing any formulations or products under development. The current and future development of our drug delivery technologies is contingent upon whether we are able to maintain licenses and access patented technologies. Without these licenses, the use of technologies would be limited and the sales of our products could be prohibited. Therefore, any disruption in access to the technologies could substantially delay the development and sale of our products.

The patent positions of biotechnology and pharmaceutical companies, including ours, which involve licensing agreements, are frequently uncertain and involve complex legal and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued. Consequently, our patents, patent applications and licensed rights may not provide protection against competitive technologies or may be held invalid if challenged or could be circumvented. Our competitors may also independently develop drug delivery technologies or products similar to ours or design around or otherwise circumvent patents issued to, or licensed by, us. In addition, the laws of some foreign countries may not protect our proprietary rights to the same extent as U.S. law.

We also rely upon trade secrets, technical know-how and continuing technological innovation to develop and maintain our competitive position. We require our employees, consultants, advisors and collaborators to execute appropriate confidentiality and assignment-of-inventions agreements with us. These agreements provide that materials and confidential information developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances and assign the ownership of relevant inventions created during the course of employment to us. These agreements may be breached, and in some instances, we may not have an appropriate remedy available for breach of the agreements. Furthermore, our competitors may independently develop substantially equivalent proprietary information and techniques, reverse engineer, or otherwise gain access to our proprietary technology. We may be unable to meaningfully protect our rights in trade secrets, technical know-how and other non-patented technology.

In addition, we may have to resort to costly and time consuming litigation to protect or enforce our rights under certain intellectual property, or to determine their scope, validity or enforceability. Enforcing or defending our rights could be expensive, could cause significant diversion of our resources and may not prove successful. Any failure to enforce or protect our rights could cause us to lose the ability to exclude others from using our technologies to develop or sell competing products.

We are dependent on third party suppliers for key components of our delivery technologies, products and product candidates.

Key components of our drug delivery technologies, products and product candidates may be provided by sole or limited numbers of suppliers, and supply shortages or loss of these suppliers could result in interruptions in supply or increased costs. Certain components used in our development activities, such as the active pharmaceutical component of our products, are currently purchased from a single or a limited number of outside sources. The reliance on a sole or limited number of suppliers could result in:

- delays associated with development and non-clinical and clinical trials due to an inability to timely obtain a single or limited source component;
- inability to timely obtain an adequate supply of required components; and
- reduced control over pricing, quality and timely delivery.

Our relationships with our manufacturers and suppliers are particularly important to us and any loss of or material diminution of their capabilities due to factors such as regulatory issues, accidents, acts of God or any other factor would have a material adverse effect on our company. Any loss of or interruption in the supply of components from our suppliers or other third-party suppliers would require us to seek alternative sources of supply or require us to manufacture these components internally, which we are currently not able to do.

If the supply of any components is lost or interrupted, product or components from alternative suppliers may not be available in sufficient quality or in volumes within required time frames, if at all, to meet our or our partners' needs. This could delay our ability to complete clinical trials, obtain approval for commercialization or commence marketing or cause us to lose sales, force us into breach of other agreements, incur additional costs, delay new product introductions or harm our reputation. Furthermore, product or components from a new supplier may not be identical to those provided by the original supplier. Such differences could have material effects on our overall business plan and timing, could fall outside of regulatory requirements, affect product formulations or the safety and effectiveness of our products that are being developed.

We have limited manufacturing experience and therefore depend on third parties to formulate and manufacture our products. We may not be able to secure or maintain the manufacture of sufficient quantities or at an acceptable cost necessary to successfully commercialize or continue to sell our products.

Our management's expertise has primarily been in commercial operations. Our management's experience in the manufacturing of pharmaceutical products is more limited and we have limited equipment and no facilities of our own from which these activities could be performed. Therefore, we are fully dependent on third parties for our formulation development, manufacturing and the packaging of our products. This is particularly true with respect to ARx and Sharp, the primary manufacturers of our approved and commercialized product, BELBUCA and BUNAVAIL. We also rely on LTS, the manufacturer for BREAKYL in the E.U. This reliance exposes us to the risk of not being able to directly oversee the production and quality of the manufacturing process and provide ample commercial supplies to formulate sufficient product to conduct clinical trials and maintain adequate supplies to meet market demand for our products.

Furthermore, these third-party contractors, whether foreign or domestic, may experience regulatory compliance difficulty, mechanical shut downs, employee strikes, or any other unforeseeable acts that may delay or limit production, which could leave our commercial partners with inadequate supplies of product to sell, especially when regulatory requirements or customer demand necessitate the need for additional product supplies. Our inability to adequately establish, supervise and conduct (either ourselves or through third parties) all aspects of the formulation and manufacturing processes, and the inability of third party manufacturers like ARx, Sharp and LTS to consistently supply quality product when required would have a material adverse effect on our ability to commercialize and sell our products. We have faced risks associated with reliance on key third party manufacturers in the past and may be faced with such risks in the future. Any future manufacturing interruptions or related supply issues could have an adverse effect on our company, including loss of sales and royalty revenue and claims by or against us or our partners for breach of contract.

There are risks associated with our reliance on third parties for managed care, distribution infrastructure and channels.

We expect that we may from time to time choose to enter into agreements with commercial partners to engage in sales, marketing and distribution efforts around our products and product candidates. We may be unable to establish or maintain third-party relationships on a commercially reasonable basis, if at all. In addition, these third parties may have similar or more established relationships with our competitors.

We may be unable to engage qualified distributors. Even if engaged, these distributors may:

- fail to satisfy financial or contractual obligations to us;
- fail to adequately market our formulations or products;
- cease operations with little or no notice to us; or
- offer, design, manufacture or promote competing formulations or products.

If we fail to develop sales, managed care, marketing and distribution channels, we would experience delays in generating sales and incur increased costs, which would harm our financial results.

The class-wide Risk Evaluation and Mitigation Strategy (REMS) for all transmucosal fentanyl products, and similar programs for other narcotic products, may slow sales and marketing efforts for products that contain narcotics, which could impact our royalty and sales revenue from such products.

Our approved product ONSOLIS is formulated with the potent narcotic fentanyl. On December 29, 2011, FDA approved a REMS program covering all transmucosal fentanyl products. The program, which is referred to as the Transmucosal Immediate Release Fentanyl (TIRF) REMS Access Program, was designed to ensure informed risk-benefit decisions before initiating treatment with a transmucosal fentanyl product, and while patients are on treatment, to ensure appropriate use. The approved program covers all approved transmucosal fentanyl products under a single program and was implemented in March 2012. Additionally, 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. BELBUCA falls 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.

There also continues to be a REMS in place for buprenorphine for the treatment of opioid dependence referred to as the BTOD (Buprenorphine-containing Transmucosal products for Opioid Dependence) REMS. BUNAVAIL falls within the existing REMS, which is 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 our products will fit within the existing REMS and will avoid the issues initially encountered with ONSOLIS, where a REMS program was yet to be developed.

Our business and operations could suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems and those of our current and any future partners, contractors, and consultants are vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war, and telecommunication and electrical failures. System failures, accidents, or security breaches could cause interruptions in our operations, and could result in a material disruption of our commercialization activities, development programs and our business operations, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the commercialization of any potential product candidate could be delayed.

Actions of activist shareholders could be disruptive and potentially costly and the possibility that activist shareholders may seek changes that conflict with our strategic direction could cause uncertainty about the strategic direction of our business.

Activist investors may attempt to effect changes in our strategic direction and how our company is governed or may seek to acquire control over our company. Some investors (commonly known as “activist investors”) seek to increase short-term stockholder value by advocating corporate actions such as financial restructuring, increased borrowing, special dividends, stock repurchases, or even sales of assets or the entire company. Activist campaigns can also seek to change the composition of our board of directors, and campaigns that contest or conflict with our strategic direction could have an adverse effect on our results of operations and financial condition as responding to proxy contests and other actions by activist shareholders can disrupt our operations, be costly and time-consuming, and divert the attention of our board of directors and senior management from the pursuit of our business strategies. In addition, perceived uncertainties as to our future direction that can arise from potential changes to the composition of our board of directors sought by activists may lead to the perception of a change in the direction of the business, instability or lack of continuity which may be exploited by our competitors, may cause concern to our current or potential customers, may result in the loss of potential business opportunities and may make it more difficult to attract and retain qualified personnel and business partners. These types of actions could divert our management’s attention from our business or cause significant fluctuations in our stock price based on temporary or speculative market perceptions or other factors that do not necessarily reflect the underlying fundamentals and prospects of our business, all of which could have a material adverse effect on our company.

Risks Related to Our Products in Development and Regulation

We depend in large part on our BEMA drug delivery technology, and the loss of access to this technology would terminate or delay the further development of our products, injure our reputation or force us to pay higher fees.

We depend, in large part, on our BEMA drug delivery technology. The loss of this key technology would seriously impair our business and future viability, and could result in delays in developing, introducing or maintaining our products and formulations until equivalent technology, if available, is identified, licensed and integrated. In addition, any defects in the BEMA technology or other technologies we gain access to in the future could prevent the implementation or impair the functionality of our products or formulations, delay new product or formulation introductions or injure our reputation. If we are required to acquire or enter into license agreements with third parties for replacement technologies, we could be subject to higher fees, milestone or royalty payments, assuming we could access such technologies at all.

Our failure to obtain government approvals, including required FDA approvals, or to comply with ongoing governmental regulations relating to our technologies and proposed products and formulations could delay or limit introduction of our proposed formulations and products and result in failure to achieve revenues or maintain our ongoing business.

Our development activities and the manufacture and marketing of our products and product candidates are subject to extensive regulation for safety, efficacy and quality by numerous government authorities in the United States and abroad. Before receiving FDA or foreign regulatory clearance to market our proposed formulations and products, we will have to demonstrate that our formulations and products are safe and effective in the patient population and for the diseases that are to be treated. Clinical trials, manufacturing and marketing of drugs are subject to the rigorous testing and approval process of the FDA and equivalent foreign regulatory authorities. The Federal Food, Drug and Cosmetic Act and other federal, state and foreign statutes and regulations govern and influence the testing, manufacture, labeling, advertising, distribution and promotion of drugs and medical devices. As a result, regulatory approvals can take a number of years or longer to accomplish and require the expenditure of substantial financial, managerial and other resources.

Our failure to complete or meet key milestones relating to the development of our technologies and proposed products and formulations would significantly impair the viability of our company.

In order to be commercially viable, we must develop, obtain regulatory approval for, manufacture, introduce, market and distribute formulations or products incorporating our technologies. For each drug that we formulate with our drug delivery technologies, we must meet a number of critical developmental milestones, including:

- demonstration of the benefit from delivery of each specific drug through our drug delivery technologies;
- demonstration, through non-clinical and clinical trials, that our drug delivery technologies are safe and effective; and
- establishment of a viable Good Manufacturing Process capable of potential scale-up.

The estimated required capital and time-frames necessary to achieve these developmental milestones is subject to inherent risks, many of which may be beyond our control. As such, we may not be able to achieve these or similar milestones for any of our proposed product candidates or other product candidates in the future. Our failure to meet these or other critical milestones would adversely affect the viability of our company.

If users of our products and product candidates are unable to obtain adequate reimbursement from third-party payers, or if new restrictive legislation is adopted, market acceptance of our proposed formulations or products may be limited and we may not achieve material revenues.

The continuing efforts of government and insurance companies, health maintenance organizations and other payers of healthcare costs to contain or reduce costs of health care may affect our future revenues and profitability, and the future revenues and profitability of our potential customers, suppliers and collaborative partners and the availability of capital. For example, in certain foreign markets, pricing or profitability of prescription pharmaceuticals is subject to government control. In the United States, given recent federal and state government initiatives directed at lowering the total cost of health care, the U.S. Congress and state legislatures will likely continue to focus on health care reform, the cost of prescription pharmaceuticals and on the reform of the Medicare and Medicaid systems. While we cannot predict whether any such legislative or regulatory proposals will be adopted, the announcement or adoption of such proposals and related laws, rules and regulations could materially harm our business, financial conditions, results of operations or stock price. Moreover, the passage of the Patient Protection and Affordable Care Act in 2010, and efforts to amend or repeal such law, has created significant uncertainty relating to the scope of government regulation of healthcare and related legal and regulatory requirements, which could have an adverse impact on sales of our products.

The ability of our company to commercialize BELBUCA and BUNAVAIL, or any partners with which we have a licensing arrangement to sell ONSOLIS will depend in part on the extent to which appropriate reimbursement levels for the cost of our proposed formulations and products and related treatments are obtained by governmental authorities, private health insurers and other organizations, such as HMOs. Consumers and third-party payers are increasingly challenging the prices charged for drugs and medical services. Also, the trend toward managed health care in the United States, which could control or significantly influence the purchase of health care services and drugs, as well as legislative proposals to reform health care or reduce government insurance programs, may all result in lower prices for or rejection of our drugs.

Our business involves environmental risks related to handling regulated substances which could severely affect our ability to develop our drug delivery technology and product candidates.

In connection with our or our partners' clinical development activities, as well as the manufacture of materials and products, we and our partners are subject to federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain materials, biological specimens and wastes. We and our partners may be required to incur significant costs to comply with environmental and health and safety regulations in the future. Our clinical development, as well as the activities of our manufacturing and commercial partners, both now and in the future, may involve the controlled use of hazardous materials, including but not limited to certain hazardous chemicals and narcotics. We cannot completely eliminate the risk of accidental contamination or injury from these materials. In the event of such an occurrence, we could be held liable for any damages that result and any such liability could exceed our resources.

Government and other efforts to reform the healthcare industry could have adverse effects on our company, including the inability of users of our current and future approved products to obtain adequate reimbursement from third-party payers, which could lead to diminished market acceptance of, and revenues from, such products.

Our ability to commercialize BELBUCA, BUNAVAIL and to sell ONSOLIS (once it is reformulated and placed back on the market in the U.S. and Canada), alone or with collaborators, will depend in part on the extent to which coverage and reimbursement for the product will be available from:

- government and health administration authorities;
- private health maintenance organizations and health insurers; and
- other healthcare payers.

Significant uncertainty exists as to the reimbursement status of newly approved healthcare products. The regulations that govern marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. In the United States, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010, or the ACA, is significantly changing the way healthcare is financed by both governmental and private insurers. While we cannot predict what impact on federal reimbursement policies this law or any amendment to it will continue to have in general or specifically on any product that we commercialize, the ACA or any such amendment may result in downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of new products. In addition, although the United States Supreme Court has upheld the constitutionality of most of the ACA, several states have not implemented certain sections of the ACA, including 19 that have rejected the expansion of Medicaid eligibility for low income citizens, and some members of the U.S. Congress are still working to repeal the ACA. More recently, President Trump and the Republican majorities in both houses of the U.S. Congress have been seeking to repeal or replace all or portions of the ACA but to date they have been unable to agree on any such legislation.

The Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain fees mandated by the ACA, including the so-called "Cadillac" tax on certain high cost employer- sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends the ACA, effective January 1, 2019, to increase from 50% to 70% the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". Congress may still consider other legislation to repeal and replace elements of the ACA. We expect that the ACA, as currently enacted or as it may be amended or repealed in the future, and other healthcare reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and on our ability to successfully commercialize our products. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we or our collaborators are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or our collaborators are not able to

maintain regulatory compliance, our products may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

In addition, we are subject to the Federal Drug Supply Chain Security Act of 2013, or the DSCSA. The U.S. government has enacted DSCSA which requires development of an electronic product tracking and tracing of each prescription drug at the salable unit level through the distribution system, which will be effective incrementally over a 10-year period. Compliance with DSCSA and future U.S. federal or state electronic requirements may increase our operational expenses and impose significant administrative burdens.

We may also be subject to healthcare laws, regulation and enforcement; our failure to comply with those laws could have a material adverse effect on our results of operations and financial conditions.

We may also be subject to several healthcare regulations and enforcement by the federal government and the states and foreign governments in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information;
- the federal healthcare programs' Anti-Kickback Law, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;
- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, the exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

Risks Related to Our Common Stock and Non-Voting Convertible Preferred Stock

Our business is subject to increasingly complex corporate governance, public disclosure, and accounting requirements and regulations that could adversely affect our business and financial results and condition.

We are subject to changing rules and regulations of various federal and state governmental authorities as well as the stock exchange on which our common stock is listed. These entities, including the Public Company Accounting Oversight Board, the Securities and Exchange Commission, or the SEC and the Nasdaq Capital Market, have issued a significant number of new and increasingly complex requirements and regulations over the course of the last several years and continue to develop additional requirements and regulations in response to laws enacted by Congress, including the Sarbanes-Oxley Act of 2002 and, most recently, the Dodd-Frank Wall Street Reform and Protection Act, or the Dodd-Frank Act.

There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act that expressly authorized or required the SEC to adopt additional rules in these areas, such as an advisory shareholder vote to approve of our executives' compensation (or Say on Pay), proxy access, and an advisory shareholder vote on how often we should include a Say on Pay proposal in our proxy materials for future annual shareholder meetings or any special shareholder meeting for which we must include executive compensation information in the proxy statement for that meeting. Our efforts to comply with these requirements are likely to result in an increase in expenses which is difficult to quantify at this time.

In addition, we are subject to often complex accounting rules and interpretations promulgated by the Financial Accounting Standards Board (including its Emerging Issues Task Force). We have faced challenges of compliance with accounting rules in the

past and may face such challenges in the future, and adjustments to or restatements of our financial statements or accounting policies based on such challenges could have a material adverse effect on our public stock price and our reputation.

Our stock price is subject to market factors and market volatility, both generally and with respect to our industry and our company specifically. As such, there is a risk that your investment in our common stock could fluctuate in value.

The overall market for securities in recent years has experienced extreme price and volume fluctuations that have particularly affected the market prices of many smaller companies. In particular, the market prices of securities of biotechnology and pharmaceutical companies have been extremely volatile and have experienced fluctuations that often have been unrelated or disproportionate to operating performance of these companies. These broad market fluctuations (as well as market reactions to particular developments with our company) have and could continue to result in extreme fluctuations in the price of our common stock, which could cause a decline in the value of your common stock. These fluctuations, as well as general economic and market conditions, may have a material or adverse effect on the market price of our common stock.

Our Series A Non-Voting Convertible Preferred Stock ranks senior to our common stock in the event of a bankruptcy, liquidation or winding up of our assets.

As of the date of this Report, we currently have 2,709,300 issued and 2,093,155 outstanding shares of Series A Non-Voting Convertible Preferred Stock ("Series A"), which we issued in connection with our $40 million financing which closed on December 2012. In the event of our bankruptcy, liquidation or winding up, our assets will be available to pay obligations on our Series A in preference to the holders of our common stock.

Our Series B Non-Voting Convertible Preferred Stock ranks senior to our common stock in the event of a bankruptcy, liquidation or winding up of our assets.

As of the date of this Report, we currently have 5,000 issued and 3,100 outstanding shares of Series B Non-Voting Convertible Preferred Stock ("Series B"), which is convertible into 17,222,223 shares of our Company Common Stock. We issued the Series B in connection with our $50 million registered direct offering which closed on May 22, 2018. In the event of our bankruptcy, liquidation or winding up, our assets will be available to pay obligations on our Series B Non-Voting Convertible Preferred Stock, which ranks on par with Series A, in preference to the holders of our common stock.

Additional authorized shares of our common stock and preferred stock available for issuance may adversely affect the market for our common stock.

As of March 14, 2019, there are 70,968,435 shares of common stock issued and 70,952,944 shares of common stock outstanding. Additionally, there were 2,709,300 shares issued and 2,093,155 shares outstanding of Series A and 5,000 shares issued and 3,100 shares outstanding of Series B. On August 2, 2018, our stockholders approved an amendment to our certificate of incorporation to increase the number of authorized shares of common stock, par value $.001, of our common stock from 75,000,000 to 125,000,000 shares. This increase in our authorized shares of common stock provides us with the flexibility to issue more shares in the future, which might cause dilution to our stockholders. In addition, the total number of shares of our common stock issued and outstanding does not include shares reserved in anticipation of the exercise of outstanding options or warrants. To the extent such options (including options under our stock incentive plan) or warrants are exercised, the holders of our common stock may experience further dilution.

Moreover, in the event that any future financing should be in the form of, be convertible into or exchangeable for, equity securities, and upon the exercise of options and warrants, investors would experience additional dilution. Finally, in addition to the above referenced shares of common stock which may be issued without stockholder approval, we have 5 million shares of authorized preferred stock, of which 2,709,300 shares have been designated as Series A and 5,000 have been designated as Series B. The remaining 2,285,700 shares of preferred stock remain undesignated shares of preferred stock, the terms of which may be fixed by our board of directors. We have issued preferred stock in the past, and our board of directors has the authority, without stockholder approval, to create and issue one or more additional series of such preferred stock and to determine the voting, dividend and other rights of holders of such preferred stock. The issuance of any of such series of preferred stock may have an adverse effect on the holders of common stock.

Additionally, on November 9, 2018, we filed a shelf registration statement (as amended on January 18, 2019) which registered up to $75 million of our securities for potential future issuance and such registration statement became effective on February 7, 2019. To the extent we issue such shares of stock under this registration statement, the current holders of our common stock may experience further dilution.

Shares eligible for future sale may adversely affect the market for our common stock.

We have a material number of shares of common stock underlying securities of our company, the future sale of which could depress the price of our publicly-traded stock. As of March 14, 2019: (i) 5,629,608 shares of common stock are issuable upon exercise

of outstanding stock options at a weighted average exercise price of $3.34 per share, (ii) 2,302,018 restricted stock units eligible to be converted shares of our common stock (iii) 2,093,155 shares of Series A eligible to be converted into shares of our common stock (iv) 3,100 Series B eligible to be converted into shares of our common stock and (v) 2,136,020 common stock shares underlying outstanding warrants at an average exercise price of $2.60 per share.

In addition, from time to time, certain of our stockholders may be eligible to sell all or some of their shares of common stock by means of ordinary brokerage transactions in the open market pursuant to Rule 144, promulgated under the Securities Act of 1933, as amended, which we refer to herein as the Securities Act, subject to certain limitations. In general, pursuant to Rule 144, after satisfying a six month holding period: (i) affiliated stockholder (or stockholders whose shares are aggregated) may, under certain circumstances, sell within any three month period a number of securities which does not exceed the greater of 1% of the then outstanding shares of common stock or the average weekly trading volume of the class during the four calendar weeks prior to such sale and (ii) non-affiliated stockholders may sell without such limitations, provided we are current in our public reporting obligations. Rule 144 also permits the sale of securities by non-affiliates that have satisfied a one year holding period without any limitation or restriction. Any substantial sale of our common stock pursuant to Rule 144 or pursuant to any resale report may have a material adverse effect on the market price of our securities.

Furthermore, sales of our common stock by our directors, officers, or employees may occur as a result of sales effected pursuant to predetermined trading plans adopted under the safe-harbor afforded by SEC Rule 10b5-1.

Our certificate of incorporation and bylaws contain provisions that may discourage, delay or prevent a change in our management team that stockholders may consider favorable.

Our certificate of incorporation, as amended, our amended and restated bylaws (which were adopted in 2010 and as amended and restated in 2017 and 2018) and Delaware law contain provisions that may have the effect of preserving our current management, such as:

- authorizing the issuance of "blank check" preferred stock without any need for action by stockholders;
- limiting the ability of stockholders to call special meetings of stockholders;
- permitting stockholder action by written consent;
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings;
- requiring a super-majority vote of our stockholders to remove directors of our company; and
- providing that our stockholders may only remove our directors for "cause" (as defined in our bylaws).

These provisions affect your rights as a stockholder since they permit our board of directors to make it more difficult for common stockholders to replace members of the board or undertake other significant corporate actions. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt to replace our current management team.

The financial and operational projections that we may make from time to time are subject to inherent risks.

The projections that our management may provide from time to time (including, but not limited to, those relating to potential peak sales amounts, production and supply dates, and other financial or operational matters) reflect numerous assumptions made by management, including assumptions with respect to our specific as well as general business, economic, market and financial conditions and other matters, all of which are difficult to predict and many of which are beyond our control. Accordingly, there is a risk that the assumptions made in preparing the projections, or the projections themselves, will prove inaccurate. There will be differences between actual and projected results, and actual results may be materially different from those contained in the projections. The inclusion of the projections in (or incorporated by reference in) this Report should not be regarded as an indication that we or our management or representatives considered or consider the projections to be a reliable prediction of future events, and the projections should not be relied upon as such.

We do not intend to pay dividends on our common stock.

We have never declared or paid any cash dividend on our capital stock. We currently intend to retain any future earnings and do not expect to pay any dividends for the foreseeable future. Therefore, you should not invest in our common stock in the expectation that you will receive dividends.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Description of Property.

Our corporate headquarters is located in Raleigh, North Carolina. We moved into our current headquarters in February 2015. The lease for this office, which commenced November 14, 2014 for 89 months, is approximately 12,000 square foot space and has remaining base rent of $1.3 million payable through July 2022. Rent is payable in monthly installments and is subject to yearly price increases and increases for our share of common area maintenance costs. The landlord for this space is HRLP Raleigh, L.P. We believe this space is adequate as our principal executive office location.

Item 3. Legal Proceedings.

Readers are advised that the following disclosure regarding our ongoing litigations with MonoSol RX, dba Aquestive Therapeutics and Reckitt Benckiser is intended to provide some background and an update on the matter as required by the rules of the SEC. Additional details regarding the past procedural history of the matter can be found in our previously filed periodic filings with the SEC.

Indivior PLC (formerly RB Pharmaceuticals Ltd.) and Aquestive Therapeutics (formerly MonoSol Rx)

Litigation related to BUNAVAIL

On October 29, 2013, Reckitt Benckiser, Inc., RB Pharmaceuticals Limited, and Aquestive (collectively, the RB Plaintiffs) filed an action against us relating to our BUNAVAIL product in the United States District Court for the Eastern District of North Carolina ("EDNC") for alleged patent infringement. BUNAVAIL is a drug approved for the maintenance treatment of opioid dependence. The RB Plaintiffs claim that the formulation for BUNAVAIL, which has never been disclosed publicly, infringes its US Patent No. 8,475,832 (the '832 Patent). On May 21, 2014, the Court granted our motion to dismiss.

On January 22, 2014, Aquestive initiated an *inter partes* review ("IPR") on U.S. Patent No. 7,579,019, the '019 Patent. The PTAB upheld all claims of our '019 Patent in 2015 and this decision was not appealed by Aquestive.

On September 20, 2014, we proactively filed a declaratory judgment action in the United States District Court for the EDNC requesting the Court to make a determination that our BUNAVAIL product does not infringe the '832 Patent, US Patent No. 7,897,080 (the "'080 Patent") and US Patent No. 8,652,378 (the "'378 Patent"). We invalidated the "'080 Patent" in its entirety in an *inter partes* reexamination proceeding. We invalidated all relevant claims of the '832 Patent in an IPR proceeding. And, in an IPR proceeding for the '378 Patent, in its decision not to institute the IPR proceeding the PTAB construed the claims of the '378 Patent narrowly. Shortly thereafter, by joint motion of the parties, the '378 Patent was subsequently removed from the action.

On June 6, 2016, in an unrelated case in which Indivior and Aquestive asserted the '832 Patent against other parties, the Delaware District Court entered an order invalidating other claims in the '832 Patent. Indivior and Aquestive cross-appealed all adverse findings in that decision to the Court of Appeals for the Federal Circuit in Case No. 17-2587. Our declaratory judgment action remains stayed pending the outcome of that cross-appeal by Indivior and Aquestive.

On September 22, 2014, the RB Plaintiffs filed an action against us (and our commercial partner) relating to our BUNAVAIL product in the United States District Court for the District of New Jersey for alleged patent infringement. The RB Plaintiffs claim that BUNAVAIL, whose formulation and manufacturing processes have never been disclosed publicly, infringes its patent U.S. Patent No. 8,765,167 (the '167 Patent. As with prior actions by the RB Plaintiffs, we believe this is another anticompetitive attempt by the RB Plaintiffs to distract our efforts from commercializing BUNAVAIL. We strongly refute as without merit the RB Plaintiffs' assertion of patent infringement. On our motion, this case was transferred to the Eastern District of North Carolina. A Joint Motion to Stay the case was granted and the case is now stayed until a final resolution of the '167 IPRs discussed directly below. We will continue to vigorously defend this case.

On October 28, 2014, we filed multiple IPR petitions on certain claims of the '167 Patent. The USPTO instituted three of the four IPR petitions. The PTAB upheld the claims and denied collateral estoppel applied to the PTAB decisions in March 2016. We appealed to Court of Appeals for the Federal Circuit. The USPTO intervened with respect to whether collateral estoppel applied to the PTAB. On June 19, 2018, we filed a motion to remand the case for further consideration by the PTAB in view of intervening authority. On July 31, 2018, the Federal Circuit vacated the decisions, and remanded the '167 Patent IPRs for further consideration on the merits.

Litigation related to BELBUCA

On January 13, 2017, Aquestive filed a complaint in the United States District Court for the District of New Jersey alleging BELBUCA infringes the '167 Patent. In lieu of answering the complaint, we filed motions to dismiss the complaint and, in the

alternative, to transfer the case to the EDNC. On July 25, 2017, the New Jersey Court administratively terminated the case pending the parties submission of a joint stipulation of transfer because the District of New Jersey was an inappropriate venue. This case was later transferred to the Delaware District Court. On October 31, 2017 we filed motions to dismiss the complaint and, in the alternative, to transfer the case to the EDNC. On October 16, 2018, denying the motion to dismiss as moot, the Delaware District Court granted our motion to transfer the case to the EDNC. The case is now pending in the EDNC. We strongly refute as without merit Aquestive's assertion of patent infringement and will vigorously defend the lawsuit.

Teva Pharmaceuticals USA (formerly Actavis)

On February 8, 2016, we received a notice relating to a Paragraph IV certification from Teva Pharmaceuticals USA, or Teva, (formerly Actavis) seeking to find invalid three Orange Book listed patents relating specifically to BUNAVAIL. The Paragraph IV certification related to an ANDA filed by Teva with the FDA for a generic formulation of BUNAVAIL. The patents subject to Teva's certification were the '019 Patent, U.S. Patent No. 8,147,866 (the "'866 Patent") and 8,703,177 (the "'177 Patent").

On March 18, 2016, we asserted three different patents against Teva, the '019 Patent, the '866 Patent, and the '177 Patent. Teva did not raise non-infringement positions about the '019 and the '866 Patents in its Paragraph IV certification. Teva did raise a non-infringement position on the '177 Patent but we asserted in our complaint that Teva infringed the '177 Patent either literally or under the doctrine of equivalents.

On December 20, 2016 the USPTO issued U.S. Patent No. 9,522,188 ("the '188 Patent"), and this patent was properly listed in the Orange Book as covering the BUNAVAIL product. On February 23, 2017 Teva sent a Paragraph IV certification adding the 9,522,188 to its ANDA. An amended Complaint was filed, adding the '188 Patent to the litigation.

On January 31, 2017, we received a notice relating to a Paragraph IV certification from Teva relating to Teva's ANDA on additional strengths of BUNAVAIL and on March 16, 2017, we brought suit against Teva and its parent company on these additional strengths. On June 20, 2017, the Court entered orders staying both BUNAVAIL suits at the request of the parties.

On May 23, 2017, the USPTO issued U.S. Patent 9,655,843 (the "'843 Patent") relating to the BEMA technology, and this patent was properly listed in the Orange Book as covering the BUNAVAIL product.

Finally, on October 12, 2017, we announced that we had entered into a settlement agreement with Teva that resolved our BUNAVAIL patent litigation against Teva pending in the U.S. District Court for the District of Delaware. As part of the Settlement Agreement, which is subject to review by the U.S. Federal Trade Commission and the U.S. Department of Justice, we have entered into a non-exclusive license agreement with Teva that permits Teva to first begin selling its generic version of BUNAVAIL in the U.S. on July 23, 2028 or earlier under certain circumstances. Other terms of the agreement are confidential.

We received notices regarding Paragraph IV certifications from Teva on November 8, 2016, November 10, 2016, and December 22, 2016, seeking to find invalid two Orange Book listed patents relating specifically to BELBUCA. The Paragraph IV certifications relate to three ANDAs filed by Teva with the FDA for a generic formulation of BELBUCA. The patents subject to Teva's certification were the '019 Patent and the '866 Patent. We filed complaints in Delaware against Teva on December 22, 2016 and February 3, 2017 in which we asserted against Teva the '019 Patent and the '866 Patent. Teva did not contest infringement of the claims of the '019 Patent and did not contest infringement of the claims of the '866 Patent.

The '019 Patent had already been the subject of an unrelated IPR before the USPTO under which we prevailed, and all claims of the '019 Patent survived. Aquestive's request for rehearing of the final IPR decision regarding the '019 Patent was denied by the USPTO on December 19, 2016. Aquestive did not file a timely appeal at the Federal Circuit.

On May 23, 2017, the USPTO issued U.S. Patent 9,655,843 (the "'843 Patent") relating to the BEMA technology, and this patent was properly listed in the Orange Book as covering the BELBUCA product.

On August 28, 2017, the Court entered orders staying both BELBUCA suits at the request of the parties.

In February 2018, we announced that we had entered into a settlement agreement with Teva that resolved our BELBUCA patent litigation against Teva pending in the U.S. District Court for the District of Delaware. As part of the settlement agreement, which is subject to review by the U.S. Federal Trade Commission and the U.S. Department of Justice, we have granted Teva a non-exclusive license (for which we will receive no current or future payments) that permits Teva to first begin selling the generic version of our BELBUCA product in the U.S. on January 23, 2027 or earlier under certain circumstances (including, for example, upon (i) the delisting of the patents-in-suit from the U.S. FDA Orange Book, (ii) the granting of a license by us to a third party to launch another

generic form of BELBUCA at a date prior to January 23, 2027, or (iii) the occurrence of certain conditions regarding BELBUCA market share). Other terms of the Agreement are confidential.

Alvogen

On September 7, 2018, we filed a complaint for patent infringement in Delaware against Alvogen Pb Research & Development LLC, Alvogen Malta Operations Ltd., Alvogen Pine Brook LLC, Alvogen, Incorporated, and Alvogen Group, Incorporated (collectively, "Alvogen"), asserting that Alvogen infringes our Orange Book listed patents for BELBUCA, including U.S. Patent Nos. 8,147,866 and 9,655,843, both expiring in July of 2027, and U.S. Patent No. 9,901,539, expiring in December of 2032. This complaint follows receipt by us on July 30, 2018 of a Paragraph IV Patent Certification from Alvogen stating that Alvogen had filed an ANDA with the FDA for a generic version of BELBUCA Buccal Film (75 mcg, 150 mcg, 300 mcg, 450 mcg, 600 mcg, 750 mcg and 900 mcg). Because we initiated a patent infringement suit to defend the patents identified in the Paragraph IV notice within 45 days after receipt of the Paragraph IV Certification, the FDA is prevented from approving the ANDA until the earlier of 30 months or a decision in the case that each of the patents is not infringed or invalid. Alvogen's notice letter also does not provide any information on the timing or approval status of its ANDA.

In its Paragraph IV Certification, Alvogen does not contest infringement of at least several independent claims of each of the '866, '843, and '539 patents. Rather, Alvogen advances only invalidly arguments for these independent claims. We believe that we will be able to prevail on our claims of infringement of these patents, particularly as Alvogen does not contest infringement of certain claims of each patent. Additionally, as we have done in the past, we intend to vigorously defend our intellectual property against assertions of invalidity. Each of the three patents carry a presumption of validity, which can only be overcome by clear and convincing evidence.

2018 Arkansas Opioid Litigation

On March 15, 2018, the State of Arkansas, and certain counties and cities in that State, filed an action in the Circuit Court of Arkansas, Crittenden County against multiple manufacturers, distributors, retailers, and prescribers of opioid analgesics, including our company. We were served with the complaint on April 27, 2018. The complaint specifically alleged that we licensed our branded fentanyl buccal soluble film ONSOLIS to Collegium, and Collegium is also named as a defendant in the lawsuit. ONSOLIS is not presently sold in the United States and the license agreement with Collegium was terminated prior to Collegium launching ONSOLIS in the United States. Therefore, on June 28, 2018, we moved to dismiss the case against us and most recently, on July 6, 2018, the plaintiffs filed a notice to voluntarily dismiss us from the Arkansas case, without prejudice.

Chemo Research, S.L

On March 1, 2019, we filed a complaint for patent infringement in Delaware against Chemo Research, S.L., Insud Pharma S.L., IntelGenx Corp., and IntelGenx Technologies Corp. (collectively, "Defendants"), asserting that the Defendants infringe our Orange Book listed patents for BELBUCA, including U.S. Patent Nos. 8,147,866 and 9,655,843, both expiring in July of 2027, and U.S. Patent No. 9,901,539 expiring December of 2032. This complaint follows a receipt by us on January 31, 2019, of a Notice Letter from Chemo Research S.L. stating that it has filed with the FDA an ANDA containing a Paragraph IV Patent Certification, for a generic version of BELBUA Buccal Film in strengths 75 mcg, 150 mcg, 300 mcg, 450 mcg, and 900 mcg. Because we initiated a patent infringement suit to defend the patents identified in the Notice Letter within 45 days after receipt, the FDA is prevented from approving the ANDA until the earlier of 30 months or a decision in the case that each of the patents is not infringed or invalid. Chemo Research S.L.'s Notice Letter also does not provide any information on the timing or approval status of its ANDA.

We believe that we will be able to prevail in this lawsuit. As we have done in the past, we intend to vigorously defend our intellectual property against assertions of invalidity.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

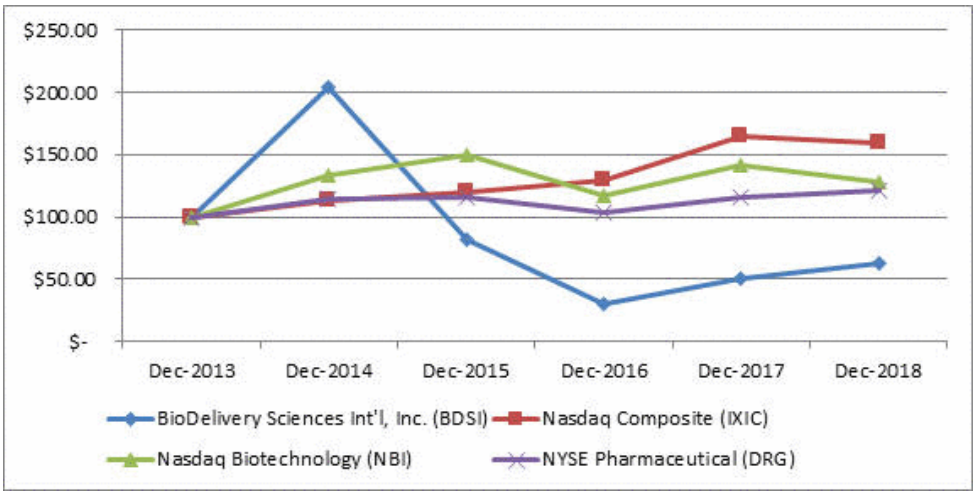
Our common stock is listed for quotation on the NASDAQ Capital Market under the symbol "BDSI".

As of March 14, 2019, we had approximately 118 holders of record of our common stock. No cash dividends have been paid on the common stock to date. We currently intend to retain earnings for further business development and do not expect to pay cash dividends in the foreseeable future.

Performance Graph

The following graph shows a comparison of the five-year total cumulative returns of an investment of $100 in cash on December 31, 2013 in (i) our common stock (ii) the Nasdaq Composite Index (iii) the Nasdaq Biotechnology Index and (iv) the NYSE Pharmaceutical Index. All values assume reinvestment of the full amount of all dividends (to date, we have not declared any dividends).

This stock performance graph shall not be deemed "filed" with the SEC or subject to Section 18 of the Securities Exchange Act, nor shall it be deemed incorporated by reference in any of our filings under the Securities Act of 1933, as amended (the "Securities Act"). Comparison of cumulative total return on investment since December 31, 2013:



	12/31/2013	12/31/2014	12/31/2015	12/31/2016	12/31/2017	12/31/2018
BioDelivery Sciences Int'l, Inc.	$ 100.00	$ 204.07	$ 81.32	$ 29.71	$ 50.08	$ 62.82
Nasdaq Composite (U.S. Companies)	100.00	113.40	119.89	128.89	165.29	158.87
Nasdaq Biotechnology	100.00	134.10	149.42	117.02	141.66	128.45
NYSE Pharmaceutical	100.00	113.83	115.67	102.88	116.42	121.52

Item 6. Selected Financial Data.

The statements of operations data and statements of cash flows data for the years ended December 31, 2018, 2017 and 2016 and the balance sheet data as of December 31, 2018 and 2017 have been derived from our audited consolidated financial statements included elsewhere in this annual report. The statements of operations data and statements of cash flows data for the years ended December 31, 2015 and 2014 and the balance sheet data as of December 31, 2016, 2015 and 2014 have been derived from our audited consolidated financial statements not included in this annual report. The following selected financial data should be read in conjunction with our "Management's Discussion and Analysis of Financial Condition and Results of Operations" and consolidated financial statements and related notes beginning on page F-1 and other financial information included in this Report.

	2018	2017	2016	2015	2014
Statements of Operations Data:					
Total revenue (1)	$ 55,640	$ 61,985	$ 15,546	$ 48,231	$ 38,944
Operating loss	(23,648)	(29,420)	(63,935)	(35,179)	(38,740)
Net (loss) income (2) (3)	(46,367)	5,285	(67,138)	(37,672)	(54,218)
Diluted net (loss) income per share	(0.73)	0.09	(1.25)	(0.72)	(1.12)
Balance Sheet Data:					
Cash, short-term and long-term investments	$ 43,822	$ 21,195	$ 32,019	$ 83,560	$ 70,472
Total assets (4)	108,533	88,101	51,720	102,772	88,840
Long-term liabilities	57,252	53,075	50,097	42,993	4,402
Accumulated deficit	(351,288)	(305,056)	(310,341)	(243,203)	(205,531)
Total stockholders' equity (deficit)	29,742	8,877	(17,665)	31,696	54,396
Statements of Cash Flows Data:					
Net cash flows from operating activities	$ (24,113)	$ (32,451)	$ (53,982)	$ (3,732)	$ (28,833)

(1) Total revenue in 2017 includes $20 million in contract revenue from Endo related to a patent extension that was previously recorded as deferred revenue because all or a portion of such $20 million was contingently refundable to Endo if a third party generic product was introduced in the U.S. during the patent extension period from 2020 to 2027. However, due to us and Endo entering into a termination agreement which terminated the BELBUCA license to Endo effective January 6, 2017, the deferred $20 million was recognized as revenue in January 2017.

(2) Net loss in 2018 includes the deemed dividend related to the beneficial conversion feature in Series B Preferred Stock of $12.5 million.

(3) Net loss in 2017 includes the bargain purchase gain of the BELBUCA acquisition from Endo totaling $27.3 million, recorded as income in January 2017.

(4) Total assets for the year ended December 31, 2017 includes the value of the BELBUCA license and distribution rights intangible asset, net, totaling $40.5 million.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes appearing elsewhere in this Report. This discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. The actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, including, but not limited to, those which are not within our control.

Our Strategy

Our strategy is evolving with the establishment of our commercial footprint in the management of chronic pain; we seek to build a well-balanced, diversified, high-growth specialty pharmaceutical company. Through our industry-leading commercialization infrastructure, BDSI is executing the commercialization of our existing products. As part of our corporate growth strategy, we have licensed, and will continue to explore opportunities to acquire or license additional products that meet the needs of patients living with debilitating chronic conditions and treated primarily by therapeutic specialists. As we gain access to these drugs and technologies, we will employ our commercialization experience to bring them to the marketplace. With a strong commitment to patient access and a focused business-development approach for transformative acquisitions or licensing opportunities, we will leverage our experience and apply it to developing new partnerships that enable us to commercialize novel products that can change the lives of people suffering from debilitating chronic conditions.

Our historical clinical and regulatory development strategy has focused primarily on our ability to use the U.S. Food and Drug Administration, or 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, with less regulatory approval risk than other FDA-approval approaches.

Our Company

We are a publicly listed company. Our common stock is listed on The Nasdaq Capital Market under the symbol "BDSI." We were incorporated in the state of Indiana in 1997 and reincorporated as a Delaware-based corporation in 2002.

2018 and Beyond Highlights

- On February 6, 2018, we announced that we had entered into a Settlement Agreement with Teva that resolves our previously reported BELBUCA patent litigation against Teva pending in the United States District Court for the District of Delaware.
- On May 7, 2018, we announced the appointment of Herm Cukier as our new Chief Executive Officer and member of our board of directors, effective as of May 8, 2018.
- On May 22, 2018, we announced the closing of the $50 million registered direct offering of newly designated Series B Stock. The offering closed on May 21, 2018, yielding net proceeds of $8048.0 million to BDSI. As part of the financing closing, Broadfin Managing Partner Kevin Kotler joined our board, along with Todd Davis and Peter Greenleaf. Furthermore, Peter Greenleaf has been named Chairman of our Board of Directors. In addition, and effective as of the closing, Thomas W. D'Alonzo, Barry I. Feinberg, Samuel P. Sears, Jr. and Timothy C. Tyson have each resigned and retired from the Board.
- On July 20, 2018, we extended an offer to Dr. Thomas Smith, as our Chief Medical Officer and member of our Executive Leadership Team effective July 30, 2018.
- On August 2, 2018, in connection with our 2018 Annual Meeting of Stockholders, our stockholders approved, among other matters, (i) amending our Certificate of Incorporation to increase the number of authorized shares of Common Stock from 75,000,000 to 125,000,000; and (ii) to ratify the issuance and sale of our Series B Preferred Stock, par value $.001 per share, and to approve the issuance of Common Stock issuable upon the conversion of the Series B Preferred Stock as required by and in accordance with NASDAQ Marketplace Rule 5635(d).
- On October 29, 2018, we announced the appointment of James Vollins as General Counsel and member of our Executive Leadership Team effective November 5, 2018. Mr. Vollins serves as our Chief Compliance Officer and Corporate Secretary. We also announced the enhanced title of Scott Plesha to President and Chief Commercial Officer of the Company.

- On November 9, 2018, we filed a shelf registration statement (as amended on January 18, 2019) which registered up to $150 million of our securities for potential future issuance and such registration statement was became effective on February 7, 2019.
- On January 15, 2019, we announced the appointment of Terry Coelho as Chief Financial Officer. Ms. Coelho will also serve as our principal financial officer and principal accounting officer. Ms. Coelho replaced Ernest De Paolantonio in these positions effective as of January 15, 2019. Mr. De Paolantonio will remain at our Company past such date in order to allow for an orderly transition.
- On February 4, 2019 – we announced that a leading national managed care organization has moved BELBUCA into preferred status across all its commercial formularies from its previous position of not-covered effective February 1, 2019. In addition, patients will no longer require a prior authorization to receive their BELBUCA script. This significant improvement in access for more than 7 million covered lives brings the total of Americans with preferred access for BELBUCA to more than 115 million.

Our Products and Related Trends

Our product portfolio currently consists of four products. As of the date of this report, three products are approved by the FDA; the fourth product, while we are not actively studying it at this time, we are evaluating further development opportunities. The three approved products utilize our patented BEMA thin film drug delivery technology.

- **BELBUCA** is indicated for the management of chronic pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. This product was originally licensed on a worldwide basis to Endo. On October 26, 2015, we announced with Endo that the FDA approved BELBUCA. BELBUCA was launched by Endo in February 2016. On December 7, 2016, we entered into an agreement with Endo terminating Endo's licensing of rights for BELBUCA. This followed a strategic decision made by Endo to discontinue commercial efforts in the branded pain business. On January 6, 2017, we announced the closing of the transaction to reacquire the license to BELBUCA from Endo. As a result, the worldwide rights to BELBUCA were transferred back to us. Behind a revised commercialization plan, we are leveraging our existing sales force to capitalize on commercial synergies with BUNAVAIL. This effort is a focused commercial approach targeting identified healthcare providers which we believe create the potential to incrementally grow BELBUCA sales without the requirement for significant resources. We also will explore other options for longer-term growth for BELBUCA. Since the initial launch in February 2017, we further expanded our sales force beginning in January 2018 and again in September to support the commercialization efforts. BELBUCA and BUNAVAIL are currently supported by a field force of approximately 113 sales representatives, thirteen regional sales managers and two area directors. As previously disclosed, the launch has been more challenging because of the increased scrutiny over the prescribing of opioids that is driven by the Centers for Disease Control and Prevention guidelines issued in March 2016. The difference that BELBUCA as Schedule III offers over Schedule II opioids, such as oxycodone, hydrocodone, morphine, etc., include higher safety index, lower addiction, diversion and abuse risks accompanied by a dose-ceiling effect on respiratory depression, but not on analgesia. The approval of BELBUCA carries a standard post-approval requirement by the FDA to conduct a study to determine the effect of BELBUCA on QT prolongation (i.e. an abnormal lengthening of the heartbeat). Also required is a study assessing the safety and efficacy of BELBUCA in pediatric patients and participation in a consortium with other holders of NDAs for long-acting opioids to assess and better understand the risk of abuse, misuse, addiction and overdose with opioids. Both studies are pending. Prescription sales of BELBUCA have significantly increased since promotion began.
- **BUNAVAIL** was approved by the FDA in June 2014 and is indicated for the treatment of opioid dependence. BUNAVAIL uses our BEMA technology combined with buprenorphine in tandem with naloxone, an opioid antagonist. We are commercializing BUNAVAIL ourselves and launched the product during the fourth quarter of 2014. We have been actively engaged in efforts to optimize our commercialization of BUNAVAIL with particular emphasis in 2016 on better aligning costs with revenue and reducing spending. We will seek to continue to manage our BUNAVAIL business by focusing sales efforts on those healthcare providers who have been prescribers of BUNAVAIL. And we will continue to use published data demonstrating "diversion" (i.e., the illicit use of a legally prescribed controlled substance) associated with the market leader's product and highlight the other attributes of BUNAVAIL as we seek to win additional managed care contracts. We also believe there will be an opportunity to introduce more patients to BUNAVAIL with the lifting of the long-standing limit on the number of buprenorphine-treated patients per practitioner from 100 to 275 (as outlined in the final ruling under the Drug Addiction Treatment Act of 2000, or DATA 2000, and effective on October 27, 2016), and a more recent legislation allowing nurse practitioners and physician assistants to prescribe buprenorphine for opioid dependence. We will continue to closely monitor commercial efforts and seek to increase revenue and profitability, as well as evaluate all options available to preserve the long-term prospects for and maximize the value of BUNAVAIL. Separately, as with all other buprenorphine-containing products for opioid dependence, the approval of BUNAVAIL

carries a standard post-approval requirement by the FDA to conduct a study to determine the effect of BUNAVAIL on QT prolongation.

- **ONSOLIS** is approved in the U.S., the EU (where it is marketed as BREAKYL) and Taiwan (where it is marketed as PAINKYL), for the management of breakthrough pain in opioid tolerant adult patients with cancer. ONSOLIS utilizes our BEMA thin film drug delivery technology in combination with fentanyl. The commercial rights to ONSOLIS were originally licensed to Mylan, a subsidiary of Mylan N.V., in 2006 and 2007 for all territories worldwide except for Taiwan (where it is licensed to TTY) and South Korea. The marketing authorization for ONSOLIS was returned to us in early 2015 as part of an assignment and revenue sharing agreement with Mylan for the United States, Canada and Mexico. Such agreement also facilitated the approval of a new formulation of ONSOLIS in the U.S. We are currently assessing our commercial options for ONSOLIS. On January 27, 2015, we announced that we had entered into an assignment and revenue sharing agreement with Mylan to return to us the marketing authorizations for ONSOLIS for the U.S. and the right to seek marketing authorizations for ONSOLIS in Canada and Mexico. On May 11, 2016, we announced the signing of a licensing agreement under which we granted the exclusive rights to commercialize ONSOLIS in the U.S. to Collegium. Under terms of the agreement, Collegium was responsible for the manufacturing, distribution, marketing and sales of ONSOLIS in the U.S. Mylan continues to commercialize ONSOLIS under the brand name BREAKYL in the E.U. However, on December 8, 2017, Collegium provided us the required 90-day notice regarding termination of the license and development agreement for ONSOLIS between us and Collegium. The license and development agreement for ONSOLIS between us and Collegium formally ended on March 8, 2018. Previous efforts to extend our supply agreement with our original ONSOLIS manufacturer Aveva, who was subsequently acquired by Apotex, were unsuccessful and the agreement expired. However, an alternate supplier was identified and data to support qualification of the new manufacturer was submitted to the FDA in June 2018. On October 22, 2018, we received notification of FDA's approval of the regulatory submission and the new ONSOLIS manufacturer. We are currently assessing options to commercialize ONSOLIS including partnership or introducing ONSOLIS utilizing the company's existing pain sales force.
- **Buprenorphine Extended Release Injection** is an injectable, extended-release, microparticle formulation of buprenorphine for the treatment of opioid dependence and chronic pain, the rights to which were secured when we entered into a definitive development and exclusive license option agreement from Evonik in October 2014. In 2015, we completed initial development work and preclinical studies which have resulted in the identification of a formulation we believe can provide 30 days of continuous buprenorphine treatment. We submitted an IND for this product candidate to the FDA in December 2016. Subsequently, the agreement has terminated and the options granted therein have expired. We continue to evaluate whether or not to further advance this particular program.

We expect to continue our development of pharmaceutical products and related drug delivery technologies, some of which will be funded by our commercialization agreements. We will continue to seek additional license agreements, which may include upfront payments. We anticipate that funding for the next several years will come primarily from earnings from sales of BELBUCA and BUNAVAIL, milestone payments and royalties from Mylan and TTY, potential sales of securities and collaborative development agreements, including those with pharmaceutical companies.

We have, since our founding, received revenue in the form of: (i) product sales from our BELBUCA and BUNAVAIL products, (ii) contract revenue from Endo related to an upfront, non-refundable payment for a license of our BELBUCA product in 2012, (iii) payment from Endo for certain patent-related milestones (iv) royalty revenue from Mylan for sales of BREAKYL and ONSOLIS, (vi) upfront non-refundable license and milestone payments from Mylan in 2007, 2008, 2009 and 2012 (vi) contract revenue from Endo related to two full database locks in 2014, (vii) contract revenue from Endo upon FDA acceptance of the filed NDA of our BELBUCA product in 2015 and subsequent regulatory approval, (viii) and sponsored research revenue from both Endo and Mylan. Only the BELBUCA and BUNAVAIL product sales and BREAKYL royalty revenues have the potential to be repeating or predictable.

Readers are cautioned that period-to-period comparisons of our operating results should not be relied upon as predictive of future performance. Our prospects must be considered in light of the risks, expenses and difficulties normally encountered by companies that are involved in the commercialization of their products and related technologies, particularly companies in new and rapidly changing markets such as pharmaceuticals, drug delivery and biotechnology. We must maintain our relationships with our key commercial partners and address regulatory, legal and/or commercial issues and risks that relate to our business from time to time, many of which could impact, perhaps negatively, our planned operations. We may not be able to appropriately address these risks and difficulties.

Critical Accounting Policies and Estimates

Estimates

The preparation of consolidated financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial

statements and the reported amounts of revenues and expenses during the period. Actual results could differ from those estimates. We review all significant estimates affecting the consolidated financial statements on a recurring basis and records the effect of any necessary adjustments prior to their issuance. Significant estimates of our include: revenue recognition, sales allowances such as returns of product sold, government program rebates, customer coupon redemptions, wholesaler/pharmacy discounts, product service fees, rebates and chargebacks, sales bonuses, stock-based compensation, determination of fair values of assets and liabilities relating to business combinations, and deferred income taxes.

Impairment Testing

In accordance with Generally Accepted Accounting Principles, or GAAP, goodwill impairment testing is performed at the reporting unit level annually, or more frequently if indicated by events or conditions. We performed an evaluation and determined that there is only one reporting unit. In performing a goodwill impairment test, GAAP allows for either a qualitative or a quantitative assessment to be performed. If a qualitative evaluation determines that no impairment exists, then no further analysis is performed. If a qualitative evaluation is unable to determine whether impairment has occurred, a quantitative evaluation is performed. The quantitative impairment test first identifies potential impairments by comparing the fair value of the reporting unit with its carrying value. If the carrying value exceeds the fair value, an impairment charge is recorded based on that difference. The determination of goodwill impairment is highly subjective. It considers many factors both internal and external and is subject to significant changes from period to period. No goodwill impairment charges have resulted from this analysis for 2018, 2017 or 2016.

An impairment of a long-lived asset other than goodwill is recognized under GAAP if the carrying value of the asset (or the group of assets of which it is a part) exceeds (i) the future estimated undiscounted cash flow from the use of the asset (or group of assets) and (ii) the fair value of the asset (or asset group). In making this impairment assessment, we predominately use an undiscounted cash flow model derived from internal forecasts. Factors that could change the result of our impairment test include, but are not limited to, different assumptions used to forecast future net sales, expenses, capital expenditures, and working capital requirements used in our cash flow models. If our management determines that the value of intangible assets have become impaired using this approach, we will record an accounting charge for the impairment. No impairment charges have been recorded for other amortizing intangibles in 2018, 2017 or 2016.

The Assigned Value of Acquired Tangible and Intangible Assets and Assumed and Contingent Liabilities Associated with Business Combinations

We account for acquisitions of businesses using the acquisition method of accounting where the cost is allocated to the underlying net tangible and intangible assets acquired, based on their respective estimated fair values. If the estimated fair values of the net assets acquired is more than the purchase price, the excess is immediately recorded in earnings as a bargain purchase gain. Alternatively, if the purchase price is greater than the estimated fair values of the net assets acquired, the excess is recorded as goodwill. Determining the fair value of certain acquired assets and liabilities is subjective in nature and often involves the use of significant estimates and assumptions, including, but not limited to, the selection of appropriate valuation methodology, projected revenue, expenses and cash flows, weighted average cost of capital, discount rates and estimates of terminal values. Business acquisitions are included in our consolidated financial statements as of the date of the acquisition.

Inventory Valuation

We provide inventory write-downs determined primarily by the accumulated cost to manufacture our inventory, which is impacted by component costs and manufacturing yields. The write-down is measured as the difference between the cost of the inventory and net realizable value and charged to cost of sales. At the point of the loss recognition, a new, lower cost basis for that inventory is established, and subsequent changes in facts and circumstances do not result in the restoration or increase in that newly established cost basis.

We provide a reserve for excess and obsolete inventories identified by a lot-by-lot analysis of our finished goods inventory which considers the expiration dates and future demand forecasts. The write-down is measured as the difference between the cost of the inventory on-hand and the expected demand of the inventory. At the point of the loss recognition, a charge to cost of sales is recorded and a reserve is established for that inventory. The inventory reserve is relieved upon the future sale or disposal of that inventory.

Stock-Based Compensation and other Stock-Based Valuation Issues

We account for stock-based awards to employees and non-employees using fair value-based method to determine compensation for all arrangements where shares of stock or equity instruments are issued for compensation. Fair values of equity securities issued are determined by management based predominantly on the trading price of our common stock. The values of these awards are based

upon their grant-date fair value. That cost is recognized over the period during which the employee is required to provide service in exchange for the award.

We use the Black-Scholes option pricing model to determine the fair value of stock option and warrant grants. In applying the Black-Scholes option pricing model, assumptions are as follows:

	2018	2017	2016
Expected price volatility	60.34%-68.77%	68.76%-78.79%	62.65%-80.78%
Risk-free interest rate	2.05%-3.00%	1.77%-2.05%	0.56%-1.70%
Weighted average expected life in years	6 years	6 years	6 years
Dividend yield	—	—	—

Revenue Recognition

Revenue from Contracts with Customers

Effective January 1, 2018, we adopted Accounting Standards Codification, or ASC, Topic 606, "Revenue from Contracts with Customers," using the modified retrospective approach. We utilized a comprehensive approach to assess the impact of the guidance on our contract portfolio. We reviewed our current accounting policies and practices to identify potential differences resulting from the application of the new requirements to our revenue contracts, including evaluation of performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price, allocating the transaction price to each separate performance obligation and accounting treatment of costs to obtain and fulfill contracts. In addition, we will update certain disclosures, as applicable, included in our financial statements to meet the requirements of the new guidance beginning in January 1, 2018. Under the new guidance, we are required to evaluate the impact of estimating variable consideration related to our product sales and licensing contracts. We will use the expected value method to estimate the total revenue of the contract, constrained by the probability that there would not be a significant revenue reversal in a future period. We will continue to evaluate the expected value of revenue over the term of the contract and adjust revenue recognition as appropriate. Based on this evaluation, the adoption will not have a material impact on our financial position, results of operations, cash flows, accounting policies, business processes, internal controls or disclosures.

Product sales

Under the new accounting guidance, we recognize revenue on product sales when control of the promised goods is transferred to our customers in an amount that reflects the consideration expected to be received in exchange for transferring those goods. We account for a contract when we have approval and commitment from both parties, the rights of the parties are identified, payment terms are identified, the contract has commercial substance and collectability of consideration is probable. When determining whether the customer has obtained control of the goods, we consider any future performance obligations. Generally, there is no post-shipment obligations on product sold.

Performance obligations

A performance obligation is a promise in a contract to transfer a distinct good or service to the customer and is the unit of account in Topic 606. A contract's transaction price is allocated to each distinct performance obligation and recognized as revenue when, or as, the performance obligation is satisfied. The majority of our product sales contracts have a single performance obligation as the promise to transfer the individual goods is not separately identifiable from other promises in the contracts and, therefore, not distinct. Our performance obligations are satisfied at a point in time. The multiple performance obligations are not allocated based off of the obligations but based off of standard selling price.

Adjustments to product sales

We recognize product sales net of estimated allowances for rebates, price adjustments, returns, chargebacks and prompt payment discounts. A significant majority of our adjustments to gross product revenues are the result of accruals for our commercial contracts, retail consumer subsidy programs, and Medicaid rebates.

We establish allowances for estimated rebates, chargebacks and product returns based on numerous qualitative and quantitative factors, including:

- the number of and specific contractual terms of agreements with customers;
- estimated levels of inventory in the distribution channel;
- historical rebates, chargebacks and returns of products;

- direct communication with customers;
- anticipated introduction of competitive products or generics;
- anticipated pricing strategy changes by us and/or our competitors;
- analysis of prescription data gathered by a third-party prescription data provider;
- the impact of changes in state and federal regulations; and
- the estimated remaining shelf life of products.

In our analyses, we use prescription data purchased from a third-party data provider to develop estimates of historical inventory channel sell-through. We utilize an internal analysis to compare historical net product shipments to estimated historical prescriptions written. Based on that analysis, management develops an estimate of the quantity of product in the channel which may be subject to various rebate, chargeback and product return exposures. To estimate months of ending inventory in our distribution channel, we divide estimated ending inventory in the distribution channel by our recent prescription data, not considering any future anticipated demand growth beyond the succeeding quarter. Monthly for each product line, we prepare an internal estimate of ending inventory units in the distribution channel by adding estimated inventory in the channel at the beginning of the period, plus net product shipments for the period, less estimated prescriptions written for the period. This is done for each product line by applying a rate of historical activity for rebates, chargebacks and product returns, adjusted for relevant quantitative and qualitative factors discussed above, to the potential exposed product estimated to be in the distribution channel. In addition, we receive daily information from the wholesalers regarding their sales and actual on hand inventory levels of our products. This enables us to execute accurate provisioning procedures.

Product returns-Consistent with industry practice, we offer contractual return rights that allow our customers to return our products within an 18-month period that begins six months prior to and ends twelve months after expiration of the products.

Rebates- The liability for government program rebates is calculated based on historical and current rebate redemption and utilization rates contractually submitted by each program's administrator.

Price adjustments and chargebacks-Our estimate of price adjustments and chargebacks are based on its estimated mix of sales to various third-party payers, which are entitled either contractually or statutorily to discounts from our listed prices of our products. If the sales mix to third-party payers is different from our estimates, we may be required to pay higher or lower total price adjustments and/or chargebacks than it had estimated, and such differences may be significant.

From time to time, we offer certain promotional product-related incentives to our customers. These programs include certain product incentives to pharmacy customers and other sales stocking allowances. We have voucher programs for BELBUCA and BUNAVAIL whereby we offer a point-of-sale subsidy to retail consumers. We estimate our liabilities for these voucher programs based on the actual redemption rates as reported to us by a third-party claims processing organization. We account for the costs of these special promotional programs as price adjustments, which are a reduction of gross revenue.

Prompt payment discounts-We typically offers our wholesale customers a prompt payment discount of 2% as an incentive to remit payments within the first 30 to 37 days after the invoice date depending on the customer and the products purchased.

Gross To Net Accruals

A significant majority of our gross to net adjustments to gross product revenues are the result of accruals for our voucher program and rebates related to Medicare Part D, the Part D Coverage Gap, Medicaid, and commercial contracts with most of those programs having an accrual to payment cycle of anywhere from one to three months. In addition to this relatively short accrual to payment cycle, we receive daily information from the wholesalers regarding their sales of our products and actual on hand inventory levels of its products. This enables us to execute accurate provisioning procedures. Consistent with the pharmaceutical industry, the accrual to payment cycle for returns is longer and can take several years depending on the expiration of the related products.

Prior to January 2017, we were recording sales when prescriptions were filled. However, beginning in January 1, 2017, we began recording revenue based on a sell-in method, as we now have achieved the ability to record sales ex-factory.

License and development agreements

We periodically enter into license and development agreements to develop and commercialize our products. The arrangements typically are multi-deliverable arrangements that are funded through upfront payments, milestone payments and other forms of payment. Depending on the nature of the contract these revenues are classified as research and development reimbursements or contract revenue.

Product Royalty Revenues

Product royalty revenue amounts are based on a percentage of net sales revenue of the ONSOLIS product under our license agreement with Mylan. Product royalty revenues are computed on a quarterly basis when revenues are fixed or determinable, collectability is reasonably assured, and all other revenue recognition criteria are met. Mylan has the right to reject products that do not comply with product, packaging, or regulatory specifications. Defective product must be identified by Mylan within 10 days after inspection at Mylan's distribution site. We bill Mylan immediately upon receipt by Mylan of product (FOB manufacturer). On a quarterly basis, a reconciliation is prepared that reflects the difference between actual net sales by Mylan multiplied by the royalty percentage, and the actual royalty payments made during the quarter (which is based on a "transfer price" at the time we invoice Mylan). The parties "true-up" the differences within 45 days of each quarter-end.

Cost of Sales

Cost of sales includes direct costs attributable to the production of BELBUCA, BUNAVAIL, BREAKYL and PAINKYL. Cost of sales also includes royalty expenses owed to third parties.

For BELBUCA and BUNAVAIL, cost of sales includes raw materials, production costs at our contract manufacturing sites, quality testing directly related to the product, lower of cost of market and depreciation on equipment that we have purchased to produce BELBUCA and BUNAVAIL. It also includes any batches not meeting specifications and raw material yield loss. Beginning January 1, 2017, cost of sales for BELBUCA and BUNAVAIL were recognized when sold to the wholesaler from our distribution center. There was no deferred cost of sales for the years ended December 31, 2017 nor 2018. Yield losses and batches not meeting specifications are expensed as incurred.

For BREAKYL and PAINKYL, we do not take ownership of the subject product as we do not have inventory. Accordingly, raw material product is transferred to Mylan, in the case of BREAKYL and TTY in the case of PAINKYL, immediately in accordance with the terms of our contractual arrangements with Mylan and TTY. LTS manufactures both products for us. Mylan's and TTY's royalty payments to us include an amount related to cost of sales. Ownership and title to the product, including insurance risk, belong to LTS from raw material through completion and inventory of the subject product, and then to Mylan and TTY upon shipment of such subject product. This is in accordance with our contracts with LTS and Mylan and TTY, which identify the subject product as FOB manufacturer.

Income taxes

On December 22, 2017, the United States enacted major tax reform legislation, Public Law No. 115-97, commonly referred to as the Tax Cuts and Jobs Act, or the 2017 Tax Act. The 2017 Tax Act, among other changes, lowers the general corporate income tax rate to 21% for tax years beginning after December 31, 2017, transitions U.S. international taxation from a worldwide tax system to a territorial system, and provides for a one-time transition tax on the mandatory deemed repatriation of cumulative foreign earnings as of December 31, 2017, which is not applicable to us. We have calculated our impact of the 2017 Tax Act in our income tax provision during the year ended December 31, 2018, in accordance with our understanding of the 2017 Tax Act and guidance available as of the date of this filing.

We recorded federal income tax benefit during 2018 due to the impact of the 2018 Tax Cuts and Jobs Act. For years beginning after December 31, 2017, the Act repeals corporate AMT. The credit becomes refundable in an amount equal to 50% of the excess of the credit for the tax year over the amount of the credit allowable for the year against regular tax liability. We recorded state income tax expense of $0.05 million due to state audit findings related to prior periods. We have recognized valuation allowances for all deferred tax assets for years ending 2018 and 2017.

We are required to reduce any deferred tax asset by a valuation allowance if, based on an assessment of positive and negative evidence, including estimates of future taxable income necessary to realize future deductible amounts, it is more likely than not (a likelihood of more than 50 percent) that some portion or all of the deferred tax assets will not be realized. The valuation allowance should be sufficient to reduce the deferred tax asset to the amount, which is more likely than not to be realized. As a result, we recorded a valuation allowance with respect to all of our deferred tax assets.

One or more of our legal entities file income tax returns in the U.S. federal jurisdiction and various U.S. state jurisdictions. Our income tax returns are subject to audit by the tax authorities in those jurisdictions. Significant disputes may arise with authorities involving issues of the timing and amount of deductions, the use of tax credits and allocations of income and expenses among various tax jurisdictions because of differing interpretations of tax laws, regulations and the interpretation of the relevant facts. We are no longer subject to U.S. federal or state tax examinations for years ended on or before December 31, 2014.

Results of Operations

For the Year Ended December 31, 2018 Compared to the Year Ended December 31, 2017

Product Sales. We recognized $51.4 million and $34.9 million in product sales during the years ended 2018 and 2017, respectively, from our products BELBUCA and BUNAVAIL. The increase in 2018 over 2017 is a result of managed care wins and the expansion of our salesforce in 2018.

Product Royalty Revenues. We recognized $3.4 million and $5.1 million in product royalty revenue during the years ended 2018 and 2017, respectively. The decrease in product royalty revenues in 2018 can be attributed to timing of BREAKYL sales from Mylan and PAINKYL sales from TTY.

Research and Development Reimbursements. We recognized $0.0 million and $0.8 million of reimbursable revenue during the years ended 2018 and 2017, respectively, which relates to our former license agreement with Collegium and composed of reimbursement to us for a pre-determined amount of the remaining expenses associated with the transfer of the manufacturing of ONSOLIS.

Contract Revenues. We recognized $0.8 million and $21.2 million in contract revenue during the years ended 2018 and 2017, respectively. We recognized $1.0 million in contract revenue during the year ended December 31, 2018 related to our license agreement with Purdue, which was for the Canadian commercial launch and related milestones. Due to the termination of the Purdue contract in March 2019, the aforementioned contract revenue was offset by the reversal of $0.2 million in milestone revenue. Contract revenue in 2017 includes $20 million from Endo related to a patent extension that was previously recorded as deferred revenue because all or a portion of such $20 million was contingently refundable to Endo if a third party generic product was introduced in the U.S. during the patent extension period from 2020 to 2027. However, due to the termination agreement with Endo signed on December 7, 2016 which terminated the BELBUCA license to Endo effective January 6, 2017, the deferred $20 million was recognized as revenue in January 2017. The remaining $1.2 million in contract revenues during 2017 was related to our license agreement with Purdue Canada.

Cost of Sales. We incurred $15.8 million and $19.5 million in cost of sales during the years ended 2018 and 2017, respectively. In 2018, we had minimum $1.5 million contractual royalty due to CDC related to our ONSOLIS and BREAKYL product. Also, in 2018, we incurred $11.5 million in cost of sales for BELBUCA and BUNAVAIL plus $0.9 million related depreciation of manufacturing equipment and $0.3 million in immediate expensing of certain production that did not meet specifications during product validation and batch size scale up and yield losses. Also included in 2018 was $0.7 million in cost of sales for BREAKYL, $0.5 million in cost of sales for PAINKYL and $0.4 million cost of sales related to BELBUCA royalty. In 2017, we had minimum $1.5 million contractual royalty due to CDC related to our ONSOLIS and BREAKYL product. Also, in 2017, we incurred $15.8 million in cost of sales for BELBUCA and BUNAVAIL royalties paid, lower of cost or net realized value, plus $0.6 million related depreciation of manufacturing equipment and $0.2 million in immediate expensing of certain production that did not meet specifications during product validation and batch size scale up and yield losses. Also included in 2017 was $1.0 million in cost of sales for BREAKYL, $0.3 million in cost of sales for PAINKYL and $0.1 million cost of sales related to ONSOLIS.

Selling, General and Administrative Expenses. During the years ended December 31, 2018 and 2017, selling, general and administrative expenses totaled $58.6 million and $58.9 million, respectively. Selling, general and administrative costs include BELBUCA and BUNAVAIL sales, marketing, and commercial expenses. These costs also include legal expenses for patent defense, professional fees, wages and stock-based compensation expense.

Interest Expense, Net. During the year ended December 31, 2018, we had net interest expense of $10.2 million, consisting of $6.1 million of scheduled interest payments and $3.0 million of related amortization of discount and loan costs and $1.1 million of warrant interest expense all related to the February 2017 CRG Term Loan Agreement. During the year ended December 31, 2017, we had net interest expense of $8.6 million, consisting of $4.4 million of scheduled interest payments and $1.1 million of related amortization of discount and loan costs and $0.6 million of warrant interest expense all related to the February 2017 CRG Term Loan Agreement. In addition, we had remaining $0.9 million of scheduled interest payments and $1.4 million of related amortization of discount, loan costs and loan pay off and $0.2 million of warrant interest expense all related to the July 2013 secured loan facility from MidCap, which was paid off with the CRG term loan.

Bargain Purchase Gain. During the year ended December 31, 2017, we recorded the value of the bargain purchase gain of the BELBUCA acquisition from Endo totaling $27.3 million to income. There was no such amount recorded during the year ended December 31, 2018 nor 2016.

Income Tax Expense and Tax Net Operating Loss Carryforwards. We have a federal net operating loss carry forward, or NOLs, of approximately $279 million as of December 31, 2018. Under Section 382 and 383 of the Internal Revenue Code, if an ownership

change occurs with respect to a "loss corporation", as defined, there are annual limitations on the amount of the NOLs and other deductions, which are available to us. The portion of the NOLs incurred prior to May 16, 2006 is subject to this limitation. As such, the use of these NOLs to offset taxable income is limited to approximately $1.5 million per year. Our State NOLs are approximately $264 million as of December 31, 2018. These loss carryforwards expire between 2024 and 2037 for federal NOLs and 2030 for state NOL generated prior to December 31, 2017. The federal NOLs generated in 2018 of $3.28 million will have an indefinite carryforward life due to tax reform. Management has evaluated all other tax positions that could have a significant effect on the financial statements and determined that we have no uncertain income tax positions at December 31, 2018.

Expenditures for Research and Development Programs (2018 vs. 2017)

Our research and development expenditures for our approved products and product candidates are as follows in thousands:

	Year Ended December 31,		Cumulative through December 31,
	2018	2017	2018
BELBUCA	$3,869	$8,497	$ 126,566
BUNAVAIL	418	2,185	41,303
ONSOLIS	615	1,254	3,669
Buprenorphine ER Injection	(14)	885	9,771
Clonidine Topical Gel*	15	219	27,534

* Clonidine Topical Gel product candidate was discontinued in December 2016. Minimal expenses in 2017 consist of the winding down of the product candidate which includes allocated wages and compensation.

Results of Operations

For the Year Ended December 31, 2017 Compared to the Year Ended December 31, 2016

Product Sales. We recognized $34.9 million and $8.3 million in product sales during the years ended 2017 and 2016, respectively, from our products BELBUCA and BUNAVAIL. The increase in 2017 over 2016 is a result of the reacquisition of BELBUCA in January 2017.

Product Royalty Revenues. We recognized $5.1 million and $3.6 million in product royalty revenue during the years ended 2017 and 2016, respectively. The increase in product royalty revenues in 2017 can be attributed to timing of BREAKYL sales from Mylan and PAINKYL sales from TTY.

Research and Development Reimbursements. We recognized $0.8 million and $1.1 million of reimbursable revenue during the years ended 2017 and 2016, respectively, which relates to our license agreement with Collegium and composed of reimbursement to us for a pre-determined amount of the remaining expenses associated with the ongoing transfer of the manufacturing of ONSOLIS.

Contract Revenues. We recognized $21.2 million and $2.5 million in contract revenue during the years ended 2017 and 2016, respectively. Contract revenue in 2017 includes $20 million from Endo related to a patent extension that was previously recorded as deferred revenue because all or a portion of such $20 million was contingently refundable to Endo if a third party generic product was introduced in the U.S. during the patent extension period from 2020 to 2027. However, due to us and Endo entering into a termination agreement on December 7, 2016 which terminated the BELBUCA license to Endo effective January 6, 2017, the deferred $20 million was recognized as revenue in January 2017. The remaining $1.2 million in contract revenues during 2017 was related to our license agreement with Purdue Canada. We recognized $2.5 million in contract revenue during 2016 related to our license agreement with Collegium for ONSOLIS.

Cost of Sales. We incurred $19.5 million and $11.3 million in cost of sales during the years ended 2017 and 2016, respectively. In 2017, we had minimum $1.5 million contractual royalty due to CDC related to our ONSOLIS and BREAKYL product. Also, in 2017, we incurred $15.8 million in cost of sales for BELBUCA and BUNAVAIL royalties paid, lower of cost or net realized value, plus $0.6 million related depreciation of manufacturing equipment and $0.2 million in immediate expensing of certain production that did not meet specifications during product validation and batch size scale up and yield losses. Also included in 2017 was $1.0 million in cost of sales for BREAKYL, $0.3 million in cost of sales for PAINKYL and $0.1 million cost of sales related to ONSOLIS. In 2016, we had $1.9 million contractual royalty due to Mylan related to our ONSOLIS licensing arrangement with Collegium and a standard, minimum $1.5 million contractual royalty due to CDC related to our ONSOLIS and BREAKYL product. Also, in 2016, we incurred $6.3 million in cost of sales for BUNAVAIL plus $0.6 million related depreciation of manufacturing equipment and $0.2 million in immediate expensing of certain production that did not meet specifications during product validation and batch size scale up. Also included in 2016 was $0.7 million in cost of sales for BREAKYL and $0.1 million cost of sales related to BELBUCA.

Selling, General and Administrative Expenses. During the years ended December 31, 2017 and 2016, selling, general and administrative expenses totaled $58.9 million and $49.3 million, respectively. Selling, general and administrative costs include BELBUCA and BUNAVAIL sales, marketing, and commercial expenses. These costs also include legal expenses for patent defense, professional fees, wages and stock-based compensation expense. The increase in selling, general and administrative expenses in 2017 can be attributed to the increased marketing related to our 2017 reacquisition of BELBUCA and expansion of our sales force as a result.

Interest Expense, Net. During the year ended December 31, 2017, we had net interest expense of $8.6 million, consisting of $4.4 million of scheduled interest payments and $1.0 million of related amortization of discount and loan costs and $0.6 million of warrant interest expense all related to the February 2017 CRG Term Loan Agreement. In addition, we had remaining $0.9 million of scheduled interest payments and $1.4 million of related amortization of discount, loan costs and loan pay off and $0.2 million of warrant interest expense all related to the July 2013 secured loan facility from MidCap, which was paid off with the CRG term loan. During the year ended December 31, 2016 we had net interest expense of $3.3 million, consisting of $2.9 million of scheduled interest payments and $0.4 million of related amortization of discount and loan costs associated with the July 2015 secured loan facility from MidCap.

Bargain Purchase Gain. During the year ended December 31, 2017, we recorded the value of the bargain purchase gain of the BELBUCA acquisition from Endo totaling $27.3 million to income. There was no such amount recorded during the year ended December 31, 2016.

Income Tax Expense and Tax Net Operating Loss Carryforwards. We had federal and state NOLs of approximately $263 million and $292 million, respectively at December 31, 2017 as compared to federal and state NOLs of $225 million and $258 million, respectively as of December 31, 2016. These loss carryforwards expire principally beginning in 2020 through 2035 for federal and 2030 for state purposes, respectively. In accordance with GAAP, it is required that a deferred tax asset be reduced by a valuation allowance if, based on an assessment of positive and negative evidence, including estimates of future taxable income necessary to realize future deductible amounts, it is more likely than not (a likelihood of more than 50 percent) that some portion or all of the deferred tax assets will not be realized. The valuation allowance should be sufficient to reduce the deferred tax asset to the amount which is more likely than not to be realized. As a result, we recorded a valuation allowance with respect to all of our deferred tax assets. Under Section 382 and 383 of the Internal Revenue Code, if an ownership change occurs with respect to a "loss corporation" (as defined in the Internal Revenue Code), there are annual limitations on the amount of the net operating loss and other deductions which are available to us.

Expenditures for Research and Development Programs (2017 vs. 2016)

Our research and development expenditures for our approved products and product candidates are as follows in thousands:

	Year Ended December 31,		Cumulative through December 31,
	2017	2016	2017
BELBUCA	$8,497	$ 31	$ 122,697
BUNAVAIL	2,185	5,161	40,885
ONSOLIS	1,254	1,487	3,054
Buprenorphine ER Injection	885	5,674	9,785
Clonidine Topical Gel*	219	6,525	27,519

* Clonidine Topical Gel product candidate was discontinued in December 2016. Minimal expenses in 2017 consist of the winding down of the product candidate which includes allocated wages and compensation.

Revenues

The following table summarizes net product sales for the years ended December 31 in thousands:

	Year ended December 31,		
	2018	2017	2016
BELBUCA	$45,988	$ 26,980	$ —
% of net product sales	89%	77%	0%
BUNAVAIL	5,422	7,942	8,266
% of net product sales	11%	23%	100%
Net product sales	$51,410	$ 34,922	$8,266

Medical Affairs Initiatives

In 2018 we transitioned from a research and development-oriented organization into one that is more commercially focused. As such, we expanded our medical affairs capabilities and honed our efforts toward maximizing our products in the market, particularly with our lead asset, BELBUCA. Specifically, our resources and energies were focused on:

- Strategically expanding our medical affairs department to include scientific communications and publications, medical science liaisons, and expertise regarding Phase 4 and Health Economic and Outcomes Research, or HEOR initiatives;
- Developing a robust medical affairs plan for BELBUCA and defining future clinical studies, publications, congress activities, and educational initiatives to deliver on the strategic imperatives in order to inform all stakeholders on the attributes of BELBUCA in order that it can become an option for patients suffering with chronic pain'
- Continuing to progress post-marketing requirements, or PMRs and plans for BELBUCA and BUNAVAIL; and
- Providing Pharmacovigilance, or PV and drug safety support for BELBUCA, BUNAVAIL, and ONSOLIS.

Our estimates of development costs, medical affairs initiatives, and our projected sales associated with each of our product candidates discussed below and elsewhere in this Report are merely estimates and subject to multiple factors, many of which are, or may be beyond our control, including those detailed in the Risk Factors section of this Report. These factors and risks could cause delays, cost overruns or otherwise cause us to not achieve these estimates. Readers are also advised that our projected sales figures do not consider the royalties and other payments we will need to make to our licensors and strategic partners. Our estimates are based upon our market research and management's reasonable judgments, but readers are advised that such estimates may prove to be inaccurate.

The following is a summary of our current and past major product and product candidate initiatives at December 31, 2018:

BELBUCA (*buprenorphine buccal film).* Following the transfer of BELBUCA to us in January 2017, we led clinical and Medical Affairs support behind BELBUCA. We have assumed responsibility for the conduct of post approval commitments specified by FDA in the approval of BELBUCA, which include a thorough QT, or TQT study and a pediatric study. In September 2013, the FDA announced that it will require all companies holding NDAs for extended-release/long-acting, or ER/LA opioid analgesic drug products to conduct four post-marketing studies regarding risks associated with their long-term use and one clinical trial to estimate risk of hyperalgesia. The FDA replaced the original requirements with new post-marketing requirements in February 2016. The Opioid PMR Consortium was formed with representatives from each of the member companies providing an opportunity for one set of studies to be completed to satisfy the FDA requirements and distributing the associated costs across all member companies. Each member company pays an equal share of the program costs and new members are required to pay equal share of the costs to date upon program entry and of future costs going forward. We joined the Opioid PMR Consortium in October 2017 and our initial share of the program cost was paid in late 2017. To date, six of eleven studies have been completed and the program is expected to continue into 2020.

BUNAVAIL. Activities in 2017 included work to support a label expansion of BUNAVAIL for the induction (conversion to buprenorphine) of opioid dependent subjects, performance of FDA post-marketing study requirements and improvements in commercial manufacturing. In May 2017, we announced that the FDA expanded the BUNAVAIL label to include induction of opioid dependent patients.

ONSOLIS. We had been collaborating with our U.S. partner Collegium on the ongoing transfer of manufacturing (including the production of registration batches) toward the submission of a Prior Approval Supplement to the FDA. In December 2017, we announced the termination of our U.S. ONSOLIS agreement with Collegium. In 2018 we continued to explore U.S. commercialization options, including the use of our current sales force, or potentially out-licensing the product, and obtained FDA approval of an alternate manufacturing site.

Buprenorphine Extended Release Injection. In 2014, we entered into an agreement with Evonik to develop and commercialize a long-acting buprenorphine injection capable of providing 30 days of continuous buprenorphine blood concentrations following a single monthly injection. In 2015, we completed initial development work and preclinical studies which have resulted in the identification of a formulation we believe can provide 30 days of continuous buprenorphine treatment. During a pre-IND meeting with FDA in November 2015, the FDA requested an additional study to assess the fate of the polymers used in the formulation. We completed this study and submitted an IND for this product candidate to FDA in December 2016. Subsequently, the agreement has terminated and the options granted therein have expired. We continue to evaluate whether or not to further advance this program.

Liquidity and Capital Resources

Since inception, we have financed our operations principally from the sale of equity securities, proceeds from borrowings, convertible notes, and notes payable, funded research arrangements, revenue generated as a result of our worldwide license and

development agreements , the commercialization of our BELBUCA and BUNAVAIL products. We intend to finance our commercialization and working capital needs from existing cash, earnings from the commercialization of BELBUCA and BUNAVAIL, royalty revenue, new sources of debt and equity financing, existing and new licensing and commercial partnership agreements and, potentially, through the exercise of outstanding common stock options and warrants to purchase common stock.

On May 11, 2016, we and Collegium executed a definitive License and Development Agreement under which we granted to Collegium the exclusive rights to develop and commercialize ONSOLIS in the U.S, resulting in a milestone of $2.5 million paid to us in June 2016.

During 2016, we received cumulative payments totaling $1.3 million which related to royalties based on product purchased in Europe by Mylan of BREAKYL.

During 2016, we received cumulative payments totaling $0.9 which related to royalties based on product purchased in Taiwan by TTY of PAINKYL.

On December 8, 2016, we announced that we had entered into an agreement Endo terminating Endo's licensing of rights for BELBUCA. The closing of the Termination Agreement, and the formal termination of the BELBUCA license to Endo and closing of the transactions occurred on January 6, 2017.

On July 12, 2017, we, along with Purdue Pharma (Canada) announced that we had signed an exclusive agreement for the licensing, distribution, marketing and sale of BELBUCA in Canada. In return for the licensing and distribution rights to BELBUCA in Canada, we were eligible to receive upfront and potential milestones of up to CAD 4.5 million as well as royalties on net sales, including approximately CAD 1.5 million (0.5 million CAD and 1.0 million CAD received August 2017 and October 2017, respectfully).

During 2017, we received cumulative payments totaling $2.2 million which related to royalties based on product purchased in Europe by Mylan of BREAKYL.

During 2017, we received cumulative payments totaling $1.2 million which related to royalties based on product purchased in Taiwan by TTY of PAINKYL.

On May 22, 2018, we announced the closing of the $50 million registered direct offering of newly designated Series B Stock. The offering closed on May 21, 2018, yielding net proceeds of $47.9 million to us.

During 2018, we received cumulative payments totaling $1.8 million which related to royalties based on product purchased in Europe by Mylan of BREAKYL.

During 2018, we received cumulative payments totaling $1.5 million which related to royalties based on product purchased in Taiwan by TTY of PAINKYL.

During 2018, we received cumulative payments totaling $1.0 million which related to milestones and royalties based on product purchased in Canada by Purdue of BELBUCA.

CRG Term Loan Agreement

On February 21, 2017, we entered into a term loan agreement, or the Term Loan Agreement with CRG, as administrative agent and collateral agent, and the lenders named in the Term Loan Agreement (the "Lenders"). We utilized approximately $29.4 million of the initial loan proceeds under the Term Loan Agreement to repay all the amounts owed by us under the 2015 MidCap Credit Agreement.

Pursuant to the Term Loan Agreement, we borrowed $45.0 million from the Lenders as of the Closing Date and were eligible to borrow up to an additional $15.0 million contingent upon achievement of certain conditions. On December 26, 2017, we were eligible and elected to receive the Second Draw for gross proceeds of $15.0 million.

After the payoff of the MidCap Credit Agreement, we utilized the initial proceeds under the Term Loan Agreement (after deducting loan origination costs and broker and other fees) of approximately $13.7 million, plus any additional amounts borrowed in the future, for general corporate purposes and working capital. The original Term Loan Agreement had a six-year term with three years of interest-only payments, (from 2017-2019). On May 16, 2018, we entered into an amendment to our Term Loan Agreement with CRG. Pursuant to the amendment: (i) the interest only period of the Loan Agreement was extended by one year, and certain milestones previously required for the extended interest only period have been removed; (ii) the "PIK" period (under which a portion

of the interest accrued under the Loan Agreement can be deferred to maturity) will also be extended for a year, (to 2020); (iii) amortization of the loan principal can be deferred until maturity (making the payment of the loan a "balloon" payment) if we achieve and maintain a market capitalization of $200 million prior to the conclusion of the interest only period (provided that if we achieve, and thereafter falls below a $200 million market capitalization, amortization of the loan principal will resume); and (iv) certain our revenue targets, the failure of which would create an event of default under the loan, have been recalculated. Interest on the amounts borrowed under the Term Loan Agreement accrues at an annual fixed rate of 12.50%, 3.5% of which may be deferred during the interest-only period by adding such amount to the aggregate principal loan amount. On each borrowing date (including the Closing Date), we are required to pay CRG a financing fee based on the loan drawn on that date. We are also required to pay the Lenders a final payment fee equivalent to 9% of the original loan amount upon repayment of the loans in full, in addition to prepayment amounts described below.

At December 31, 2018, we had cash of approximately $43.8 million. We used $24.1 million of cash in operations during the year ended December 31, 2018 and had stockholders' equity of $29.7 million, versus stockholders' equity of $8.9 million at December 31, 2017. We believe that we have sufficient current cash, along with expected proceeds from sales to manage the business as currently planned.

Additional capital may be required to support the continued commercialization of our BELBUCA and BUNAVAIL products, the anticipated commercial relaunch of ONSOLIS, the potential continued development of Buprenorphine Extended Release Injection or other products which may be acquired or licensed by us, and for general working capital requirements. Based on product development timelines and agreements with our development partners, the ability to scale up or reduce personnel and associated costs are factors considered throughout the product development life cycle. Available resources may be consumed more rapidly than currently anticipated, potentially resulting in the need for additional funding. Additional funding, capital or loans (including, without limitation, milestone or other payments from commercialization agreements) may be unavailable on favorable terms, if at all.

Also, product development timelines and agreements with our development partners, the ability to scale up or reduce personnel and associated costs are factors considered throughout the product development life cycle. Available resources may be consumed more rapidly than currently anticipated, resulting in the need for additional funding.

Accordingly, we anticipate that we will be required to raise additional capital, which may be available to us through a variety of sources, including:

- public equity markets;
- private equity financings;
- commercialization agreements and collaborative arrangements;
- sale of product royalty;
- grants and new license revenues;
- bank loans;
- equipment financing;
- public or private debt; and
- exercise of existing warrants and options.

Readers are cautioned that additional funding, capital or loans (including, without limitation, milestone or other payments from commercialization agreements) may be unavailable on favorable terms, if at all. If adequate funds are not available, we may be required to significantly reduce or refocus our operations or to obtain funds through arrangements that may require us to relinquish rights to certain technologies and drug formulations or potential markets, either of which could have a material adverse effect on us, our financial condition and our results of operations in 2019 and beyond. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of such securities would result in ownership dilution to existing stockholders.

Contractual Obligations and Commercial Commitments

Our non-cancellable contractual obligations as of December 31, 2018 are as follows (in thousands):

		Payments Due by Period			
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating lease obligations	$ 1,300	$ 351	$ 730	$ 219	$ —
Secured loan facility	61,784	—	30,892	30,892	—
Interest on secured loan facility	22,568	5,638	11,292	5,638	—

	Payments Due by Period				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Minimum royalty expenses*	12,750	1,500	3,000	3,000	5,250
Purchase obligations**	1,508	493	1,015	—	—
Total contractual cash obligations	$99,910	$ 7,982	$46,929	$39,749	$ 5,250

* Minimum royalty expenses represent a contractual floor that we are obligated to pay CDC and NB Athyrium LLC regardless of actual sales. The minimum payment is $0.4 million per quarter or $1.5 million per year until patent expiry on July 23, 2027.

** Purchase obligations represent an agreement for the supply of active pharmaceutical ingredient for use in production.

Off Balance Sheet Arrangements

We are not a party to any off balance sheet arrangements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Interest rate risk

Our cash includes all highly liquid investments with an original maturity of three months or less. Because of the short-term maturities of our cash, we do not believe that an increase in market rates would have a significant impact on the realized value of our investments. We place our cash on deposit with financial institutions in the United States. The Federal Deposit Insurance Corporation covers $0.25 million for substantially all depository accounts. As of December 31, 2018, we had approximately $43.6 million, which exceeded these insured limits.

Foreign currency exchange risk

We currently have limited, but may in the future have increased, clinical and commercial manufacturing agreements which are denominated in Euros, CAD or other foreign currencies. As a result, our financial results could be affected by factors such as a change in the foreign currency exchange rate between the U.S. dollar and the Euro, CAD or other applicable currencies, or by weak economic conditions in Europe, Canada or elsewhere in the world. We are not currently engaged in any foreign currency hedging activities.

Market indexed security risk

We have issued warrants to various holders underlying shares of our common stock. These warrant investments were measured at their fair value at date of issuance and recorded as warrant expense in the accompanying consolidated statement of operations. We use the Black-Scholes model for valuation of the warrants.

Item 8. Financial Statements and Supplementary Data.

Our Consolidated Financial Statements and Notes thereto and the report of Cherry Bekaert LLP, our independent registered public accounting firm, are set forth on pages F-1 through F-35 of this Report.

Item 9. Changes In and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, at December 31, 2018, such disclosure controls and procedures were effective.

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time

periods specified by the SEC. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, or persons performing similar functions, as appropriate, to allow timely decisions regarding required disclosure.

Limitations on the Effectiveness of Controls

Our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within a company have been detected. Our Chief Executive Officer and Chief Financial Officer have concluded, based on their evaluation as of the end of the period covered by this Report that our disclosure controls and procedures were sufficiently effective to provide reasonable assurance that the objectives of our disclosure control system were met.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the year ended December 31, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control Over Financial Reporting

As required by the SEC rules and regulations for the implementation of Section 404 of the Sarbanes-Oxley Act, our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our consolidated financial statements for external reporting purposes in accordance with GAAP. Our internal control over financial reporting includes those policies and procedures that:

(1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of our company,

(2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors, and

(3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the consolidated financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect errors or misstatements in our consolidated financial statements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree or compliance with the policies or procedures may deteriorate. Management assessed the effectiveness of our internal control over financial reporting at December 31, 2018. In making these assessments, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework) (COSO). Based on our assessments and those criteria, management determined that we maintained effective internal control over financial reporting at December 31, 2018.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Our directors and executive officers and their ages as of March 14, 2019 are as follows:

Name	Age	Position(s) Held
Peter S. Greenleaf	48	Chairman of the Board and Director
Mark A. Sirgo, Pharm.D.	65	Vice Chairman and Director
Herm Cukier	52	Chief Executive Officer and Director
Scott M. Plesha	54	President and Chief Commercial Officer
Mary Theresa Coelho	57	Chief Financial Officer and Treasurer
Thomas B. Smith, M.D.	58	Chief Medical Officer
James Vollins	50	General Counsel, Chief Compliance Officer and Corporate Secretary
Frank E. O'Donnell, Jr., M.D.	69	Director
William M. Watson	68	Director
Todd C. Davis	58	Director
Kevin Kotler	47	Director

There are no family relationships between any of our directors or executive officers.

Peter S. Greenleaf, age 48, has been our Chairman of the Board and Director since May 2018. He has served as the Chief Executive Officer of Cerecor, Inc., since March 2018 and previously served as Chief Executive Officer of Sucampo Pharmaceuticals, Inc. from March 2014 to February 2018, when Sucampo was sold to Mallinckrodt PLC. Prior to that, Mr. Greenleaf served as Chief Executive Officer of Histogenics Corporation from June 2013 to March 2014, as President of MedImmune, Inc., and MedImmune Ventures from 2010 to June 2013, and Senior Vice President, Commercial Operations of MedImmune from 2006 to 2010. Mr. Greenleaf also held senior commercial roles at Centocor Biotech, Inc. (now Janssen Biotechnology, Johnson & Johnson), from 1998 to 2006, and at Boehringer Mannheim G.m.b.H. (now Roche Holdings) from 1996 to 1998. Mr. Greenleaf is a member of the board of directors of Cerecor since May 2017, EyeGate Pharmaceuticals since August 2018 and Antares Pharma since December 2018. Mr. Greenleaf chairs the Maryland Venture Fund Authority and serves a member of the board of directors of the Biotechnology Industry Organization. He previously served on the boards of PhARMA, the Tech Council of Maryland and the University of Maryland Baltimore Foundation, Inc. Mr. Greenleaf earned an MBA degree from St. Joseph's University and a BS degree from Western Connecticut State University.

Mark A. Sirgo, Pharm.D., age 65, has been our Director since August 2005 and Vice Chairman since October 2016. He was formerly our President since January 2005 and Chief Executive Officer since August 2005. He joined our company in August 2004 as Senior Vice President of Commercialization and Corporate Development upon our acquisition of Arius Pharmaceuticals, of which he was a co-founder and Chief Executive Officer. He has also served as our Executive Vice President, Corporate and Commercial Development and our Chief Operating Officer. Dr. Sirgo has over 35 years of experience in the pharmaceutical industry, including 16 years in clinical drug development, 7 years in marketing, sales, and business development, and 12 years in executive management positions. 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., a leading contract service provider to the pharmaceutical industry. Dr. Sirgo served on the Board of Directors and as Chairman of the Compensation Committee of Salix Pharmaceuticals, Inc. (NASDAQ:SLXP), a specialty pharmaceutical company specializing in gastrointestinal products, from 2008 until its sale in 2015. Dr. Sirgo was added to the Board of Directors of Biomerica, Inc. (NASDAQ: BMRA), a diagnostics and therapeutic company, in July 2016 and as Chairman of the Board of RDD Pharma, a private gastrointestinal development company, in April 2018. In January 2019, Dr. Sirgo was appointed Chief Executive Officer of ArunA Bio, a private CNS and neurodegenerative disorder development company. Dr. Sirgo received his BS in Pharmacy from The Ohio State University and his Doctorate from Philadelphia College of Pharmacy and Science.

Herm Cukier, age 52, has been our Chief Executive Officer and a member of our Board of Directors since May 2018. From December 2013 to April 2018, he served in various capacities at Allergan plc, ultimately as Senior Vice President, Head of Commercial Strategy and Innovation. He also served as the Senior Vice President of Allergan's Eye Care division and as Senior Vice President of Allergan's Woman's Healthcare division. From 2010 to 2013, he served as Vice President of Bayer HealthCare, and from

2009 to 2010, he served as President, Chief Executive Officer and board member at Reverion Pharmaceuticals, Inc., a start-up company associated with Weill Cornell Medical College. From 2005 to 2008, he served as Chief Marketing Officer and member of the Executive Committee at Organon Biosciences, which was acquired by Schering-Plough. He began his career in 1992 at Pfizer and later served as Executive Director of Global Marketing at Bristol-Myers Squibb. Mr. Cukier received an MBA from the Columbia Business School and a BSE in Bioengineering from the University of Pennsylvania.

Scott M. Plesha, age 54, joined the company in August 2015 as our Senior Vice President, Sales, with more than 26 years of sales experience and over 18 years of sales management experience within the pharmaceutical and medical industries. Mr. Plesha assumed the additional responsibility of leading our Marketing department in December 2015. In January 2018, Mr. Plesha was appointed to the role of President of the Company. Mr. Plesha leads our Specialty Sales Force, Marketing, and Training departments. Prior to joining the company, Mr. Plesha was Senior Vice President, GI Sales Force & Training at Salix Pharmaceuticals, where since 2002 he led Salix's top rated gastrointestinal (GI) sales forces, the sales training department as well as many other sales operations functions. During Mr. Plesha's tenure at Salix he was responsible for launching or growing product sales as well as optimizing and expanding the sales force to accommodate the multiple companies and products that Salix acquired. Prior to joining Salix, Mr. Plesha was a Regional Sales Manager for the O'Classen Dermatologics division of Watson Pharmaceuticals, Inc. Mr. Plesha began his pharmaceutical sales career with Solvay Pharmaceuticals where he was a field as well institutional sales representative. Mr. Plesha received a Bachelor of Arts in Pre-Medical Studies from DePauw University.

Terry Coelho, age 57, has been our Chief Financial Officer since January 2019 and has more than 30 years of financial and operational experience. Ms. Coelho's extensive experience includes serving in diverse leadership capacities across various industries for both private and public global companies. Prior to joining the company, Ms. Coelho served as Chief Financial Officer and Treasurer at Balchem Corporation. Previously, she served as Chief Operating Office for Diversey, Inc., a multi-billion dollar global private equity carve-out from Sealed Air Corporation and held senior finance positions at Diversey Care from 2014 through 2017. Ms. Coelho has also served in senior finance leadership roles at Novartis from 2007 to 2014. She spent the previous twenty years at Mars, Incorporated where she held roles of increasing responsibility and encompassing leadership across all areas of finance and general management. Ms. Coelho earned an MBA in Finance from IBMEC in Brazil and a Bachelor of Arts degree in both Economics and International Relations, summa cum laude, from The American University School of International Service.

Thomas B. Smith, M.D., age 58, has been Chief Medical Officer since July 2018 and brings nearly thirty years of medical experience and expertise in the field of pain management. His extensive and wide-ranging roles include having served as Chief Medical Officer at various leading pain companies, head of medical affairs at top tier pharma and CRO companies, as well as running his own private practice. Dr. Smith served as Chief Medical Officer at Charleston Labs, Inc., since 2017 and from 2014 to 2017, he served as the Chief Medical Officer of Ameritox, Ltd. Dr. Smith previously served as Chief Medical Officer for Mallinckrodt Pharmaceuticals from 2012 to 2014 and held clinical leadership roles at Abbott Laboratories, Teva Pharmaceuticals, Kendle International, Akros Pharma and Genzyme during 2001 to 2014. Dr. Smith earned a Doctor of Medicine degree from the Indiana University School of Medicine and a Bachelor of Science degree from Purdue University. He is a member of several medical societies and organizations including the American Medical Association and the American Academy of Family Physicians. Dr. Smith is a highly published scientific author and has delivered more than 150 presentations in his field of expertise.

James Vollins, age 50, has been our General Counsel, Chief Compliance Officer and Corporate Secretary, and member of the Executive Leadership Team since November 2018. Mr. Vollins has twenty-five years of legal experience with over ten years of in-house experience in the pharmaceutical industry, which includes work on several major strategic transactions and a successful initial public offering. From 2014 to 2018, Mr. Vollins was General Counsel, Chief Compliance Officer and Corporate Secretary for Bio Products Laboratory Limited, a UK based manufacturer of plasma-derived therapies, where he helped lead the transformation of the business from a government owned not-for-profit to a high-performing commercial enterprise that successfully launched three new drugs in the U.S., expanded its sales force, and achieved significant revenue growth. Mr. Vollins has also worked for other industry-leading pharmaceutical companies, including Grifols Inc., Talecris Biotherapeutics, Inc. and Pfizer Inc. Mr. Vollins received a Juris Doctor from Case Western Reserve University School of Law and a Bachelor of Arts from Wesleyan University.

Frank E. O'Donnell, Jr., M.D., age 69, has served as a member of our Board of Directors since March 2002 and served as our Chairman of the Board until May 2018. Dr. O'Donnell has previously served as our President and Chief Executive Officer. In January 2005, he relinquished the title of President and in August 2005 he relinquished the title of Chief Executive Officer. Until November 2016, Dr. O'Donnell previously served as a Manager of The Hopkins Capital Group, an affiliation of limited liability companies which engage in private equity and venture capital investing in disruptive technologies in healthcare. Dr. O'Donnell is Chairman of Defender Pharmaceuticals, Inc., a privately-held company developing pharmaceuticals for national defense. Until November 2016, Dr. O'Donnell was also Chairman of the Board of Directors of Hedgepath Pharmaceuticals, Inc., which is developing oncology drugs for an orphan indication. Dr. O'Donnell is qualified to serve on our board of directors because of his long history with our company and his extensive experience in managing and investing in biopharmaceutical companies. Dr. O'Donnell is a graduate of The Johns Hopkins School of Medicine and received his residency training at the Wilmer Ophthalmological Institute, Johns Hopkins Hospital.

Dr. O'Donnell is a former professor and Chairman of the Department of Ophthalmology, St. Louis University School of Medicine. He is a trustee of St. Louis University.

William Mark Watson, CPA, age 68, joined our board as an independent member in December 2017 and is Chairman of the Audit Committee of our board of directors. Mr. Watson is a Certified Public Accountant with over 40 years of experience in public accounting and auditing, having spent his entire career from January 1973 to June 2013 at Deloitte Touche Tohmatsu and its predecessor, most recently as Central Florida Marketplace Leader. Among other industries, he has a particular expertise in the health and life sciences sector, having played a significant role in the development of Deloitte's audit approach for health and life sciences companies and leading its national healthcare regulatory and compliance practice. He has served as lead audit partner and advisory partner on the accounts of many public companies ranging from middle market firms to Fortune 500 enterprises. Mr. Watson is a member of American Institute of Certified Public Accountants and the Florida Institute of Certified Public Accountants. Mr. Watson is a member of the board of directors and Chairman of the Audit Committee of HedgePath Pharmaceuticals, Inc. (OTCQX:HPPI). Mr. Watson was elected to the Board of Directors of Sykes Enterprises Inc. in May 2018 and serves on its Audit Committee. Mr. Watson is qualified to serve on our board due to his expertise in public accounting and his experience with pharmaceutical companies. He received his undergraduate degree in Accounting from Marquette University.

Todd C. Davis, age 58, has served as a member of our Board of Directors since May 2018. Mr. Davis is the Founder and Managing Partner of RoyaltyRx Capital, a special opportunities investment firm. From 2006 until 2018, Mr. Davis was a Founder & Managing Partner of Cowen/HealthCare Royalty Partners, a global healthcare investment firm. He has almost thirty years of experience in both operations and investing in the biopharmaceutical and life science industries. Mr. Davis has been involved in over $3 billion in healthcare financings including growth equity, public equity turnarounds, structured debt and royalty acquisitions. He has also led, structured and closed over 40 additional intellectual property licenses, as well as hybrid royalty-debt deals. Previously, Mr. Davis was a partner at Paul Capital Partners, where he co-managed that firm's royalty investments as a member of the Royalty Management Committee. He also served as a partner responsible for biopharmaceutical growth equity investments at Apax Partners. Mr. Davis began his business career in sales at Abbott Laboratories where he held several commercial roles of increasing responsibility. He subsequently held general management, business development, and licensing roles at Elan Pharmaceuticals. Mr. Davis is a navy veteran and holds a B.S. from the U.S. Naval Academy and an M.B.A. from Harvard University. He currently serves on the board of Palvella Therapeutics Inc., and Ligand Pharmaceuticals. He is also a board member of the Harvard Business School Healthcare Alumni Association.

Kevin Kotler, age 47, has served as a member of our Board of Directors since May 2018. Mr. Kotler has over 25 years of experience as an investor and analyst following the healthcare industry. He is the Founder and Managing Member of Broadfin Capital, which is the investment advisor for Broadfin Healthcare Master Fund, Ltd., a healthcare-focused investment fund that he launched in 2005. Mr. Kotler serves as a Director of Avadel Pharmaceuticals since 2018 and as a director of InnerSpace Neuro Solutions, Inc., a privately-held medical device company, since 2014. He served as Director of Novelion Therapeutics Inc., from 2016 to 2018. Mr. Kotler earned a BS in Economics from the Wharton School at the University of Pennsylvania in 1993.

Key Employees

Below are the biographies of certain key non-executive officer employees of our company:

Ernest R. De Paolantonio, *CPA, MBA*, served as our Chief Financial Officer and Treasurer from October 2013 to January 2019. Mr. De Paolantonio remains at our Company to allow for an orderly transition to the new CFO. Mr. De Paolantonio has over 35 years of varied financial and business experience in the pharmaceutical industry. Prior to joining the company, he 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 controllership 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 he 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.

Joseph Lockhart was promoted to Senior Vice President of Operations for our company in January 2018 after having served as our Vice President of Manufacturing and Supply Chain since joining the company in November 2015. Drawing upon over 30 years of experience in the pharmaceutical industry with specific focus in the areas of manufacturing, supply chain, product development, CMC (Chemistry, Manufacturing, and Controls) and quality, Mr. Lockhart now provides senior-level management to our company's overall Operations, including Clinical, Quality, Regulatory, and Manufacturing/Supply Chain. Prior to joining our company, Mr. Lockhart

served as Vice President, Pharmaceutical Development and Manufacturing at Salix Pharmaceuticals, where since 2001 he established the Pharmaceutical Development and Manufacturing team and contributed to multiple NDA submissions, as well as multiple product acquisitions and launches. During Mr. Lockhart's tenure at Salix he held positions of increasing responsibility and was responsible for managing Manufacturing, Technical Operations, Formulation Development, and Clinical Trial Material Operations. From 1986 thru 2001 Mr. Lockhart served in various pharmaceutical CMC-related roles and responsibilities at both the Manager and the Director levels of management. Mr. Lockhart received a Master of Business Administration degree from the University of North Carolina at Charlotte as well as a Bachelor of Arts degree in Chemistry from the University of North Carolina at Chapel Hill.

Director Independence

We believe that Peter S. Greenleaf, William M. Watson, Todd C. Davis and Kevin Kotler qualify as independent directors for NASDAQ Stock Market purposes. This means that our board of directors is composed of a majority of independent directors as required by NASDAQ Stock Market rules.

Meetings of the Board of Directors and Stockholders

Our board of directors met in person and telephonically six times during 2018 and also acted by unanimous written consent. Each member of our board of directors was present at least 83% of the board of directors' meetings held. It is our policy that all directors must attend all stockholder meetings, barring extenuating circumstances. All directors were present at the 2018 Annual Meeting of Stockholders.

Board Committees

Our board of directors has established three standing committees: Audit, Compensation, and Nominating and Corporate Governance. Historically, all independent directors have been members of each board committee. All standing committees operate under a charter that has been approved by the board. Our board of directors has also, from time to time, appointed non-standing committees to assist the board in its duties to our company. The charters for each of our board committees are available at http://ir.bdsi.com/corporate-governance/governance-overview.

Audit Committee

Our board of directors has an Audit Committee, composed of William M. Watson, Peter S. Greenleaf and Todd C. Davis, all of whom are independent directors as defined in accordance with section 3(a)(58)(A) of the Exchange Act and the rules of NASDAQ. Mr. Watson serves as chairman of the committee. The board of directors has determined that Mr. Watson is an "audit committee financial expert" as defined in Item 407(d)(5)(ii) of Regulation S-K. The Audit Committee met four times during 2018. Each member of the Audit Committee was present at 100% of the Audit Committee meetings held during such director's tenure as a member of the Audit Committee.

Our Audit Committee oversees our corporate accounting, financial reporting practices and the audits and reviews of financial statements. For this purpose, the Audit Committee has a charter (which is reviewed annually). As summarized below, the Audit Committee:

- evaluates the independence and performance of, and assesses the qualifications of, our independent auditor and engages such independent auditor;
- approves the plan and fees for the annual audit, quarterly reviews, tax and other audit-related services and approves in advance any non-audit service and fees therefor to be provided by the independent auditor;
- monitors the independence of the independent auditor and the rotation of partners of the independent auditor on our engagement team as required by law;
- reviews the financial statements to be included in our Annual Report on Form 10-K and Quarterly Reports on Form 10-Q and reviews with management and the independent auditors the results of the annual audit and reviews of our quarterly financial statements;
- oversees all aspects of our systems of internal accounting and financial reporting control; and
- provides oversight in connection with legal, ethical and risk management compliance programs established by management and the board, including compliance with requirements of Sarbanes-Oxley and makes recommendations to the board of directors regarding corporate governance issues and policy decisions.

Nominating and Corporate Governance Committee

Our board of directors has a Nominating and Corporate Governance Committee composed of Kevin Kotler, William M. Watson and Todd C. Davis. Kevin Kotler serves as the chairman of the committee. The Nominating and Corporate Governance Committee is charged with the responsibility of reviewing our corporate governance policies and with proposing potential director nominees to the board of directors for consideration. The Nominating and Corporate Governance Committee met three times in 2018 and has a charter which is reviewed annually. All members of the Nominating and Corporate Governance Committee are independent directors as defined by the rules of the NASDAQ Stock Market. The Nominating and Corporate Governance Committee will consider director nominees recommended by security holders. To recommend a nominee please write to the Nominating and Corporate Governance Committee c/o James Vollins, BioDelivery Sciences International, Inc, 4131 ParkLake Avenue. Suite #225, Raleigh, NC. 27612. The Nominating and Corporate Governance Committee has established nomination criteria by which board candidates are to be evaluated. The Nominating and Corporate Governance Committee will assess all director nominees using the same criteria. During 2018, we did not pay any fees to any third parties to assist in the identification of nominees. In April 2018, the Company received notice from Broadfin Capital, LLC of its intention to nominate certain individuals to stand for election to the Board at the 2018 annual meeting of the Company's stockholders, which notice was irrevocably withdrawn pursuant to the Broadfin Agreement.

The Nominating and Corporate Governance Committee has adopted a set of criteria by which it will seek to evaluate candidates to serve on our board of directors. The evaluation methodology includes a scored system based on criteria including items such as experience in the biotechnology sector, experience with public companies, executive managerial experience, operations and commercial experience, fundraising experience and contacts in the investment banking industry, personal and skill set compatibility with current board members, industry reputation, knowledge of our company generally, independence and ethnic and gender diversity. While diversity is considered as a board qualification criteria, it would not be weighted any more or less in an evaluation process than any other criteria. The established criteria do not distinguish board candidates based on whether the candidate is recommended by a stockholder of our company.

Compensation Committee

Our board of directors also has a Compensation Committee, which reviews or recommends the compensation arrangements for our management and employees and also assists the board of directors in reviewing and approving matters such as company benefit and insurance plans, including monitoring the performance thereof. The Compensation Committee has a charter (which is reviewed annually) and is composed of three members: Todd C. Davis, Peter S. Greenleaf and Kevin Kotler. Todd C. Davis serves as chairman of this committee. The Compensation Committee met five times during 2018.

The Compensation Committee has the authority to directly engage, at our expense, any compensation consultants or other advisers as it deems necessary to carry out its responsibilities in determining the amount and form of employee, executive and director compensation. In 2018, the Compensation Committee engaged Radford, an AON Consulting Company, to obtain market data against which it has measured the competitiveness of our compensation programs. In determining the amount and form of employee, executive and director compensation, the Compensation Committee has reviewed and discussed historical salary information as well as salaries for similar positions at comparable companies. We paid consultant fees to Radford of $0.1 million in 2018.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires that our directors and executive officers and persons who beneficially own more than 10% of our common stock (referred to herein as the "reporting persons") file with the SEC various reports as to their ownership of and activities relating to our common stock. Such reporting persons are required by the SEC regulations to furnish us with copies of all Section 16(a) reports they file.

Based solely upon a review of copies of Section 16(a) reports and representations received by us from reporting persons, and without conducting any independent investigation of our own, in fiscal year 2018, all Forms 3, 4 and 5 were timely filed with the SEC by such reporting persons, with the exception of Mark A. Sirgo, who filed a Form 4, which was due January 5, 2018 on January 19, 2018, Scott Plesha, Ernest De Paolantonio and Francis E. O'Donnell, who filed Form 4s, which were due on February 21, 2018 on February 23, 2018, Ernest De Paolantonio, who filed a Form 4, which was due on April 5, 2018 on April 6, 2018, Mark A. Sirgo, who filed a Form 4, which was due April 10, 2018 on April 13, 2018, and Scott Plesha, who filed a Form 4, which was due October 19, 2018 on October 25, 2018.

Code of Ethics

We have adopted a code of ethics that applies to all employees, as well as each member of our board. Our code of ethics is posted on our website, and we intend to satisfy any disclosure requirement under Item 5.05 of Form 8-K regarding an amendment to, or waiver from, a provision of our code of ethics by posting such information on our website, www.bdsi.com. A copy of our code of

ethics is also available in print, without charge, upon written request to 4131 ParkLake Avenue, Suite #225, Raleigh, NC 27612. Attn: James Vollins.

Involvement in Certain Legal Proceedings

None

Compensation Committee Report

The Compensation Committee has reviewed and discussed the foregoing Compensation Discussion and Analysis with management. Based on this review and discussion, the Compensation Committee recommended to the Board that the Compensation Discussion and Analysis be included in the Company's Annual Report on Form 10-K for the year ended December 31, 2018.

This Report was submitted by the following members of the Compensation Committee of the Board:

Todd C. Davis, Chairman
Peter C. Greenleaf
Kevin Kotler

The information contained in the foregoing Compensation Committee Report shall not be deemed to be "soliciting material" or "filed" with the SEC, nor shall such information be incorporated by reference into a future filing under the Securities Act or the Exchange Act, except to the extent BioDelivery Sciences International, Inc. specifically incorporates this Report by reference therein.

Compensation Discussion and Analysis

The Compensation Committee of our board of directors has the responsibility to review, determine and approve the compensation for our executive officers. Further, the Compensation Committee oversees our overall compensation strategy, including compensation policies, plans and programs that cover all employees.

We employed seven executive officers, each of whom served as a "Named Executive Officer" (or NEO) for purposes of SEC reporting during 2018: (1) Herm Cukier, our Chief Executive Officer; (2) Mark A. Sirgo, Pharm.D., our former President and Chief Executive Officer who retired on January 2, 2018 and who continues to serve as Vice Chairman of our board of directors; (3) Ernest R. De Paolantonio, CPA, MBA, our retiring Treasurer and Chief Financial Officer; (4) Scott Plesha, our President and Chief Commercial Officer; (5) Dr. Thomas Smith, our Chief Medical Officer; (6) James Vollins, our General Counsel, Chief Compliance Officer and Corporate Secretary and (7) Niraj Vasisht, Ph.D., our former Senior Vice President and Chief Technology Officer who retired on February 4, 2018.

This Compensation Discussion and Analysis sets forth a discussion of the compensation for our NEOs as of December 31, 2018 as well as a discussion of our philosophies underlying the compensation for our NEOs and our employees generally.

Objectives of Our Compensation Program

The Compensation Committee's philosophy seeks to align the interests of our stockholders, officers and employees by tying compensation to individual performance and the Company's performance, both short-term in the form of salary and annual cash bonus payments, and long-term in the form of incentive equity awards. The objectives of our compensation program enhance our ability to:

- attract and retain qualified and talented individuals;
- share the risks and rewards of our business with our NEOs and employees; and
- provide reasonable and appropriate incentives to our team for building long-term value within our company, in each case in a manner comparable to companies similar to ours.

In addition, we strive to be competitive with other similarly-situated companies in our industry. The process of developing and commercializing pharmaceutical products is a long-term proposition and outcomes may not be measurable for several years. Therefore, to build long-term value for our stockholders, and to achieve our business objectives, we believe that we must compensate our officers and employees in a competitive and fair manner that reflects our current activities but also reflects contributions to building long-term value.

We utilize the services of the Radford Group, an AON consulting company (which we refer to herein as Radford) to review compensation programs of peer companies to assist the Compensation Committee in determining the compensation levels for our

NEOs, as well as for other employees of ours. Radford is a recognized independent consulting company and services clients throughout the United States.

The companies that comprise our peer group are selected and reviewed no less frequently than biennially. The current peer group used to evaluate compensation for the fiscal year ended December 31, 2018 was approved by the Compensation Committee in September 2017 and includes the following companies:

Company	Location
AcelRx Pharmaceuticals, Inc.	Redwood City, CA
Adamis Pharmaceuticals	San Diego, CA
Alimera Sciences, Inc.	Alpharetta, GA
Antares Pharma, Inc.	Ewing, NJ
BioCryst Pharmaceuticals, Inc.	Durham, NC
Collegium Pharmaceutical	Stoughton, MA.
Corium	Menlo Park, CA.
CTI BioPharma Corp.	Seattle, WA
Cumberland Pharmaceuticals, Inc.	Nashville, TN
DURECT Corporation	Cupertino, CA
KemPharm	Coralville, IA.
Neos Therapeutics, Inc.	Grand Prairie, TX
Recro Pharma	Malvern, PA
Sorrento Therapeutics	San Diego, CA
Strongbridge BioPharma plc	Trevose, PA
Vivus, Inc.	Campbell, CA

With respect to our employees and non-senior management, we will also take into consideration regional market data in determining appropriate compensation packages, and we have in the past relied on Radford to provide us with such data.

Elements of Our Compensation Program and Why We Chose Each

Main Compensation Components

Our company-wide compensation program, including for our NEOs, is broken down into three main components: base salary, performance cash bonuses and potential long-term compensation in the form of stock options or restricted stock units (or RSUs). We believe these three components constitute the minimum essential elements of a competitive compensation package in our industry. We also have a Performance Long Term Incentive Plan (which we refer to herein as the LTIP) for our NEOs and selected senior officers, which compensates such employees with RSUs based on our achievement of certain pre-determined revenue performance goals.

Salary

Base salary is used to recognize the experience, skills, knowledge and responsibilities required of our NEOs as well as recognizing the competitive nature of the biopharmaceutical industry. This is determined partially by evaluating our peer companies as well as the degree of responsibility and experience levels of our NEOs and their overall contributions to our company. Base salary is one component of the compensation package for NEOs; the other components being cash bonuses, annual equity grants, a long-term incentive plan and our benefit programs. Base salary is determined in advance whereas the other components of compensation are awarded in varying degrees following an assessment of the performance of a NEO. This approach to compensation reflects the philosophy of our board of directors and its Compensation Committee to emphasize and reward, on an annual basis, performance levels achieved by our NEOs, and to provide appropriate retention incentives based on future performance.

Performance Cash Bonus Plan

We have a performance cash bonus plan under which bonuses are paid to our NEOs based on achievement of our performance goals and objectives established by the Compensation Committee and/or our board of directors as well as on individual performance. The bonus program is discretionary and is intended to: (i) strengthen the connection between individual compensation and our achievements; (ii) encourage teamwork among all disciplines within our company; (iii) reinforce our pay-for-performance philosophy by awarding higher bonuses to higher performing employees; and (iv) help ensure that our cash compensation is competitive. Depending on our company's cash position, the Compensation Committee and our board of directors have the discretion after consulting with our NEOs to not pay (or pay more limited) cash bonuses in order that we may conserve cash and support ongoing development programs and commercialization efforts. Regardless of our cash position, we consistently grant annual merit-based stock

options (and, more recently in the case of senior executives, RSUs) to continue incentivizing both our senior management and our employees.

Based on their employment agreements, each NEO is assigned a target payout under the performance cash bonus plan, expressed as a percentage of base salary for the year. Actual payouts under the performance cash bonus plan are based on the achievement of corporate performance goals and an assessment of individual performance. For the NEOs, the corporate goals receive the highest weighting to ensure that the bonus system for our management team is closely tied to our corporate performance. Each employee also has specific individual goals and objectives as well that are tied to the overall corporate goals. For employees, mid-year and end-of-year progress is reviewed with the employees' managers.

Equity Incentive Compensation

We view long-term compensation, currently in the form of stock options and RSUs, which generally vest in annual increments over three years (other than awards under our LTIP, which vest immediately if awarded, and performance based awards as described below), as a tool to align the interests of our NEOs and employees generally with the creation of stockholder value, to motivate our employees to achieve and exceed corporate and individual objectives and to encourage them to remain employed by us. While cash compensation is a significant component of employees' overall compensation, the Compensation Committee and our board of directors (as well as our NEOs) believe that the driving force of any employee working in a growing pharmaceutical company should be strong equity participation. We believe that this not only creates the potential for substantial longer term corporate value but also serves to motivate employees and retain their loyalty and commitment with appropriate personal compensation over a longer period of time. Our equity awards are granted under our 2011 Equity Incentive Plan (as the same may be amended, supplemented or superseded from time to time, which we refer to herein as the Plan).

During 2018, we granted equity incentive awards with two types of vesting: time-based and performance-based.

Time-based vesting. The Compensation Committee believes that because time-vested stock options and RSUs have a three-year vesting schedule that begins one year after the date of the award, the equity grants constitute a significant retention incentive and a tool to foster continuity of management, an important factor for a company with a relatively low number of employees.

Performance-based vesting. Based on the Compensation Committee's review in 2017 of market practices, pronouncements by corporate governance advisory services and discussions with our institutional investors, beginning with the annual equity awards granted to senior executives (including our NEOs) in February 2017 and February 2018, one-half of the RSUs granted were performance-based and vest over a three-year period based on the level of achievement of specified predetermined net revenue and operating income targets, with the remaining one-half being time-vested as described above.

On January 31, 2019, the Compensation Committee determined that 1/3rd of the 2018 performance-based RSUs would vest at a rate of 100% according to the achievement of the aforementioned targets. Such RSUs will vest on the first open window after the filing of our Annual Report on Form 10-K.

Performance Long Term Incentive Plan

In December 2012, in anticipation of the commencement of revenue generating operations by our company by means of product commercialization, the Compensation Committee approved our LTIP. The LTIP is designed as an incentive for our senior management (including our NEOs) to generate revenue for us.

The LTIP consists of RSUs (which we refer to herein as Performance RSUs), which are rights to acquire shares of our common stock upon satisfaction of performance-based goals. All Performance RSUs granted under the LTIP will be granted under the Plan as "Performance Compensation Awards" under such plan. The participants in the LTIP are either NEOs or senior officers of ours.

The term of the LTIP began with our fiscal year ended December 31, 2012 and lasts through our fiscal year ended December 31, 2019. The total number of Performance RSUs covered by the LTIP is 1,078,000, of which an aggregate of 978,000 were awarded in 2012 (and an aggregate of 35,000 in 2015). The Performance RSUs under the LTIP are subject to potential vesting each year over the eight-year term of the LTIP depending on the achievement of revenue by us, as reported in our Annual Report on Form 10-K. During years 2013 through 2018, a cumulative total of 139,882 Performance RSUs vested. Performance RSUs will be valued on the day of issuance and will vest annually on the last day preceding the first open trading window after filing our Annual Report on Form 10-K based on the revenue achieved during the prior fiscal year as a proportion of the total cumulative revenue target for the entire term of the LTIP (which we call the Predefined Cumulative Revenue). Predefined Cumulative Revenue is a predefined aggregate revenue target for the entire term of the LTIP that was determined by the

Compensation Committee in conjunction with our executive management. The Predefined Cumulative Revenue may be adjusted by the Compensation Committee upon the occurrence of extraordinary corporate events during the term of the LTIP (such as acquisitions by us of revenue generating businesses or assets).

Other Compensation

In addition to the main components of compensation outlined above, we also provide contractual severance and/or change in control benefits to the NEOs as well as to Terry Coelho, who was appointed as our Chief Financial Officer as of January 15, 2019, (see "Appointment of Chief Financial Officer" below), to Joseph Lockhart, our Senior Vice President Operations and to Albert J. Medwar, our former Senior Vice President, Corporate and Business Development (who retired from our company on April 1, 2018 and received a retirement benefits package that included equity features). Ernest R. De Paolantonio, our former Treasurer and Chief Financial Officer, executed a transitional service and separation agreement with us on January 23, 2019 and received contractual severance benefits as a condition of his retirement (see "De Paolantonio Retirement Agreement"). The change in control benefits for all applicable persons has a "double trigger." A double-trigger means that the executive officers will receive the change in control benefits described in the agreements only if there is both (1) a Change in Control of our company (as defined in the agreements) and (2) a termination by us of the applicable person's employment "without cause" or a resignation by the applicable persons for "good reason" (as defined in the agreements) within a specified time period prior to or following the Change in Control. We believe this double trigger requirement creates the potential to maximize stockholder value because it prevents an unintended windfall to management as no benefits are triggered solely in the event of a Change in Control while providing appropriate incentives to act in furtherance of a change in control that may be in the best interests of the stockholders. We believe these severance or change in control benefits are important elements of our compensation program that assist us in retaining talented individuals at the executive and senior management levels and that these arrangements help to promote stability and continuity of our executives and senior management team. We also believe that the interests of our stockholders will be best served if the interests of these members of our management are aligned with theirs. Furthermore, we believe that providing change in control benefits lessens or eliminates any potential reluctance of members of our management to pursue potential change in control transactions that may be in the best interests of the stockholders. Finally, we believe that it is important to provide severance benefits to members of our management to promote stability and to focus on the job at hand.

We also provide benefits to the executive officers that are generally available to all regular full-time employees of ours, including our medical and dental insurance, life insurance and a 401(k) match for all individuals who participate in the 401(k) plan. Currently, we do not provide any perquisites to any of our NEOs. Further, we do not have pension arrangements or post-retirement health coverage for our executive officers or employees. We also do not have deferred compensation plans other than allowing senior executive recipients of RSUs to defer payment of RSUs that may vest in future years, subject to compliance with Section 409A of the Internal Revenue Code (or the Code) and related rules.

All our employees not specifically under contract are "at-will" employees, which means that their employment can be terminated at any time for any reason by either us or the employee. Our NEOs (as well as certain of our senior managers) have employment agreements that provide lump sum compensation in the event of their termination without cause or, under certain circumstances, upon a Change of Control.

Determination of Compensation Amounts

Many factors impact the determination of compensation amounts for our NEOs, including the individual's role in our company and individual performance, length of service with us, competition for talent, individual compensation package, assessments of internal pay equity and industry data. Stock price performance has generally not been a significant factor in determining annual compensation because the price of our common stock is subject to a variety of factors outside of our control.

Industry Survey Data

In collaboration with our compensation advisor, our Compensation Committee establishes a list of peer companies to best ensure that we are compensating our executives on a fair and reasonable basis, as set forth above under the heading "Objectives of our Compensation Program." We also utilize data for below-executive level personnel, which data focuses on similarly-sized life science companies in the Southeastern region of the United States. The availability of peer data is used by the Compensation Committee strictly as a guide in determining compensation levels regarding salaries, cash bonuses and annual equity grants to all employees. However, the availability of this data does not imply that the Compensation Committee is under any obligation to exactly follow peer companies in compensation matters.

Determination of Base Salaries

As a guideline for NEO base salary, we perform formal benchmarking against respective comparable positions in our established peer group. Our guideline is to set targeted NEO salary ranges between the 25th and 50th percentile for comparable positions within our peer group. We then adjust salaries based on our assessment of our NEOs' levels of responsibility, experience, overall compensation structure and individual performance. The Compensation Committee has the discretion if it believes circumstances warrant, to go above the 50th percentile of the peer group. The Compensation Committee is not obliged to raise salaries purely on the availability of data. Merit-based increases to salaries of executive officers are based on our assessment of individual performance and the relationship to applicable salary ranges. Cost of living adjustments may also be a part of that assessment. The Compensation Committee, in recent years, has tended to maintain cash compensation levels at or near the 50th percentile but to exceed that level in determining equity compensation. The emphasis on equity compensation reflects the Committee's objective, given that we have only recently engaged in revenue generating operations, to incentivize personnel and to preserve cash in a prudent manner and yet reward personnel for outstanding performance.

Performance Cash Bonus Plan

Concurrently with the beginning of each calendar year, preliminary corporate goals that reflect our business priorities for the coming year are prepared by our NEOs with input from other officers. The draft goals are presented to the Compensation Committee and our full board at the beginning of each year and discussed, revised as necessary, and then approved by our board of directors. The Compensation Committee then reviews the final goals to determine and confirm their appropriateness for use as performance measurements for purposes of the bonus program. The goals may be re-visited during the year and potentially restated in the event of significant changes in corporate strategy or the occurrence of significant corporate events. Following the agreement of our board of directors on the corporate objectives, the goals are then shared with all employees in a formal meeting(s) and are reviewed periodically throughout the year at monthly staff meetings and quarterly board of director meetings.

The performance cash bonus plan for our executive officers and employees in 2018 was adopted by the Compensation Committee in February 2018. The plan sets forth target bonus opportunities, as a percentage of salary, based on the level of responsibility of the position, ranging up to 55% of salary for Herm Cukier, our CEO, up to 45% of salary for our NEOs and up to 30% of salary for certain other officers. In setting these percentages, the Compensation Committee determined that the above percentages were reasonable and in line with our peer group. Each employee has the opportunity to achieve a targeted amount, depending on how corporate goals and objectives are achieved, with variances on an "employee by employee" basis to be determined by our Compensation Committee in consultation with senior executives and employees' direct reports.

Determination of Equity Incentive Compensation

To assist us in assessing the reasonableness of our equity grant amounts, historically we have reviewed information supplied by our compensation consultant. Such information included equity data from a cross-section of the companies in the above-mentioned surveys. Initially, on-hire stock option grant amounts have generally been targeted at the 25th to 50th percentile for that position or similar industry position, adjusted for internal equity, experience level of the individual and the individual's total mix of compensation and benefits provided in his or her offer package. Initial on-hire grants typically vest over three years.

Beginning in January 2016, the Compensation Committee expanded its criteria for equity awards, considering not only the financial value of awards, but also the "burn rate" (meaning the number of shares awarded as a percentage of total outstanding shares). These two criteria (i.e. financial value and burn rate) often result in disparate computations when contrasted to peer group criteria. Accordingly, the Compensation Committee has attempted to equitably balance those two factors to achieve appropriate equity awards.

In early 2017 and early 2018, with respect to equity awards to senior executives, including NEOs, one-half of the RSUs were awarded in the form of time-based RSUs, as have been exclusively awarded to those executives in recent years, and for the first time, one-half of the RSUs were in the form of performance-based RSUs as described above. In early 2019, the Compensation Committee further expanded upon its prior equity grant philosophy and decided to make award decisions that were more in line with current industry standards.

For a discussion of equity awards made in early 2019, see "Equity Awards in January 2019" under "Compensation Decisions For Performance in 2018" below.

Equity Grant Practices

All stock options and/or RSUs granted to the NEOs and other executives are approved by the Compensation Committee. Exercise prices for options are set using a 30-day volume weighted average price method, which we define as the closing price of our common stock on the Nasdaq Capital Market on the trading day of the date of grant and the 30 trading days preceding that date. RSU grants are valued on the day of issuance and are vested (in the case of either time-based or performance-based vesting), if earned on

the last day preceding an open trading window after filing our Annual Report on Form 10-K. Grants are generally made: (i) on the employee's start date and (ii) at board of director meetings held each January or February and following annual performance reviews. However, grants have been made at other times during the year. The size of year-end grants for each NEO is assessed against our internal equity guidelines. Current market conditions for grants for comparable positions and internal equity may also be assessed. Also, grants may be made relating to promotions or job-related changes in responsibilities. In addition, on occasion, the Compensation Committee may make special awards for extraordinary individual or our company performance.

Compensation Setting Process

At the first of the year, meetings of our board of directors and the Compensation Committee, overall corporate performance and relative achievement of the corporate goals for the prior year are assessed. The relative achievement of each goal is assessed, and the summation of the individual components results in an overall corporate goal rating, expressed as a percentage.

Also, near the end of the year, the CEO evaluates the individual performance of each NEO (other than himself) and provides the Compensation Committee with an assessment of the performance of such NEO. In determining the individual performance ratings of the NEOs, we assess performance against many factors, including each NEO's relative contributions to our corporate goals, demonstrated career growth, level of performance in the face of available resources and other challenges, and the respective officer's department's overall performance. This assessment is conducted in a holistic fashion, in contrast to the summation of individual components as is done to arrive at the corporate goal rating.

Following a qualitative assessment of each individual NEO's performance, our policies provide guidelines for translating this performance assessment into a numerical rating. Both the initial qualitative assessment and the translation into a numerical rating are made by the Compensation Committee on a discretionary basis. We believe that conducting a discretionary assessment for the individual component of the NEOs' performance provides for flexibility in the evaluation of our NEOs and their adaptability to addressing potential changes in our priorities throughout the year.

The Compensation Committee looks to the CEO's performance assessments of the other NEOs and his recommendations regarding a performance rating for each, as well as input from the other members of our board of directors. These recommendations may be adjusted by the Compensation Committee prior to finalization. For the CEO, the Compensation Committee evaluates his performance, taking into consideration input from the other members of our board of directors, and considers the achievement of overall corporate objectives by both the CEO specifically and our company generally. The CEO is not present during the Compensation Committee's deliberations regarding his compensation.

The CEO may also present any recommended changes to base salary and recommendations for annual equity grant amounts for NEOs and other senior executives.

The Compensation Committee has the authority to directly engage, at our expense, any compensation consultants or other advisors (such as Radford) that it deems necessary to determine the amount and form of employee, executive and director compensation. In determining the amount and form of employee, executive and director compensation, the Compensation Committee has reviewed and discussed historical salary information as well as salaries for similar positions at comparable companies. However, the availability of this data does not imply that the Compensation Committee is under any obligation to exactly follow peer companies' compensation practices.

We paid consultant fees to Radford of $0.1 million in 2018. NEOs may have indirect input in the compensation results for other executive officers by virtue of their participation in the performance review and feedback process for the other executive officers.

Compensation Decisions for Performance in 2018

General Assessment of Management Performance in 2018

The Compensation Committee and our board of directors conducted the performance and compensation review for 2018 in January 2019. The Compensation Committee compared performance as elaborated below.

The key corporate objectives for 2018 included the following:

(1) Key financial objectives including targeted revenue and cash on hand, (2) commercial objectives including BELBUCA sales and preferred coverage, (3) organizational objectives including hiring of key NEOs and sales team expansions, (4) operational objectives including cost of goods reductions and improve production and inventory efficiencies, (5) medical objectives including development of medical communication and data generation plans, and (6) legal objectives including continued success in ongoing and prospective litigation with respect to our intellectual property and patent portfolio.

The Compensation Committee determined that the Company had achieved all 2018 key objectives as established and exceeded expectations of targeted performance measures.

2018 Cash Bonus Calculations

After reviewing the achievement of the corporate goals and objectives for 2018 as noted above, the Compensation Committee determined that all NEOs should be awarded a cash bonus at 110% of their target, adjusting for time-served during 2018 for newly hired NEOs. A cash bonus pool, equal to 110% of the aggregate of individual bonus opportunities of all other employees, was established with our executives having the authority to award individual bonuses from that pool with respect to these employees who reported to them. The cost of all such cash bonuses for 2018 performance (but paid in March 2019) was approximately $0.8 million for NEOs and approximately $0.7 million for employees.

Equity Awards in January 2019

On January 31, 2019, the total amount of stock options awarded to our NEOs and senior executives was 1,120,000, which options vest annually in one-third equal increments beginning one year after the date of grant and had an approximate Black Scholes value of $4.4 million.

The total amount of the RSUs awarded to our NEOs and senior executives was 190,250, having an approximate value on the date preceding the grant of $0.9 million based on a share price of $4.50.

All RSUs and stock options awarded in January 2019 were granted pursuant to the Plan, as amended.

Individual Compensation of Herm Cukier, our Chief Executive Officer

Mr. Cukier, who joined our Company May 2018, received a base salary of $570,000 in 2018.

Mr. Cukier was awarded a cash bonus for 2018 in the amount of $231,050, which is 110% of his target bonus of 55% of his base salary in 2018, after further adjustment for time served during 2018, a calculation consistent with our cash bonus policy. Mr. Cukier was also granted in January 2019, 540,000 stock options and 93,750 RSUs, which are subject to time-based vesting.

Individual Compensation of Ernest R. De Paolantonio, our Chief Financial Officer during 2018.

Mr. De Paolantonio's received a base salary of $370,000 in 2018.

Mr. De Paolantonio was awarded a cash bonus for 2018 in the amount of $162,800, which is 110% of his target bonus of 40% of his base salary in 2018, a calculation consistent with our cash bonus policy.

Individual Compensation of Scott Plesha, our President and Chief Commercial Officer

Mr. Plesha, who joined our Company in August 2015 and promoted to President in January 2018, received a base salary of $365,000 in 2018.

Mr. Plesha was awarded a cash bonus for 2018 in the amount of $180,675, which is 110% of his target bonus of 40% of his base salary in 2018, a calculation consistent with our cash bonus policy. Mr. Plesha was also granted in January 2019, 245,000 stock options and 40,000 RSUs, which are subject to time-based vesting.

Individual Compensation of Dr. Thomas Smith, our Chief Medical Officer

Dr. Smith, who joined our Company in July 2018, received a base salary of $345,000 in 2018.

Dr. Smith was awarded a cash bonus for 2018 in the amount of $50,094, which is 110% of his target bonus of 40% of his base salary in 2018, after further adjustment for time served during 2018, a calculation consistent with our cash bonus policy. Dr. Smith was also granted in January 2019, 130,000 stock options and 23,000 RSUs, which are subject to time-based vesting.

Individual Compensation of James Vollins, our General Counsel, Chief Compliance Officer and Corporate Secretary

Mr. Vollins, who joined our Company in November 2018, received a base salary of $310,000 in 2018.

Mr. Vollins' target bonus is 40% of his base salary in 2018, a calculation consistent with our cash bonus policy. Mr. Vollins was also granted in January 2019, 65,000 stock options and 11,500 RSUs, which are subject to time-based vesting.

Appointment of Chief Financial Officer

Ms. Coelho joined our Company in January 2019 and receives a base salary of $385,000. Ms. Coelho's target bonus is 45% of her base salary for 2019, a calculation consistent with our cash bonus policy.

De Paolantonio Retirement Agreement

On January 23, 2019, we entered into a Transitional Service and Separation Agreement (the "Separation Agreement") with Mr. De Paolantonio, our former Chief Financial Officer and Treasurer. Unless Mr. De Paolantonio resigns, or his employment is terminated earlier, Mr. De Paolantonio will continue as a senior advisor to the Company until April 30, 2019, at which time his employment with us will end (the "Retirement Date").

The Separation Agreement provides for, among other things, Mr. De Paolantonio to (i) continue to receive his current base salary, (ii) remain eligible to participate in our group employee benefit plans as a regular full-time employee, and (iii) continue to vest in his outstanding equity awards until his Retirement Date. At the termination of his employment with us, provided that, among other things, Mr. De Paolantonio is not terminated by us for "cause," Mr. De Paolantonio will be entitled to receive (a) a one-time cash payment of $0.36 million, subject to applicable deductions and withholdings, representing one full year of his current base salary, provided that Mr. De Paolantonio has not breached any of his continuing obligations, including that he signs and does not revoke a general release of claims against us, (b) his target annual incentive compensation for 2018 (subject to determination by the board of directors of the Company), and (c) a monthly cash payment for three months in an amount equal to the actual costs of continuation of Mr. De Paolantonio's group health and dental insurance under the Consolidated Omnibus Reconciliation Act of 1985.

Additionally, the option exercise period for the vested incentive stock options granted to Mr. De Paolantonio on October 1, 2013 shall be extended through the remainder of the option period which ends on October 17, 2023. All time-based restricted stock units held by Mr. De Paolantonio that would have vested had Mr. De Paolantonio remained employed by us through December 31, 2020 shall be deemed vested as of the Retirement Date, and all time-based restricted stock units held by Mr. De Paolantonio that by their terms vest after December 31, 2020 will be forfeited as of the Retirement Date. Subject to Mr. De Paolantonio's service through the Retirement Date, all performance-based restricted stock units shall remain outstanding and eligible to vest with respect to our performance through December 31, 2020 and any performance-based restricted stock units that do not vest based upon performance through December 31, 2020 shall be forfeited.

Accounting and Tax Considerations

ASC 718. On January 1, 2006, we began accounting for share-based payments in accordance with the requirements of Accounting Standards Codification 718 (ASC 718), Share-Based Payments. To date, the adoption of ASC 718 has not impacted our stock option granting practices.

Internal Revenue Code Section 162(m). Generally, Section 162(m) of the Code ("Section 162(m)") disallows a federal income tax deduction for public corporations of remuneration in excess of $1 million paid in any fiscal year to certain specified executive officers. For taxable years beginning before January 1, 2018 (i) these executive officers consisted of a public corporation's chief executive officer and up to three other executive officers (other than the chief financial officer) whose compensation is required to be disclosed to stockholders under the Exchange Act because they are our most highly-compensated executive officers and (ii) qualifying "performance-based compensation" was not subject to this deduction limit if specified requirements are met.

Pursuant to the Tax Cuts and Jobs Act of 2017 (the "Tax Act"), for taxable years beginning after December 31, 2017, the remuneration of a public corporation's chief financial officer is also subject to the deduction limit. In addition, subject to certain transition rules (which apply to remuneration provided pursuant to written binding contracts which were in effect on November 2, 2017 and which are not subsequently modified in any material respect), for taxable years beginning after December 31, 2017, the exemption from the deduction limit for "performance-based compensation" is no longer available. Consequently, for fiscal years beginning after December 31, 2017, all remuneration in excess of $1 million paid to a specified executive will not be deductible. These changes will cause more of our compensation to be non-deductible under Section 162(m) in the future and will eliminate the Company's ability to structure performance-based awards to be exempt from Section 162(m).

In designing our executive compensation program and determining the compensation of our executive officers, including our named executive officers, our compensation committee considers a variety of factors, including the potential impact of the Section 162(m) deduction limit. However, our compensation committee will not necessarily limit executive compensation to that which is or may be deductible under Section 162(m). The deductibility of some types of compensation depends upon the timing of an executive officer's vesting or exercise of previously granted rights. Further, interpretations of and changes in the tax laws, and other factors beyond our compensation committee's control also affect the deductibility of compensation. Our compensation committee will consider various alternatives to preserving the deductibility of compensation payments and benefits to the extent consistent with its compensation goals and will continue to monitor developments under Section 162(m).

To maintain flexibility to compensate our executive officers in a manner designed to promote our short-term and long-term corporate goals, our compensation committee has not adopted a policy that all compensation must be deductible. Our compensation committee believes that our stockholders' interests are best served if its discretion and flexibility in awarding compensation is not restricted, even though some compensation awards may result in non-deductible compensation expense.

Section 409A. Section 409A of the Code generally changed the tax rules that affect most forms of deferred compensation that were not earned and vested prior to 2005. Under Section 409A, deferred compensation is defined broadly and may potentially cover compensation arrangements such as severance or change in control pay outs and the extension of the post-termination exercise periods of stock options. We take Code Section 409A into account, where applicable, in determining the timing of compensation paid to our executive officers in order to comply with, or be exempt from, its requirements.

Item 11. Executive Compensation.

The following table sets forth all compensation paid to our named executive officers at the end of the fiscal years ended December 31, 2018, 2017 and 2016. Individuals we refer to as our "named executive officers" include our Vice Chairman (formerly served as our Chief Executive Officer), our former Chief Financial Officer, our former Senior Vice President and Chief Technology Officer and our most highly compensated executive officers

whose salary and bonus for services rendered in all capacities exceeded $100,000 during the fiscal year ended December 31, 2018.

Summary Compensation Table

Name and principal position	Year	Salary ($)	Bonus ($)	Stock Awards ($)(17)	Option Awards ($)(17)	Non-Equity Incentive Plan Compensation ($)	Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Mark A. Sirgo, Pharm.D.	2018	68,385(2)	—	792,000	—	—	—	978,249(3)	1,838,643
Vice Chairman and	2017	590,000	247,800	1,387,500	—	—	—	847,714	3,073,014
Director (1)	2016	571,154	264,000	1,045,000	—	—	—	19,485	1,899,639
Herm Cukier, Chief	2018	359,539(4)	281,050(5)	526,000	1,288,000	—	—	14,459(6)	2,469,048
Executive Officer and	2017	—	—		—	—	—	—	—
Director	2016	—	—		—	—	—	—	—
Scott M. Plesha, President	2018	371,080	180,675	332,813	—	—	—	34,423(8)	918,991
and Chief Compliance	2017	296,920	83,138	92,500	—	—	—	32,466	505,024
Officer (7)	2016	308,340	89,076	280,000	—	—	—	33,062	710,478
Thomas Smith, M.D., Chief	2018	139,327(9)	75,094(5)	—	165,944	—	—	3,441(10)	383,806
Medical Officer	2017	—	—	—	—	—	—	—	—
	2016	—	—	—	—	—	—	—	—
James Vollins, General	2018	41,731(11)	35,000(5)	—	210,269	—	—	351(12)	287,351
Counsel, Chief	2017	—	—	—	—	—	—	—	—
Compliance Officer and	2016	—	—	—	—	—	—	—	—
Corporate Secretary									
Ernest R. De Paolantonio,	2018	370,000	162,800	294,000	—	—	—	32,790(14)	941,901
CPA MBA Former Chief	2017	350,000	98,000	351,500	—	—	—	32,632	1,030,558
Financial Officer and	2016	363,461	112,000	342,000	—	—	—	33,269	1,023,558
Treasurer (13)									
Niraj Vasisht, Ph.D. Former	2018	58,078	—	637,686	—	—	—	358,823(16)	941,901
Senior VP and Chief	2017	310,000	86,800	303,573	—	—	—	32,508	1,030,558
Technology Officer (15)	2016	321,923	99,200	570,000	—	—	—	32,435	1,023,558

(1) Mark A. Sirgo served as our President, Chief Executive Officer, Director and Vice Chairman until his retirement date of January 2, 2018. Upon retirement, Dr. Sirgo now serves as a Director and Vice Chairman.
(2) Includes compensation in the amount of $52,500 for serving as Vice Chairman and Director post-retirement.
(3) Includes: Second and final gross, retirement payment in 2018 of $787,000, $131,625 of payments made through consulting company post-retirement during 2018, $40,846 of accrued vacation paid in 2018, $5,528 of health insurance premiums paid and 401(k) matching of $13,250 paid in 2018.
(4) Herm Cukier was hired as our Chief Executive Officer and Director on May 8, 2018. As such, the salary compensation presented in this table has been annualized.
(5) Includes a new hire sign-on bonus in 2018.
(6) Includes: $709 of health insurance premiums and 401(k) matching of $13,750 paid in 2018.
(7) Scott Plesha was promoted to our President, and therefore a reporting officer, on January 2, 2018.
(8) Includes: $18,919 of health insurance premiums paid, $1,754 telephone reimbursement and 401(k) matching of $13,750 paid in 2018.
(9) Thomas Smith M.D. was hired as our Chief Medical Officer on July 30, 2018. As such, the salary compensation presented in this table has been annualized.
(10) Includes: $3,090 of health insurance premiums paid and $351 telephone reimbursement paid in 2018.
(11) James Vollins was hired as our General Counsel, Chief Compliance Officer and Corporate Secretary on November 5, 2018. As such, the salary compensation presented in this table reflects the salary earned for his partial year of employment.
(12) Includes: $351 telephone reimbursement paid in 2018. As such, the salary compensation presented in this table has been annualized.
(13) Ernest De Paolantonio retired as our Chief Financial Officer and Treasurer on December 31, 2018 and executed a transitional service and separation agreement with an effective date of retirement to be April 30, 2019.
(14) Includes: $18,689 of health insurance premiums paid, $351 telephone reimbursement and 401(k) matching of $13,750 paid in 2018.
(15) Niraj Vasisht served as our Senior Vice President and Chief Technology Officer until his retirement date of February 5, 2018.
(16) Includes: retirement payment in 2018 of $330,000, $15,723 of accrued vacation paid in 2018, $3,254 of health insurance premiums paid and 401(k) matching of $9,846 paid in 2018.
(17) The reported amounts represent the aggregate grant date fair value of the awards computed in accordance with Financial Accounting Standards Board Account Standards Codification Topic 718, Stock Compensation, as modified or supplemented, or FASB ASC Topic 718.

Grants of Plan-Based Awards in 2018

Name	Grant Date	Estimated Future Payouts Under Non-Equity Incentive Plan Awards			Estimated Future Payouts Under Equity Incentive Plan Awards			All Other Stock Awards: Number of Shares of Stocks or Units (#)	All Other Option Awards: Number of Securities Underlying Options (#)	Exercise or Base Price of Option Awards ($/Sh)	Closing stock price on Award date ($/Sh)	Grant Date Fair Value of Stock and Option Awards ($)
		Threshold ($)	Target ($)	Maximum ($)	Threshold (#)	Target (#)	Maximum (#)					
Mark A. Sirgo, Pharm.D.	3/23/18(1)							285,305				$ 613,406
Herm Cukier	5/8/18(2)						200,000					$ 526,000
	6/4/18								800,000	$ 2.18	$ 2.60	$1,288,000
Scott Plesha	2/18/18(3)					62,500		62,500				$ 262,500
	10/17/18(4)					18,750						$ 70,313
Thomas Smith, M.D.	8/1/18								117,691	$ 2.93	$ 2.55	$ 165,944
James Vollins	11/5/18								89,476	$ 3.46	$ 3.85	$ 210,269
Ernest R. De Paolantonio, CPA MBA	2/18/18(3)					70,000		70,000				$ 294,000
Niraj Vasisht, Ph.D.	2/18/18(1)							198,129				$ 416,071

(1) As of each of the Retirement Dates, the stock awards disclosed in this item during 2018 related to one-half time-vesting and one-half performance-based RSUs issued to each of Dr. Sirgo and Dr. Vasisht pursuant to the Plan for 2017 performance, then terminated. In lieu thereof, Dr. Sirgo and Dr. Vasisht each received a one-time issuance of fully vested shares of Common Stock under the Plan, the number of which was determined with reference to the time-vesting RSUs by dividing (A) the Net Present Value of such time-vesting RSUs by (B) the 30-day VWAP as of the Retirement Date and with reference to the performance-based RSUs by multiplying the remaining half by 66%. Dr. Sirgo deferred this stock award to March 2018.

(2) The stock awards disclosed in this item consists of performance-based RSUs issued under our 2011 Equity Incentive Plan with a FMV of $2.63, which vest under certain performance criteria beginning May 2019.

(3) The stock awards disclosed in this item consists of half time-based RSUs and half performance based RSUs issued under our 2011 Equity Incentive Plan with a FMV of $2.10, which vest ratably in thirds beginning March 2019.

(4) The stock awards disclosed in this item consists of performance-based RSUs issued under our 2011 Equity Incentive Plan with a FMV of $3.75, which vested under certain performance criteria in October 2018.

Narrative Disclosure to Summary Compensation Table and Grants of Plan-Based Awards Table

Employment Agreements

Except as set forth below, we currently have no written employment agreements with any of our officers, directors, or key employees. All directors and officers have executed confidentiality and noncompetition agreements with us.

The following is a description of our current executive employment agreements:

Herm Cukier, Chief Executive Officer – Mr. Cukier's employment agreement, dated May 2, 2018 includes a base salary of $570,000, target bonus of up to 55% of his base salary (which is subject to modification by our Compensation Committee), and other employee benefits. Under the terms of his agreement, Mr. Cukier also received in 2018 a sign-on bonus of $50,000.

We or Mr. Cukier may terminate his agreement for any reason or no reason upon sixty (60) days prior written notice to the other. Solely in the case of an event of cause, we cannot terminate Mr. Cukier for cause unless we haves provided written notice to Mr. Cukier of the existence of the circumstances providing grounds for termination for a cause capable of cure, and Mr. Cukier has had at least thirty (30) days from the date on which such notice is provided to cure such circumstances to the reasonable satisfaction of us.

Mr. Cukier cannot terminate his employment for Good Reason unless he has provided written notice to us of the existence of the circumstances providing grounds for termination for good reason within sixty (60) days (thirty (30) days in the event of the grounds of the date Mr. Cukier learns of the initial existence of such grounds and we have had at least thirty (30) days from the date on which such notice is provided to cure such circumstances.) If Mr. Cukier does not terminate his employment for good reason within ninety (90) days after the date Mr. Cukier learns of the first occurrence of the applicable grounds, then Mr. Cukier will be deemed to have waived his right to terminate for good reason with respect to such grounds.

In the event of a termination by us for Cause or Mr. Cukier's resignation without good reason, we will pay Mr. Cukier (i) the base salary earned and expenses reimbursable incurred through the date of Mr. Cukier's termination, (ii) the prior year bonus (if applicable), and (iii) all amounts otherwise required to be paid or provided by law and shall thereafter have no further responsibility for termination or other payments to Mr. Cukier.

In the event of a termination by us without Cause, resignation by Mr. Cukier for good reason, or a non-renewal by us: We shall pay Mr. Cukier a one-time cash severance payment equal to two (2) times the amount of his then current annual base salary (or, in the event of a resignation by Mr. Cukier for good reason as a result of a reduction in Mr. Cukier's base salary, two (2) times the amount of his annual base salary prior to the reduction that gave rise to grounds for good reason). We shall pay Mr. Cukier on the payment date his pro-rated bonus through the date of termination and his prior year bonus (if applicable). In addition, all unvested option awards shall immediately become fully vested and exercisable and shall be exercisable over a period of three (3) years, and any performance-based equity awards shall continue to vest and settled upon achievement of the applicable annual financing or performance objectives. Mr. Cukier's employment agreement will terminate prior to its scheduled expiration date in the event of Mr. Cukier's death or disability.

In the event that Mr. Cukier's employment with the Company is terminated by the Company or its successor without Cause, or by Mr. Cukier for good reason, in any case in anticipation of, upon, or within twelve (12) months following the occurrence of a "Change of Control" (as defined in the employment agreement), Mr. Cukier will be entitled to receive a one-time severance payment equal to two (2) times the sum of (i) his base salary plus (ii) his bonus for the applicable year (calculated at 100% of target). In addition, all unvested option awards shall immediately become fully vested and exercisable and shall be exercisable over a period of three (3) years, and any performance-based equity awards shall continue to vest and settled upon achievement of the applicable annual financing or performance objectives.

Mr. Cukier's employment agreement also includes 5-year non-competition and non-solicitation and confidentiality covenants. Under the terms of this agreement, he was also entitled to the following benefits: medical, dental, life, disability and 401(k).

Scott M. Plesha, President – Mr. Plesha was promoted to the role as our President and his current employment agreement, dated December 20, 2017 includes a base salary of $365,000, target bonus of up to 45% of his base salary (which is subject to modification by our Compensation Committee), and other employee benefits. Under the terms of his agreement, Mr. Plesha received a bonus in 2018 of $83,138, which bonus was related to 2017 performance.

We may terminate Mr. Plesha's employment agreement without cause and Mr. Plesha may resign without notice. We may immediately terminate Mr. Plesha's employment agreement for Good Cause (as defined in the agreement). Upon the termination of Mr. Plesha's employment for any reason, Mr. Plesha will continue to receive payment of any base salary earned but unpaid through the date of termination and any other payment or benefit to which he is entitled under the applicable terms of any applicable company arrangements. If Mr. Plesha is terminated during the term of the employment agreement other than for Good Cause (as defined in the employment agreement), or if Mr. Plesha terminates his employment for Good Reason (as defined in the employment agreement), Mr. Plesha is entitled to a lump sum severance payment equal to 1 times the amount of his annual base salary. In the event that such termination is within six months following a Change of Control (as defined in the employment agreement), the lump sum paid to Mr. Plesha will equal to one times the amount of his then current annual base salary. In the event of Mr. Plesha's death or disability, the amount owed to Mr. Plesha will be a one-time cash severance payment equal to one times his then current base salary.

Mr. Plesha's employment agreement also includes 2-year non-competition and non-solicitation and confidentiality covenants. Under the terms of this agreement, he is also entitled to the following benefits: medical, dental, life, disability and 401(k).

Thomas Smith, M.D., Chief Medical Officer- Dr. Smith's employment agreement, dated July 30, 2018 includes a base salary of $345,000, target bonus of up to 40% of his base salary (which is subject to modification by our Compensation Committee), and other employee benefits. Under the terms of his agreement, Dr. Smith also received in 2018 a sign-on bonus of $25,000.

We may terminate Dr. Smith's employment agreement without cause and Dr. Smith may resign without notice. We may immediately terminate Dr. Smith's employment agreement for Cause (as defined in his agreement). Upon the termination of Dr. Smith's employment for any reason, Dr. Smith will continue to receive payment of any base salary earned but unpaid through the date of termination and any other payment or benefit to which he is entitled under the applicable terms of any applicable company arrangements. If Dr. Smith is terminated during the term of the employment agreement other than for Cause (as defined in the employment agreement) Dr. Smith is entitled to a lump sum severance payment equal to one times the amount of his annual base salary. In the event that such termination is within six months following a Change of Control (as defined in the employment agreement), the lump sum paid to Dr. Smith will equal to one times the amount of his then current annual base salary.

In the event that Dr. Smith's employment with the Company is terminated by the Company or its successor without Cause within six (6) months following the occurrence of a "Change of Control" (as defined in the employment agreement), Dr. Smith will be entitled to receive a one-time severance payment equal to a one-time cash severance payment equal to his then current annual base salary. In addition, all unvested time-based options, RSUs or other equity securities to acquire shares of Company common stock shall immediately become fully vested and shall be exercisable to the extent provided for in the Plan.

Dr. Smith's employment agreement also includes 2-year non-competition and non-solicitation and confidentiality covenants. Under the terms of this agreement, he is also entitled to the following benefits: medical, dental, life, disability and 401(k).

James Vollins, General Counsel, Chief Compliance Officer and Corporate Secretary- Mr. Vollins' employment agreement, dated November 5, 2018 includes a base salary of $310,000, target bonus of up to 40% of his base salary (which is subject to modification by our Compensation Committee), and other employee benefits. Under the terms of his agreement, Mr. Vollins also received in 2018 a sign-on bonus of $35,000.

We may terminate Mr. Vollins' employment agreement without cause and Mr. Vollins may resign without notice. We may immediately terminate Mr. Vollins' employment agreement for Cause (as defined in his agreement). Upon the termination of Mr. Vollins' employment for any reason, Mr. Vollins will continue to receive payment of any base salary earned but unpaid through the date of termination and any other payment or benefit to which he is entitled under the applicable terms of any applicable company arrangements. If Mr. Vollins is terminated during the term of the employment agreement other than for Cause (as defined in the employment agreement) Mr. Vollins is entitled to a lump sum severance payment equal to one times the amount of his annual base salary. In the event that such termination is within six months following a Change of Control (as defined in the employment agreement), the lump sum paid to Mr. Vollins will equal to one times the amount of his then current annual base salary.

In the event that Mr. Vollins' employment with the Company is terminated by the Company or its successor without Cause within six (6) months following the occurrence of a "Change of Control" (as defined in the employment agreement), Mr. Vollins will be entitled to receive a one-time severance payment equal to a one-time cash severance payment equal to his then current annual base salary. In addition, all unvested time-based options, RSUs or other equity securities to acquire shares of Company common stock shall immediately become fully vested and shall be exercisable to the extent provided for in the Plan.

Mr. Vollins' employment agreement also includes 2-year non-competition and non-solicitation and confidentiality covenants. Under the terms of this agreement, he is also entitled to the following benefits: medical, dental, life, disability and 401(k).

Ernest R. De Paolantonio, CPA, MBA, Chief Financial Officer, Secretary and Treasurer – Mr. De Paolantonio's prior employment agreement, dated October 1, 2013, included a base salary of $300,000, target bonus of up to 40% of his base salary (which was subject to modification by our Compensation Committee), and other employee benefits. Under the terms of his agreement in 2018, Mr. De Paolantonio received a base salary of $370,000 and a bonus of $98,000, which bonus was related to 2017 performance.

On January 23, 2019, the Company entered into a transitional service and separation agreement with Mr. De Paolantonio. Unless Mr. De Paolantonio resigns or his employment is terminated earlier, Mr. De Paolantonio will continue as a senior advisor to us until April 30, 2019, at which time his employment with us will end. (See Compensation Discussion and Analysis for details on Mr. De Paolantonio's separation agreement.)

Mr. De Paolantonio's transitional service and separation agreement also includes 2-year non-competition and non-solicitation and confidentiality covenants on terms identical to the prior employment agreement. Under the terms of this agreement, he was also entitled to the following benefits: medical, dental, life, disability and 401(k).

Amended and Restated 2001 Incentive Plan

In July 2011, our original Amended and Restated 2001 Incentive Plan expired. Options to purchase 578,645 shares of common stock were outstanding and exercisable as of December 31, 2018 under the Amended and Restated 2001 Incentive Plan. In April 2011, our board approved, and in July 2011, our stockholders approved a new 2011 Equity Incentive Plan, which is discussed below.

2011 Equity Incentive Plan

Our 2011 Equity Incentive Plan was originally comprised of 4,200,000 shares of our common stock. The purpose of the 2011 Equity Incentive Plan is: (i) to align our interests and recipients of options under the plan by increasing the proprietary interest of such recipients in our growth and success, and (ii) to advance our interests by providing additional incentives to officers, key employees and well-qualified non-employee directors and consultants who provide services to us, who are responsible for our management and growth, or otherwise contribute to the conduct and direction of our business, operations and affairs. The Compensation Committee of our board of directors administers our incentive plan, selects the persons to whom options are granted and fixes the terms of such options. In July 2013, 2014, 2015 and in December 2017, our stockholders approved increases to our 2011 Equity Incentive Plan in the amounts of 2,600,000, 2,000,000, 2,250,000 and 7,100,000, respectively.

Options may be awarded during the ten-year term of the plan to our employees, directors, or consultants who are not employees and our other affiliates. Our plan provides for the grant of options that qualify as incentive stock options, or Incentive Stock Options, under Section 422 of the Internal Revenue Code of 1986, as amended, and options which are not Incentive Stock Options, or Non-Statutory Stock Options, as well as restricted stock and other awards. Only our employees may be granted Incentive Stock Options. Our affiliates or consultants or others as may be permitted by our

board of directors, may be granted Non-Statutory Stock Options.

Options to purchase 4,406,004 shares of our common stock at prices ranging from $1.78 to $16.47 are outstanding at December 31, 2018.

Options issued during 2018 to directors and employees under the 2011 Equity Incentive Plan totaled 2,549,177 shares, at exercise prices ranging from $2.07 to $3.72.

Outstanding equity awards

The following table summarizes outstanding unexercised options, unvested stock and equity incentive plan awards held by each of our name executive officers, as of December 31, 2018.

OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END

	OPTION AWARDS (1)					STOCK AWARDS			
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Options Exercise Prices ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not vested ($)
Mark A. Sirgo, Pharm.D(7)	—	—	—	—	—	—	—	327,170(2)	1,210,529
	25,000	—	—	3.47	7/20/21	—	—	—	—
	22,369	—	—	3.55	2/25/21	—	—	—	—
	37,348	—	—	3.90	1/21/20	—	—	—	—
	25,000	—	—	5.40	7/22/19	—	—	—	—
	100,000	—	—	4.83	4/30/19	—	—	—	—
	9,175	—	—	3.05	1/22/19	—	—	—	—
Herm Cukier	—	800,000	—	2.18	6/14/28	—	—	—	—
	—	—	—	—	—	—	—	200,000(3)	740,000
Scott Plesha	—	—	—	—	—	—	—	11,666(4)	43,164
	—	—	—	—	—	16,667(5)	—	16,667(5)	123,336
	—	—	—	—	—	62,500(6)	—	62,500(6)	462,500
Thomas Smith, M.D.	—	117,691	—	2.93	8/1/28	—	—	—	—
James Vollins	—	89,476	—	3.46	11/5/28	—	—	—	—
Ernest R. De Paolantonio, CPA MBA	—	—	—	—	—	—	—	31,781(2)	117,590
	—	—	—	—	—	—	—	30,000(4)	111,000
	—	—	—	—	—	63,333(5)	—	63,333(5)	468,664
	55,659	—	—	5.39	10/17/23	70,000(6)	—	70,000(6)	518,000
Niraj Vasisht, Ph.D.(8)	14,297	—	—	1.96	2/15/22	—	—	—	—
	12,105	—	—	3.55	2/25/21	—	—	—	—
	25,000	—	—	3.47	1/25/21	—	—	—	—
	17,686	—	—	3.90	1/21/20	—	—	—	—

(1) All time-based stock options vest ratably over three years.

(2) Unvested stock awards consist of Restricted Stock Units (RSUs) from our Long-Term Incentive Plan (as defined under our 2011 Equity Incentive Plan, the "2011 EIP") and which we refer to as Performance RSUs, which are rights to acquire shares of our common stock.

(3) Unvested stock awards consist of RSU (as defined under the 2011 EIP) which are rights to acquire shares of our common stock. These performance-based RSUs provide for vesting if specified net revenue and operating income goals are achieved with respect to the annual fiscal years 2019 through 2021.

(4) Unvested stock awards consist of RSUs (as defined under the 2011 EIP) which are rights to acquire shares of our common stock. These unvested RSUs vest in thirds beginning March 2017.

(5) Unvested stock awards consist of RSUs (as defined under the 2011 EIP) which are rights to acquire shares of our common stock. One-half of which are time-based and one-half of which are performance-based, all of which vest over a three-year period beginning in March 2018. The performance-based RSUs provide for vesting if specified net revenue and operating income goals are achieved with respect to the annual fiscal years 2017 through 2019.

(6) Unvested stock awards consist of RSUs (as defined under the 2011 EIP) which are rights to acquire shares of our common stock. One-half of which are time-based and one-half of which are performance-based, all of which vest over a three-year period beginning in March 2019. The performance-based RSUs provide for vesting if specified net revenue and operating income goals are achieved with respect to the annual fiscal years 2018 through 2020.

(7) Mark A. Sirgo served as our President, Chief Executive Officer, Director and Vice Chairman until his retirement date of January 2, 2018. Upon retirement, Dr. Sirgo now serves as a Director and Vice Chairman.
(8) Niraj Vasisht served as our Senior Vice President and Chief Technology Officer until his retirement date of February 5, 2018.

Option Exercises and Stock Vested

The following information sets forth stock options exercised by the executive officers during the year ended December 31, 2018:

	OPTION AWARDS		STOCK AWARDS	
Name	Number of Shares Acquired on Exercise (#)	Value Realized on Exercise ($)	Number of Shares Acquired on Vesting (#)	Value Realized on Vesting ($)
Mark A. Sirgo, Pharm.D.	—	—	1,799,782	4,664,266
Herm Cukier	—	—	—	—
Scott Plesha	—	—	124,400	261,240
Thomas Smith, M.D.	—	—	—	—
James Vollins	—	—	—	—
Ernest R. De Paolantonio, CPA MBA	—	—	107,307	306,109
Niraj Vasisht, Ph.D.	61,908	31,043	622,586	1,874,667

Pension Benefits

None of our employees participate in or have account balances in qualified or non-qualified defined benefit plans sponsored by us. Our Compensation Committee may elect to adopt qualified or non-qualified benefit plans in the future if it determines that doing so is in our company's best interests.

Nonqualified Deferred Compensation

None of our employees participate in or have account balances in nonqualified defined contribution plans or other nonqualified deferred compensation plans maintained by us. Our Compensation Committee may elect to provide our officers and other employees with non-qualified defined contribution or other nonqualified deferred compensation benefits in the future if it determines that doing so is in our company's best interests.

Potential Payments Under Severance/Change in Control Arrangements

The table below sets forth potential payments payable to our current executive officers in the event of a termination of employment under various circumstances. For purposes of calculating the potential payments set forth in the table below, we have assumed that (i) the date of termination was December 31, 2018 and (ii) the stock price was $3.70, which was the closing market price of our common stock on December 31, 2018, the last business day of the 2018 fiscal year.

Name	If Company Terminates Executive Without Cause or Executive Resigns with Good Reason($)	Termination Following a Change in Control without Cause or Executive Resigns with Good Reason($)
Mark A. Sirgo, Pharm.D. (1)	—	—
Total Sirgo cash and benefits	**$ —**	**$ —**
Herm Cukier		
Cash severance payment	$ 1,140,000	$ 1,140,000
Pro-rata bonus	203,560	517,060
Accrued and unused vacation time	21,923	21,923
Acceleration of options (2)	1,216,000	1,216,000
Acceleration of restricted stock units (3)	—	740,000
Total Cukier cash and benefits	**$ 2,581,483**	**$ 3,634,983**
Scott Plesha		
Cash severance payment	$ 365,000	$ 365,000
Pro-rata bonus	164,250	164,250
Accrued and unused vacation time	14,038	14,038
Acceleration of options	—	—
Acceleration of restricted stock units (3)	—	629,000
Total Plesha cash and benefits	**$ 543,288**	**$ 1,172,288**
Ernest R. De Paolantonio, CPA		
Cash severance payment	$ 360,000	$ 360,000
Pro-rata bonus	144,000	144,000
Accrued and unused vacation time	13,846	13,846
Acceleration of options	—	—
Acceleration of restricted stock units (3)	—	1,215,254
Total De Paolantonio cash and benefits	**$ 517,846**	**$ 1,733,100**
Thomas Smith, MD.		
Cash severance payment	$ 0	$ 345,000
Pro-rata bonus	58,225	58,225
Accrued and unused vacation time	5,268	5,268
Acceleration of options (2)	90,622	90,622
Acceleration of restricted stock units	—	—
Total Smith cash and benefits	**$ 154,115**	**$ 499,115**
James Vollins		
Cash severance payment	$ —	$ 310,000
Pro-rata bonus	19,025	19,025
Accrued and unused vacation time	3,672	3,672
Acceleration of options (2)	21,474	21,474
Acceleration of restricted stock units	—	—
Total Vollins cash and benefits	**$ 44,171**	**$ 354,171**
Niraj Vasisht, Ph.D. (4)	—	—
Total Vasisht cash and benefits	**$ —**	**$ —**

(1) Pursuant to retirement on January 2, 2018, Dr. Sirgo was not party to an employment agreement or change of control benefits as of December 31, 2018.
(2) Determined by taking the excess of the fair market value of our common stock on December 31, 2018, less the exercise price of each accelerated option, multiplied by the number of unvested shares subject to outstanding options.
(3) Determined by taking the fair market value of our common stock on December 31, 2018, multiplied by the number of shares subject to invested RSUs.
(4) Pursuant to retirement on April 4, 2018, Dr. Vasisht was not party to an employment agreement or change of control benefits as of December 31, 2018.

For each of our executive officers, in their employment agreements the term "change of control" means the occurrence of any one or more of the following events (it being agreed that, with respect to paragraphs (i) and (iii) of this definition below, a "change of control" shall not be deemed to have occurred if the applicable third party acquiring party is an "affiliate" of our company within the meaning of Rule 405 promulgated under the Securities Act of 1933, as amended):

(i) An acquisition (whether directly from our company or otherwise) of any voting securities of our company by any person or entity, immediately after which such person or entity has beneficial ownership of forty percent (40%) or more of the combined voting power of our then outstanding voting securities.

(ii) The individuals who, as of the date hereof, are members of our board of directors' cease, by reason of a financing, merger, combination, acquisition, takeover or other non-ordinary course transaction affecting our company, to constitute at least fifty-one percent (51%) of the members of our board of directors; or

(iii) Approval by our board of directors and, if required, our stockholders of, or our execution of any definitive agreement with respect to, or the consummation of (it being understood that the mere execution of a term sheet, memorandum of understanding or other non-binding document shall not constitute a change of control):

(A) A merger, consolidation or reorganization involving our company, where either or both of the events described in clauses (i) or (ii) above would be the result;

(B) A liquidation or dissolution of or appointment of a receiver, rehabilitator, conservator or similar person for, or the filing by a third party of an involuntary bankruptcy against, our company; or

(C) An agreement for the sale or other disposition of all or substantially all of the assets of our company to any person or entity (other than a transfer to a subsidiary of our company).

The cash component (as opposed to option accelerations) of any change of control payment would be structured as a one-time cash severance payment.

CEO Pay Ratio – 21:1

We believe our executive compensation program must be consistent and internally equitable to motivate our employees to perform in ways that enhance shareholder value. We are committed to internal pay equity, and the Compensation Committee monitors the relationship between the pay of our executive officers and the pay of our non-executive employees. The Compensation Committee reviewed a comparison of Herm Cukier's, our Chief Executive Officer (which we refer to for these purposes as the CEO), annualized total compensation in fiscal year 2018 to that of the median annual compensation of all other company employees for the same period. The calculation of annual total compensation of all employees was determined in the same manner as the "Total Compensation" shown for our CEO in the "Summary Compensation Table" on page 65 of this Report. Pay elements that were included in the annual total compensation for each employee are:

- annualized salary in fiscal year 2018;
- annual bonus payment received for performance in fiscal year 2018;
- grant date fair value of stock option exercises and RSU grants in fiscal year 2018;
- company-paid 401(k) Plan match made during fiscal year 2018; and
- auto and phone allowance paid in fiscal year 2018.

Our calculation includes all employees as of December 31, 2018.

We determined our median employee by: (i) calculating the annual total compensation described above for each of our employees, (ii) ranking the annual total compensation of all employees except for the CEO from lowest to highest (a list of

157 employees), and (iii) since we have an odd number of employees when not including the CEO, we used ranked employee number 79 on the list as our ("Median Employee"). In 2018, we experienced a substantial increase in our headcount. Accordingly, we determined it was appropriate to re-calculate our Median Employee for 2018.

The annualized total compensation for fiscal year 2018 for our CEO was $2,679,509 and for the Median Employee was $125,563. We estimate that the resulting ratio of our CEO's pay to the pay of our Median Employee for fiscal year 2018 is 21 to 1.

Compensation of Directors Summary Table

DIRECTOR COMPENSATION

Name (a)	Fees Earned or Paid in Cash ($)	Stock Awards ($) (12)	Option Awards ($) (12)	Non-Equity Incentive Plan Compensation ($)	Non-Qualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Peter S. Greenleaf ±	27,088	300,931(1)	90,472(2)	—	—	—	418,491
Frank E. O'Donnell, Jr.	62,052(3)	189,000(4)	—	—	—	11,728(5)	262,780
William M. Watson	66,997	293,405(6)	77,183(7)	—	—	—	437,584
Todd C. Davis ±	28,022	257,941(8)	67,854(9)	—	—	—	353,817
Kevin Kotler ±	23,352	257,941(8)	67,854(9)	—	—	—	349,147
Samuel P. Sears, Jr. *	74,375	26,813(10)	9,694(12)	—	—	—	110,882
Thomas W. D'Alonzo *	53,750	26,813(10)	9,694(12)	—	—	—	90,257
Barry I. Feinberg *	61,875	26,813(10)	9,694(12)	—	—	—	98,382
Timothy C. Tyson *	48,750	26,813(10)	9,694(12)	—	—	—	85,257

± Newly elected directors as of May 17, 2018

* Retiring directors as of May 17, 2018

(1) The stock awards disclosed in this item consists of 112,288 RSUs issued in 2018 with a FMV of $2.68 for serving on the board which vested ratably from 2018-2022. Mr. Greenleaf holds 108,644 shares of unvested RSUs which vest ratably from August 2019 to August 2022.

(2) The stock options disclosed in this item consists of 64,164 options granted in 2018 with a FMV of $1.41 for serving on the board which vest ratably from 2018-2022. Mr. Greenleaf holds options to purchase 2,082 shares of common stock, all of which are currently exercisable. Mr. Greenleaf also holds options to purchase 62,082 shares of common stock, none of which are currently exercisable.

(3) Compensation for serving as Chairman through May 2018. Dr. O'Donnell now serves as Director.

(4) The stock awards disclosed in this item consists of 90,000 RSUs issued as executive grants in 2018 with a FMV of $2.10 which half vest in ratably in thirds beginning in 2019 and half vest pursuant to achievement of certain performance criteria. Dr. O'Donnell holds options to purchase 107,500 shares of our common stock, all of which is currently exercisable. Dr. O'Donnell holds an aggregate of 216,000 shares of unvested RSUs which vest in thirds from March 2019 to March 2021. Does not include 170,000 shares of unvested RSUs potentially issuable in thirds if certain pre-determined company revenue targets are achieved. Dr. O'Donnell also holds 164,022 shares of unvested RSUs potentially issuable under our LTIP if certain pre-determined company revenue targets are achieved.

(5) Includes $11,728 in health benefits paid in 2018.

(6) The stock awards disclosed in this item consists of 109,479 RSUs issued in 2018 with a FMV of $2.68 for serving on the board which vest ratably from 2018-2022. Mr. Watson holds 99,739 shares of unvested RSUs which vest ratably from August 2019 to August 2022.

(7) The stock options disclosed in this item consists of 54,740 options granted in 2018 with a FMV of $1.41 for serving on the board which vest ratably from 2018-2022. Mr. Watson holds options to purchase 4,870 shares of common stock, all of which are currently exercisable. Mr. Watson also holds options to purchase 49,870 shares of common stock, none of which are currently exercisable.

(8) The stock awards disclosed in this item consists of 96,247 RSUs issued in 2018 with a FMV of $2.68 for serving on the board which vest ratably from 2018-2022. Mr. Kotler holds 93,123 shares of unvested RSUs which vest ratably from August 2019 to August 2022. Mr. Davis holds 93,123 shares of unvested RSUs which vest ratably from August 2019 to August 2022.

(9) The stock options disclosed in this item consists of 48,123 options granted in 2018 with a FMV of $1.41 for serving on the board which vest ratably from 2018-2022. Mr. Davis holds options to purchase 1,561 shares of common stock, all of which are currently exercisable. Mr. Davis also holds options to purchase 46,562 shares of common stock, none of which are currently exercisable. Mr. Kotler holds options to purchase 1,561 shares of common stock, all of which are currently exercisable. Mr. Kotler also holds options to purchase 46,562 shares of common stock, none of which are currently exercisable.

(10) The stock awards disclosed in this item consists of 13,750 RSUs issued in 2018 with a FMV of $1.95 pursuant to retirement from the board which half vested in 2018 and the remaining half vest in 2019.

(11) The stock options disclosed in this item consists of 6,875 options granted in 2018 with a FMV of $1.41 pursuant to retirement from the board which half vested in 2018 and the remaining half vest in 2019.

(12) The reported amounts represent the aggregate grant date fair value of the awards computed in accordance with Financial Accounting Standards Board Account Standards Codification Topic 718, Stock Compensation, as modified or supplemented, or FASB ASC Topic 718.

Narrative to Director Compensation

The Compensation Committee of our board of directors reviews the Director Remuneration Policy, which establishes the compensation our directors earn for serving on our board of directors and individual committees. The policy during 2018 follows (all annual cash retainers are paid quarterly in arrears):

- $45,000 annual cash retainer to each board member.
- $10,000 annual cash retainer to the Lead Director.
- $20,000 annual cash retainer to the Chairman of the Audit Committee.
- $15,000 annual cash retainer to the Chairman of the Compensation Committee.
- $10,000 annual cash retainer to the Chairman of the Nominating & Corporate Governance Committee.
- $10,000 annual cash retainer to each non-Chairman Audit Committee member.
- $7,500 annual cash retainer to each non-Chairman Compensation Committee member.
- $5,000 annual cash retainer to each non-Chairman Nominating & Corporate Governance Committee member.
- $7,500 annual cash retainer to each Special Committee member.
- 30,000 restricted stock units of our common stock per year, to each director.
- 5,000 additional restricted stock units of our common stock per year to the Lead Director.
- 15,000 stock options of our common stock per year, to each director.
- 5,000 additional stock options of our common stock per year to the Lead Director.
- New directors will earn a pro-rated portion (based on months to be served in the fiscal year in which they join) of cash and restricted stock units.

In August 2018, we granted our directors upfront awards of options and restricted stock units to cover the options and restricted stock units they would be entitled to receive over the next four years, subject to vesting over such four-year period. Options granted to directors expire in 10 years and are outstanding for the life of the option, as long as service criteria is met. Director options qualify as Non-Statutory Stock Options. The total number of options granted to members of our board of directors during the year ended December 31, 2018 was 242,650, which vests ratably during the first open window upon issuance in August 2018 to August 2022.

The total number of RSUs granted to members of our board of directors during the year ended December 31, 2018 was 469,261 which vests ratably during the first open window upon issuance in August 2018 to August 2022.

Compensation Committee Interlocks and Insider Participation

None of our executive officers serves as a member of the Compensation Committee of our board of directors, or other committee serving an equivalent function. None of the members of our Compensation Committee has ever been our employee or one of our officers.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The following table sets forth, as of March 14, 2019, by: (i) each of our directors, (ii) all persons who, to our knowledge, are the beneficial owners of more than 5% of the outstanding shares of common stock, (iii) each of the executive officers, and (iv) all of our directors and executive officers, as a group. Each person named in this table has sole investment power and sole voting power with respect to the shares of common stock set forth opposite such person's name, except as otherwise indicated. Unless otherwise indicated, the address for each person listed below is in care of BioDelivery Sciences International, Inc., 4131 ParkLake Avenue, Suite #225, Raleigh, NC 27612.

Name and Address of Beneficial Owner	Amount and Nature of Beneficial Ownership	Percentage of Class as of March 14, 2019(1)
venBio Select Advisor LLC (2)	4,725,700	6.67%
Broadfin Capital, LLC (3)	4,375,066	6.18%
Stonepine Capital Management (4)	3,981,867	5.62%
Herm Cukier (5)	0	*
Scott M. Plesha (6)	224,004	*
Mary Theresa Coelho (7)	0	*
Thomas Smith, M.D. (8)	0	*
James Vollins (9)	0	*
Peter S. Greenleaf(10)	5,726	*
Mark A. Sirgo, Pharm.D. (11)	2,699,259	3.80%
Frank E. O'Donnell, Jr., M.D.(12)	628,687	*
William M. Watson (13)	16,110	*
Todd C. Davis (14)	421,352	*
Kevin Kotler (15)	4,379,751	6.19%
All Directors and Officers as a group (11 persons)	8,047,598	11.75%

* Less than 1%

(1) Based on 70,953,944 shares of Common Stock outstanding as of March 14, 2019 and shares beneficially owned by the referenced parties as described below.

(2) Based on 13G filed by venBio Select Advisor LLC with the SEC on February 14, 2019 for the year ended December 31, 2018. Does not include 3,888,888 shares of Common Stock issuable upon conversion of 700 shares of Series B Preferred Stock beneficially owned by venBio Select Advisor LLC.

(3) Based on 13F filed by Broadfin Capital, LLC with the SEC on February 14, 2019 for the year ended December 31, 2018. Does not include 12,222,223 shares of Common Stock issuable upon conversion of 2,200 shares of Series B Preferred Stock beneficially owned by Broadfin Capital LLC.

(4) Based on 13G/A filed by Stonepine Capital Management with the SEC on February 13, 2019 for the year ended December 31, 2018.

(5) Mr. Cukier is our Chief Executive Officer and a director. Does not include 200,000 shares of unvested RSUs potentially issuable in thirds if certain pre-determined company revenue targets are achieved. Also, does not include 93,750 shares of unvested RSUs which vest in thirds from January 2020 to January 2022. Does not include options to purchase 1,340,000 shares of common stock, none of which are currently exercisable.

(6) Mr. Plesha is our President. This number is 224,004 shares owned by Mr. Plesha. Does not include an aggregate of 119,167 shares of unvested RSUs which vest from March 2019 to January 2022. Also, does not include 79,167 shares of unvested RSUs potentially issuable if certain pre-determined company revenue targets are achieved, which vest from March 2019 to March 2021. Does not include options to purchase 245,000 shares of common stock, none of which are currently exercisable.

(7) Ms. Coelho became our Chief Financial Officer on January 15, 2019. Does not include 55,000 shares of unvested RSUs which vest in thirds from January 2020 to January 2022. Does not include options to purchase 107,109 shares of common stock, none of which are currently exercisable.

(8) Dr. Smith became our Chief Medical Officer on July 30, 2018. Does not include 23,000 shares of unvested RSUs which vest in thirds from January 2020 to January 2022. Does not include options to purchase 247,691 shares of common stock, none of which are currently exercisable.

(9) Mr. Vollins became our General Counsel, Chief Compliance Officer and Corporate Secretary on November 5, 2018. Does not include 11,500 shares of unvested RSUs which vest in thirds from January 2020 to January 2022. Does not include options to purchase 154,476 shares of common stock, none of which are currently exercisable.

(10) Mr. Greenleaf became our Chairman of the Board and a director in May 2018. Includes 3,644 shares owned by Mr. Greenleaf. Includes options to purchase 2,082 shares of common stock, all of which are currently exercisable. Does not include 108,644 shares of unvested RSUs which vest ratably from August 2019 to August 2022.Does not include options to purchase 62,082 shares of common stock, none of which are currently exercisable.

(11) Includes 2,489,542 shares owned by Dr. Sirgo, our Vice Chairman. Includes options to purchase 209,717 shares of common stock, all of which are currently exercisable. Does not include 327,170 unvested RSUs potentially issuable under our LTIP if certain pre-determined company revenue targets are achieved.

(12) Dr. O'Donnell is a director. Excludes 167,500 shares owned by The Francis E. O'Donnell, Jr. Irrevocable Trust #1, of which Dr. O'Donnell's sister, Kathleen O'Donnell, is trustee, and as to which Dr. O'Donnell disclaims beneficial interest. This number includes 521,187 shares owned by Dr. O'Donnell and options to purchase 107,500 shares of our common stock, all of which is currently exercisable. Does not include an aggregate of 170,000 shares of unvested RSUs which vest in thirds from March 2019 to March 2021. Does not include 170,000 shares of unvested RSUs potentially issuable in thirds if certain pre-determined company revenue targets are achieved. Also, does not include 170,828 shares of unvested RSUs potentially issuable under our LTIP if certain pre-determined company revenue targets are achieved.

(13) Mr. Watson is a director. Includes 11,240 shares owned. Includes options to purchase 4,870 shares of common stock, all of which are currently exercisable. Does not include 99,739 shares of unvested RSUs which vest ratably from August 2019 to August 2022. Does not include options to purchase 49,870 shares of common stock, none of which are currently exercisable.

(14) Mr. Davis became a director in May 2018. Includes 419,791 shares owned. Includes options to purchase 1,561 shares of common stock, all of which are currently exercisable. Does not include 93,123 shares of unvested RSUs which vest ratably from August 2019 to August 2022. Does not include options to purchase 46,562 shares of common stock, none of which are currently exercisable.

(15) Mr. Kotler became a director in May 2018. Includes 3,124 shares owned by Mr. Kotler. Does not include 12,222,223 shares of Series B Non-Voting Convertible Stock which are held in the account of Broadfin Healthcare Master Fund, Ltd., a private investment fund managed by Broadfin Capital, LLC, and may be deemed to be beneficially owned by Mr. Kotler, managing member of Broadfin Capital, LLC. Includes 4,375,066 shares owned by Broadfin, Capital LLC. Includes options to purchase 1,561 shares of common stock, all of which are currently exercisable. Does not include 93,123 shares of unvested RSUs which vest ratably from August 2019 to August 2022. Does not include options to purchase 46,562 shares of common stock, none of which are currently exercisable.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table indicates shares of common stock authorized for issuance under our 2011 Equity Incentive Plan as of December 31, 2018:

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (1)	Weighted-average exercise price of outstanding options, warrants and rights (2)	Number of securities remaining available for future issuance
Equity compensation plans approved by security holders	8,708,126	$ 2.73	1,874,086
Equity compensation plans not approved by security holders	—	—	—
Total	8,708,126	$ 2.73	1,874,086

(1) Includes 578,645 shares of common stock underlying options previously granted under our Amended and Restated 2001 Incentive Plan, which are still exercisable despite the fact that such plan expired July 2011.

(2) Weighted average exercise price does not include restricted stock units.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

As of December 31, 2001, our board of directors appointed an audit committee consisting of independent directors. This committee, among other duties, is charged to review, and if appropriate, ratify all agreements and transactions which had been entered into with related parties, as well as review and ratify all future related party transactions. The audit committee and/or our independent directors independently reviewed, ratified and/or approved, as the case may be, the agreements described below. From time to time, after compliance with our internal policies and procedures, we have entered into related party contracts, some of which were amended subsequently in accordance with the same policies and procedures.

We are currently not a party to any related party transactions.

As a matter of corporate governance policy, we have not and will not make loans to officers or loan guarantees available to "promoters" as that term is commonly understood by the SEC and state securities authorities.

All future transactions between us and our officers, directors or five percent stockholders, and respective affiliates will be on terms no less favorable than could be obtained from unaffiliated third parties and will be approved by a majority of our independent directors who do not have an interest in the transactions and who had access, at our expense, to our legal counsel or independent legal counsel.

To the best of our knowledge, other than as set forth above, there were no material transactions, or series of similar transactions, or any currently proposed transactions, or series of similar transactions, to which we were or are to be a party, in which the amount involved exceeds $120,000, and in which any director or executive officer, or any security holder who is known by us to own of record or beneficially more than 5% of any class of our common stock, or any member of the immediate family of any of the foregoing persons, has an interest.

Item 14. Principal Accountant Fees and Services.

Audit Fees. The aggregate fees billed by Cherry Bekaert LLP for professional services rendered for the audit of our annual financial statements, review of the financial information included in our Forms 10-Q for the respective periods and other required filings with the SEC for the years ended December 31, 2018 and 2017 totaled $216,000 and $188,500, respectively. The above amounts include interim procedures and audit fees, as well as attendance at audit committee meetings.

Audit-Related Fees. The aggregate fees billed by Cherry Bekaert LLP for audit-related fees for the years ended December 31, 2018 and 2017 were $131,776 and $149,839, respectively. The fees were provided in consideration of services consisting of review and update procedures associated with registration statements and other SEC filings.

Tax Fees. The aggregate fees billed by Cherry Bekaert LLP for professional services rendered for tax compliance for the years ended December 31, 2018 and 2017 were $34,600 and $42,460, respectively. The fees were provided in consideration of services consisting of preparation of tax returns and related tax advice.

All Other Fees. None

The Audit Committee of our board of directors has established its pre-approval policies and procedures, pursuant to which the Audit Committee approved the foregoing audit and non-audit services provided by Cherry Bekaert LLP in 2018. Consistent with the Audit Committee's responsibility for engaging our independent auditors, all audit and permitted non-audit services require pre-approval by the Audit Committee. The full Audit Committee approves proposed services and fee estimates for these services. The Audit Committee chairperson has been designated by the Audit Committee to approve any audit-related services arising during the year that were not pre-approved by the Audit Committee. Any non-audit service must be approved by the full Audit Committee. Services approved by the Audit Committee chairperson are communicated to the full Audit Committee at its next regular meeting and the Audit Committee reviews services and fees for the fiscal year at each such meeting. Pursuant to these procedures, the Audit Committee approved the foregoing services provided by Cherry Bekaert LLP.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

The following exhibits are filed with this Report.

Number	Description
3.1	Articles of Incorporation of the Company (1)
3.2	Amended and Restated Bylaws of the Company (11)
3.3	Second Amended and Restated By-laws of the Company, adopted on November 17, 2017 (27)
3.4	Certificate of Amendment to the Company's Certificate of Incorporation (i) declassify board of directors (ii) clarify voting standards and (iii) increase the number of authorized shares, dated August 6, 2018 (34)
4.1	Certificate of Designation of Series A Non-Convertible Preferred Stock, dated November 20, 2012 (17)
4.2	Form of Warrant issued to several lenders pursuant to the CRG Services LLC, Loan Agreement (21)
4.3	Form of Certificate of Designation of Series B Non-Voting Convertible Preferred Stock (32)
10.1	Amended and Restated 2001 Incentive Plan (2)
10.2	Amendment No. 1 to Amended and Restated 2001 Incentive Plan (3)
10.3	Intellectual Property Assignment Agreement, dated August 2, 2006, by and between QLT USA, Inc. and Arius Two, Inc. (4)+
10.4	License and Development Agreement, dated August 2, 2006, by and between the Company, Arius Pharmaceuticals, Inc. and Meda AB (4)+
10.5	BEMA Fentanyl Supply Agreement, dated August 2, 2006, by and between the Company, Arius Pharmaceuticals, Inc. and Meda AB (4)+
10.6	Sublicensing Consent, dated August 2, 2006, between Arius Two, Inc. and Arius Pharmaceuticals, Inc. (4)+
10.7	Letter agreement, dated August 2, 2006, between Meda AB, Arius Pharmaceuticals, Inc, Arius Two, Inc. and the Company (4)
10.8	Sublicensing Consent dated September 5, 2007, between Arius Pharmaceuticals, Inc. and Arius Two, Inc. (5)+
10.9	License Agreement dated, September 5, 2007, by and between Arius Two, Inc., and Arius Pharmaceuticals, Inc. (5)+
10.10	Intellectual Property Assignment Agreement dated, September 5, 2007 by and between QLT USA, Inc. and Arius Two. (5)+
10.11	Assignment of Patent and Trademarks, dated September 5, 2007. (5)
10.12	Royalty Purchase and Amendment Agreement, dated as of September 5, 2007 between BioDelivery Sciences International, Inc., and CDC IV, LLC (5)+
10.13	Letter Amendment, effective January 2, 2009, between the Company, Arius Pharmaceuticals, Inc. and Meda AB relating to European commercialization rights for ONSOLIS (6)+
10.14	Amendment Consent (EU), dated January 2, 2009, between Arius Pharmaceuticals, Inc. and Arius Two, Inc. (6)
10.15	Process Development Agreement, dated February 8, 2008, between the Company and LTS (7)+
10.16	Amendment to Amended and Restated 2001 Incentive Plan of the Company, dated November 19, 2008 (7)
10.17	License and Supply Agreement, dated October 4, 2010, between the Company, Arius Pharmaceuticals and TTY Biopharm Co., Ltd. (8)+
10.18	2011 Equity Incentive Plan (9)
10.19	Manufacturing, Supply, and License Agreement dated April 26, 2012 between the Company, Arius Pharmaceuticals and LTS Lohmann Therapie-Systeme AG (10)+
10.20	Amendment No. 1 to 2011 Equity Incentive Plan (12)
10.21	Conditional Offer of Employment, dated October 1, 2013, between the Company and Ernest R. De Paolantonio (13)

Number	Description
10.22	Amendment No. 2 to 2011 Equity Incentive Plan (14)
10.23	Development and Exclusive License and Option Agreement, dated October 27, 2014, by and between the Company and Evonik Corporation.(15)+
10.24	Definitive Assignment and Revenue Sharing Agreement, dated January 23, 2015, by and among the Company, Arius and Meda AB (16)+
10.25	Performance Long Term Incentive Plan (18)
10.26	Amendment No. 3 to 2011 Equity Incentive Plan (19)
10.27	Extension Agreement, dated February 27, 2016, by and among the Company, Arius and Meda AB (20)
10.28	Term Loan Agreement, dated February 21, 2017 as amended September 1, 2017, among the Company, Arius, Arius Two, CRG Servicing LLC, as administrative agent, and certain lenders named therein (21)(27)+
10.29	Form of Security Agreement among the Company, Arius, Arius Two and CRG Servicing LLC. (27)
10.30	Amended and Restated Clinical Development and License Agreement dated as of November 2, 2016, by and among the Company, Arius, Arius Two, CDC V, LLC and NB Athyrium LLC (22)+
10.31	Termination Agreement dated as of December 7, 2016, by and among the Company, Arius, Arius Two and Endo Pharmaceuticals Inc. (22)+
10.32	BELBUCA® Product Line of Endo Pharmaceuticals, Inc. Statement of Net assets acquired (23)
10.33	BELBUCA® Product Line of Endo Pharmaceuticals, Inc. Statement of Revenues and Direct Expenses (23)
10.34	Retirement agreement, dated August 23, 2017, by and between the Company and Mark Sirgo (24)
10.35	Amendment No. 4 to 2011 Equity Incentive Plan (25)
10.36	License Agreement dated July 12, 2017 by and between the Company, Arius and Purdue Pharma (26)+
10.37	Offer of Promotion, dated December 20, 2017, by and between the Company and Scott M. Plesha (28)
10.38	Retirement agreement, dated January 12, 2018, by and between the Company and Niraj Vasisht (29)
10.39	Form of Director Indemnification Agreement, by and between the Company and each of the Directors of the Company (30)
10.40	Consulting Agreement dated February 2, 2018, by and between the Company and Mark Sirgo (30)
10.41	Employment Agreement, dated May 2, 2018, between the Company and Herm Cukier (31)
10.42	Director Indemnification Agreement, dated May 2, 2018, by and between the Company and Herm Cukier (31)
10.43	Confidentiality, Intellectual Property and Non-Competition Agreement, dated May 2, 2018, between the Company and Herm Cukier (31)
10.44	Placement Agency Agreement, dated May 17, 2018, between the Company and William Blair & Company, L.L.C. (32)
10.45	Form of Securities Purchase Agreement, dated May 17, 2018, between the Company and the Investors (32)
10.46	Registration Rights Agreement, dated May 17, 2018, between the Company and Broadfin Healthcare (32)
10.47	Agreement, dated May 17, 2018, between the Company and Broadfin Healthcare (32)
10.48	Amendment 2 to Term Loan Agreement, dated May 16, 2018, among the Company, CRG and the lenders named therein (32)
10.49	Form of Retirement Agreement, dated May 17, 2018, between the Company, the Retiring Directors and Broadfin Healthcare (32)
10.50	Amendment, dated May 20, 2018, by and among the Company and Broadfin (33)
10.51	Conditional Offer of Employment, dated July 20, 2018, between the Company and Thomas Smith (35)
10.52	Form of Incentive Stock Option Agreement under the 2011 Equity Incentive Plan (35)
10.53	Form of Nonqualified Stock Option Agreement for Company Employees under the 2011 Equity Incentive Plan (35)
10.54	Form of Nonqualified Stock Option Agreement for Non-Employee Directors under the 2011 Equity Incentive Plan (35)

Table of Contents

Number	Description
10.55	Form of Restricted Stock Unit Award Agreement for Company Employees under the 2011 Equity Incentive Plan (35)
10.56	Form of Restricted Stock Unit Award Agreement for Non-Employee Directors under the 2011 Equity Incentive Plan (35)
10.57	Form of Performance Restricted Stock Unit Award Agreement for Company Employees under the 2011 Equity Incentive Plan (35)
10.58	Transition Period and Separation of Employment, dated January 23, 2019 by and between the Company and Ernest De Paolantonio (36)
10.59	Conditional Offer of Employment, dated November 5, 2018, between the Company and James Vollins*
10.60	Conditional Offer of Employment, dated January 15, 2019, between the Company and Terry Coelho*
21.1	Subsidiaries of the Registrant *
23.1	Consent of Cherry Bekaert LLP*
31.1	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
31.2	Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.*
32.1	Certification of the Chief Executive Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*#
32.2	Certification of the Chief Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*#
101.ins	XBRL Instance Document
101.sch	XBRL Taxonomy Extension Schema Document
101.cal	XBRL Taxonomy Calculation Linkbase Document
101.def	XBRL Taxonomy Definition Linkbase Document
101.lab	XBRL Taxonomy Label Linkbase Document
101.pre	XBRL Taxonomy Presentation Linkbase Document

* Filed herewith
\+ Confidential treatment has been granted for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.8(b)(4) and 240.24b-2.
\# A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.
‡ Confidential treatment extension of confidential treatment previously granted for certain portions of this exhibit pursuant to 17 C.F.R. Sections 200.8(b)(4) and 240.24b-2 is currently pending with the Securities and Exchange Commission.
(1) Previously filed with Form SB-2, Amendment No. 2, dated February 1, 2002.
(2) Previously filed with PRE14A, dated June 17, 2003.
(3) Previously filed as Annex A to Schedule 14A, dated June 27, 2006.
(4) Previously filed with Form 8-K, dated August 9, 2006.
(5) Previously filed with Form 8-K, dated September 10, 2007.
(6) Previously filed with Form 8-K, January 6, 2009.
(7) Previously filed with Form 10-K, March 20, 2009.
(8) Previously filed with Form 8-K, October 8, 2010.
(9) Previously filed with PRE14A, dated June 1, 2011
(10) Previously filed with Form 8-K, dated September 19, 2012.
(11) Previously filed with Form 8-K, July 23, 2010.
(12) Previously filed with PRE14A, dated June 12, 2013
(13) Previously filed with Form 8-K, dated October 23, 2013.
(14) Previously filed with PRE14A, dated June 10, 2014.
(15) Previously filed with Form 8-K, dated October 31, 2014.
(16) Previously filed with Form 8-K, dated January 28, 2015.
(17) Previously filed with Form 8-K, dated November 28, 2012.
(18) Previously filed with Form 10-K, dated March 16, 2015.
(19) Previously filed with DEF14A, dated June 5, 2015.
(20) Previously filed with Form 10-K, dated March 10, 2016.
(21) Previously filed with Form 8-K, dated February 27, 2017.
(21) Previously filed with Form 8-K/A, dated September 1, 2017.
(22) Previously filed with Form 10-K, dated March 16, 2017.
(23) Previously filed with Form 8-K/A No.2, dated June 1, 2017.
(24) Previously filed with Form 8-K, dated August 29, 2017.
(25) Previously filed with DEF14A, dated November 1, 2017.
(26) Previously filed with Form 10-Q/A, dated March 30, 2018.
(27) Previously filed with Form 8-K, dated November 17, 2017.
(28) Previously filed with Form 8-K, dated December 22, 2017.
(29) Previously filed with Form 8-K, dated January 18, 2018.
(30) Previously filed with Form 8-K, dated February 6, 2018.
(31) Previously filed with Form 8-K, dated May 8, 2018.

(32) Previously filed with Form 8-K, dated May 17, 2018.
(33) Previously filed with Form 8-K, dated May 21, 2018.
(34) Previously filed with Form 8-K, dated August 6, 2018.
(35) Previously filed with 10-Q, dated November 8, 2018
(36) Previously filed with Form 8-K, dated January 23, 2019.

BIODELIVERY SCIENCES INTERNATIONAL, INC.

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
BioDelivery Sciences International, Inc.

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of BioDelivery Sciences International, Inc. and Subsidiaries (the "Company") as of December 31, 2018 and 2017, and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for each of the years in the three-year period ended December 31, 2018, the related notes, and Schedule II – Valuation and Qualifying Accounts and Reserves (the financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO").

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control—Integrated Framework (2013)* issued by COSO.

Basis for Opinion

The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report of Internal Control over Financial Reporting included in Item 9A – Controls and Procedures in the Company's 2018 Annual Report on Form 10-K. Our responsibility is to express an opinion on the Company's financial statements and an opinion on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the financial statements included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Cherry Bekaert LLP

We have served as the Company's auditor since 2003.

Raleigh, North Carolina
March 14, 2019

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(U.S. DOLLARS, IN THOUSANDS, EXCEPT SHARE AND PER SHARE AMOUNTS)

	December 31, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash	$ 43,822	$ 21,195
Accounts receivable, net	13,627	8,852
Inventory, net	5,406	6,091
Prepaid expenses and other current assets	3,188	3,610
Total current assets	66,043	39,748
Property and equipment, net	3,072	3,778
Goodwill	2,715	2,715
BELBUCA license and distribution rights, net	36,000	40,500
Other intangible assets, net	703	1,360
Total assets	$ 108,533	$ 88,101
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 21,539	$ 26,149
Total current liabilities	21,539	26,149
Notes payable, net	51,652	47,660
Other long-term liabilities	5,600	5,415
Total liabilities	78,791	79,224
Commitments and contingencies (Notes 7 and 17)		
Stockholders' equity:		
Preferred Stock, 5,000,000 shares authorized; Series A Non-Voting Convertible Preferred Stock. $.001 par value, 2,093,155 shares outstanding at both December 31, 2018 and December 31, 2017, respectively; Series B Non-Voting Convertible Preferred Stock, $.001 par value, 3,100 and 0 shares outstanding at December 31, 2018 and December 31, 2017, respectively.	2	2
Common Stock, $.001 par value; 125,000,000 and 75,000,000 shares authorized at December 31, 2018 and December 31, 2017, respectively; 70,793,725 and 55,904,072 shares issued;70,778,234 and 55,888,581 shares outstanding at September 30, 2018 and December 31, 2017, respectively.	71	56
Additional paid-in capital	381,004	313,922
Treasury stock, at cost, 15,491 shares	(47)	(47)
Accumulated deficit	(351,288)	(305,056)
Total stockholders' equity	29,742	8,877
Total liabilities and stockholders' equity	$ 108,533	$ 88,101

See notes to consolidated financial statements

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(U.S. DOLLARS, IN THOUSANDS, EXCEPT SHARE AND PER SHARE AMOUNTS)

	Year Ended December 31,		
	2018	2017	2016
Revenues:			
Product sales	$ 51,410	$ 34,922	$ 8,266
Product royalty revenues	3,389	5,070	3,646
Research and development reimbursements	—	799	1,134
Contract revenue	841	21,194	2,500
Total revenues	55,640	61,985	15,546
Cost of sales	15,783	19,496	11,258
Expenses:			
Research and development	4,903	13,040	18,878
Selling, general and administrative	58,602	58,869	49,345
Total expenses	63,505	71,909	68,223
Loss from operations	(23,648)	(29,420)	(63,935)
Interest expense	(10,192)	(8,577)	(3,267)
Bargain purchase gain	—	27,336	—
Other (expense) income, net	(14)	(26)	64
Loss before income taxes	(33,854)	(10,687)	(67,138)
Income tax benefit	(13)	15,972	—
Net (loss) income	(33,867)	5,285	(67,138)
Beneficial conversion feature of convertible preferred stock	(12,500)	—	—
Net (loss) income attributable to common stockholders	$ (46,367)	$ 5,285	$ (67,138)
Basic:			
Weighted average common stock shares outstanding	63,165,063	55,355,802	53,679,134
Basic (loss) earnings per share	$ (0.73)	$ 0.10	$ (1.25)
Diluted:			
Diluted weighted average common stock shares outstanding	63,165,063	56,402,479	53,679,134
Diluted (loss) earnings per share	$ (0.73)	$ 0.09	$ (1.25)

See notes to consolidated financial statements

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
(U.S. DOLLARS, IN THOUSANDS, EXCEPT SHARE DATA)

	Preferred Stock Series A		Preferred Stock Series B		Common Stock		Additional Paid-In	Treasury	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Stock	Deficit	Equity
Balances, January 1, 2016	2,093,155	$ 2	—	$ —	52,730,799	$ 53	$274,891	$ (47)	$ (243,203)	$ 31,696
Stock-based compensation	—	—	—	—	—	—	14,931	—	—	14,931
Stock option exercises	—	—	—	—	147,426	—	297	—	—	297
Restricted stock awards	—	—	—	—	592,065	—	—	—	—	—
Common stock issuance upon retirement	—	—	—	—	663,221	1	2,459	—	—	2,460
Issuance of warrants	—	—	—	—	—	—	49	—	—	49
Equity finance costs	—	—	—	—	—	—	40	—	—	40
Net loss	—	—	—	—	—	—	—	—	(67,138)	(67,138)
Balances, December 31, 2016	2,093,155	$ 2	—	$ —	54,133,511	$ 54	$292,667	$ (47)	$ (310,341)	$ (17,665)
Stock-based compensation	—	—	—	—	—	—	14,801	—	—	14,801
Stock option exercises	—	—	—	—	202,519	—	439	—	—	439
Restricted stock awards	—	—	—	—	1,568,042	2	(2)	—	—	—
Issuance of warrants	—	—	—	—	—	—	6,017	—	—	6,017
Net income	—	—	—	—	—	—	—	—	5,285	5,285
Balances, December 31, 2017	2,093,155	$ 2	—	$ —	55,904,072	$ 56	$313,922	$ (47)	$ (305,056)	$ 8,877
Stock-based compensation	—	—	—	—	—	—	5,941	—	—	5,941
Stock option exercises	—	—	—	—	350,441	—	670	—	—	670
Restricted stock awards	—	—	—	—	1,733,731	2	(2)	—	—	—
Common stock issuance upon retirement	—	—	—	—	2,249,925	2	(2)	—	—	—
Series B issuance, net of issuance costs	—	—	5,000	—	—	—	47,986	—	—	47,986
Series B conversion to Common Stock	—	—	(1,900)	—	10,555,556	11	(11)	—	—	—
Series B beneficial conversion feature	—	—	—	—	—	—	12,500	—	(12,500)	—
Cumulative effect of accounting change	—	—	—	—	—	—	—	—	135	135
Net loss	—	—	—	—	—	—	—	—	(33,867)	(33,867)
Balances, December 31, 2018	2,093,155	$ 2	3,100	$ —	70,793,725	$ 71	$381,004	$ (47)	$ (351,288)	$ 29,742

See notes to consolidated financial statements

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(U.S. DOLLARS, IN THOUSANDS)

	Year Ended December 31,		
	2018	**2017**	**2016**
Operating activities:			
Net (loss) income	$(33,867)	$ 5,285	$(67,138)
Adjustments to reconcile net (loss) income to net cash flows used in operating activities			
Depreciation	740	693	437
Accretion of debt discount and loan costs	4,138	2,392	397
Amortization of intangible assets	5,157	5,425	971
(Recovery from) provision for inventory obsolescence	(56)	243	—
Impairment loss on equipment	78	—	—
Stock-based compensation expense	5,941	14,801	14,931
Deferred income taxes	40	(15,972)	—
Bargain purchase gain	—	(27,336)	—
Changes in assets and liabilities, net of effect of acquisition:			
Accounts receivable	(4,640)	(5,884)	(862)
Inventories	741	2,448	(810)
Prepaid expenses and other assets	422	526	(203)
Accounts payable and accrued expenses	(2,807)	6,644	(1,546)
Deferred revenue	—	(21,716)	(159)
Net cash flows used in operating activities	(24,113)	(32,451)	(53,982)
Investing activities:			
BELBUCA acquisition	(1,951)	(5,853)	—
Purchase of equipment	(112)	(11)	(405)
Net cash flows used in investing activities	(2,063)	(5,864)	(405)
Financing activities:			
Proceeds from sales of securities, net of costs incurred	—	—	40
Proceeds from exercise of stock options	670	439	297
Issuance of common stock	—	—	2,460
Issuance of warrants	—	—	49
Proceeds from issuance of Series B preferred stock	50,000	—	—
Payment on note payable	—	(30,000)	—
Proceeds from notes payable	—	60,000	—
Equity finance costs	(1,417)	—	—
Payment of deferred financing fees	(450)	(2,948)	—
Net cash flows from financing activities	48,803	27,491	2,846
Net change in cash and cash equivalents	22,627	(10,824)	(51,541)
Cash and cash equivalents at beginning of year	21,195	32,019	83,560
Cash and cash equivalents at end of year	**$ 43,822**	**$ 21,195**	**$ 32,019**
Cash paid for interest	$ 6,053	$ 5,285	$ 2,870

See notes to consolidated financial statements

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
SUPPLEMENTAL CASH FLOW INFORMATION
(U.S. DOLLARS IN THOUSANDS EXCEPT SHARE DATA)

Non-cash Financing and Investing Activities:

The Company recorded the intrinsic value related to the beneficial conversion feature of the Series B Non-Voting Convertible Preferred Stock during the year ended December 31, 2018 totaling $12.5 million to retained earnings and additional paid-in capital in accordance with accounting principles generally accepted in the United States ("GAAP").

The Company recorded the fair value of an accumulated total of 2,119,925 shares of common stock issued to officers who retired from the Company during the year ended December 31, 2018 totaling approximately $5.3 million to expense in accordance with GAAP.

The Company recorded $0.6 million of accrued financing expenses related to the Series B Non-Voting Convertible Preferred Stock offering during the year ended December 31, 2018. Such expense is recorded as accounts payable and accrued liabilities in the consolidated balance sheet.

The Company recorded the fair value of the bargain purchase price of the BELBUCA® acquisition totaling $27.3 million to income during the year ended December 31, 2017 in accordance with GAAP (see note 7, Business Combinations and BELBUCA Acquisition).

The Company recorded the fair value of warrants totaling $6.0 million to equity with an offsetting amount to Notes payable in connection with the CRG Term Loan Agreement (as defined in note 11) during the year ended December 31, 2017 in accordance with GAAP (see note 14, Stockholders' Equity).

See notes to consolidated financial statements

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(U.S. DOLLARS IN THOUSANDS)

1. Nature of business and summary of significant accounting policies:

Organization

BioDelivery Sciences International, Inc. and subsidiaries (the "Company") was incorporated in the State of Indiana on January 6, 1997 and reincorporated as a Delaware corporation in 2002. The Company's subsidiaries are Arius Pharmaceuticals, Inc., a Delaware corporation ("Arius One") and Arius Two, Inc., a Delaware corporation ("Arius Two"), each of which are wholly-owned, and its majority-owned subsidiary, Bioral Nutrient Delivery, LLC, a Delaware limited liability company ("BND").

The Company is a rapidly growing commercial-stage specialty pharmaceutical company dedicated to patients living with chronic pain. The Company has built a portfolio of products utilizing its novel and proprietary BioErodible MucoAdhesive (BEMA®) drug-delivery technology, and other drug-delivery technologies to develop and commercialize new applications of proven therapies aimed at addressing important unmet medical needs. The Company now commercializes in the United States using its own sales force while working in partnership with third parties to commercialize its products outside the United States.

The Company's historical clinical and regulatory development strategy has focused primarily on its ability to use the U.S. Food and Drug Administration's ("FDA's") 505(b)(2) approval process to obtain more timely and efficient approval of new formulations of previously approved, active therapeutics incorporated into the Company's drug-delivery technology.

As used herein, the Company's common stock, par value $.001 per share, is referred to as the "Common Stock" and the Company's preferred stock, par value $0.001 per share, is referred to as the "Preferred Stock".

Principles of consolidation

The consolidated financial statements include the accounts of the Company, Arius One, Arius Two and BND. For each period presented BND has been an inactive subsidiary. All significant inter-company balances and transactions have been eliminated.

Significant accounting policies:

Use of estimates in financial statements

The preparation of the accompanying consolidated financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the period. Actual results could differ from those estimates. The Company reviews all significant estimates affecting the consolidated financial statements on a recurring basis and records the effect of any necessary adjustments prior to their issuance. Significant estimates of the Company include: revenue recognition, sales allowances such as returns of product sold, government program rebates, customer coupon redemptions, wholesaler/pharmacy discounts, product service fees, rebates and chargebacks, sales bonuses, stock-based compensation, determination of fair values of assets and liabilities relating to business combinations, and deferred income taxes.

Certain risks, concentrations and uncertainties

The Company relies on certain materials used in its development and third-party manufacturing processes, most of which are procured from three contract manufacturers and two active pharmaceutical ingredient ("API") suppliers for BELBUCA and BUNAVAIL®. The Company purchases its pharmaceutical ingredients pursuant to long-term supply agreements with a limited number of suppliers. The failure of a supplier, including a subcontractor, to deliver on schedule could delay or interrupt the development or commercialization process and thereby adversely affect the Company's operating results. In addition, a disruption in the commercial supply of or a significant increase in the cost of the API from any of these sources could have a material adverse effect on the Company's BELBUCA and BUNAVAIL business, which would affect the Company's financial position and results of operations.

In addition, the Company utilizes only two contract manufacturers to create the BELBUCA and BUNAVAIL laminates and only one contract manufacturer to package the laminates into final product. Although the Company has long term supply agreements with these two vendors, any problems or regulatory issues at either of these vendors could create significant BELBUCA and BUNAVAIL supply delays. Amounts due to these vendors represented approximately 6.3% and 22.8% of total accounts payable as of December 31, 2018 and 2017, respectively.

Key components used in the manufacture of ONSOLIS® are currently provided by a limited number of suppliers. This could result in the Company's inability to timely obtain an adequate supply of required components and reduce control over pricing, quality and timely delivery. Also, if the supply of any components is interrupted, components from alternative suppliers may not

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(U.S. DOLLARS IN THOUSANDS)

1. Nature of business and summary of significant accounting policies (continued):

be available in sufficient volumes within required time frames, if at all, to meet the Company's obligations under certain supply agreements. This could delay timely commercialization efforts causing the Company's obligations to not be fulfilled.

The Company sells its BELBUCA and BUNAVAIL products primarily to large national wholesalers, which in turn may resell the products to smaller or regional wholesalers, retail pharmacies, chain drug stores, government agencies and other third parties. The following table lists the Company's customers that individually comprise greater than 10% of total accounts receivable:

	December 31,	
Customers	**2018**	**2017**
Customer A	47%	47%
Customer B	22%	22%
Customer C	25%	26%
Total	**94%**	**95%**

These three customers accounted for 92%, 92% and 91% of total annual sales during the years ended December 31, 2018, 2017 and 2016 respectively.

Cash

The Company places cash on deposit with financial institutions in the United States. The Federal Deposit Insurance Corporation covers $0.25 million for substantially all depository accounts. As of December 31, 2018, the Company had approximately $43.6 million, which exceeded these insured limits. As of December 31, 2017, the Company had approximately $21.2 million, which exceeded these insured limits.

Accounts receivable

The Company typically requires its customers to remit payments within the first 30 to 37 days, depending on the customer and the products purchased and agreed upon terms. In addition, the Company offers wholesale distributors a prompt payment discount if they make payments within these deadlines. This discount is generally 2% but may be higher in some instances due to product launches or customer and/or industry expectations. Because the Company's wholesale distributors typically take the prompt payment discount, the Company accrues 100% of the prompt payment discounts, based on the gross amount of each invoice, at the time of sale, and the Company applies earned discounts at the time of payment. The allowance for prompt payment discounts was $0.3 million and $0.2 million as of December 31, 2018 and 2017, respectively.

The Company performs ongoing credit evaluations and does not require collateral. As appropriate, the Company establishes provisions for potential credit losses. There were no allowances for doubtful accounts as of December 31, 2018 or 2017. The Company writes off accounts receivable when management determines they are uncollectible and credits payments subsequently received on such receivables to bad debt expense in the period received.

Inventory

Inventories are stated at the lower of cost or net realizable value with costs determined for each batch under the first-in, first-out method and specifically allocated to remaining inventory. Inventory consists of raw materials, work in process and finished goods. Raw materials include amounts of active pharmaceutical ingredient for a product to be manufactured, work in process includes the bulk inventory of laminate (the Company's drug delivery film) prior to being packaged for sale, and finished goods include pharmaceutical products ready for commercial sale.

On a quarterly basis, the Company analyzes its inventory levels and records allowances for inventory that has become obsolete, inventory that has a cost basis more than the expected net realizable value and inventory that is more than expected demand based upon projected product sales. The Company recorded a $0.2 million in reserve for inventory obsolescence as of December 31, 2018, and 2017.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(U.S. DOLLARS IN THOUSANDS)

1. Nature of business and summary of significant accounting policies (continued):

Inventory is composed of the following at December 31:

	2018	2017
Raw Materials & Supplies	$ 645	$1,338
Work-in-process	2,093	3,135
Finished Goods	2,855	1,861
Finished Goods Reserve	(187)	(243)
Total Inventories	$5,406	$6,091

Property and equipment

The Company records property and equipment at cost less accumulated depreciation, which is computed on a straight-line basis over its estimated useful lives, generally 3 to 10 years.

The Company evaluates the carrying value of equipment when events or changes in circumstances indicate the related carrying amount may not be recoverable. The Company has certain manufacturing equipment that isn't currently in production, which has been deemed idle. There was no impairment of equipment recorded during the year ended December 31, 2018 or 2017.

Intangibles and goodwill

The Company reviews intangible assets with finite lives ("other intangible assets") for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The Company uses an estimate of the undiscounted cash flows over the remaining life of its other intangible assets, or related group of assets where applicable, in measuring whether the assets to be held and used will be realizable. In the event of impairment, the Company would discount the future cash flows using its then estimated incremental borrowing rate to estimate the amount of the impairment.

There were no impairment charges recognized on finite lived intangibles in 2018, 2017 or 2016.

Intangible assets with finite useful lives are amortized over the estimated useful lives as follows:

	Estimated Useful Lives
Licenses	15 years
BELBUCA license and distribution rights	10 years
U.S. product rights	8-12 years
EU product rights	7-11 years

Goodwill is evaluated for impairment at least annually or more frequently if events or changes in circumstances indicate that the carrying amount may not be recoverable. During the evaluation of the potential impairment of goodwill, either a qualitative or a quantitative assessment may be performed. If a qualitative evaluation determines that it is more likely than not that no impairment exists, then no further analysis is performed. If a qualitative evaluation is unable to determine whether it is more likely than not that impairment has occurred, a quantitative evaluation is performed. If the carrying value exceeds the fair value, an impairment charge is recorded based on that difference. There were no goodwill impairment charges in 2018, 2017 or 2016.

Revenue recognition

Product sales

As discussed further below in Note 2, effective January 1, 2018, the Company adopted Accounting Standards Update ("ASU") 2014-09, "Revenue from Contracts with Customers" ("Topic 606") and began recognizing revenue under the new accounting guidance on that date. Under the new accounting guidance, the Company recognizes revenue on product sales when control of the promised goods is transferred to its customers in an amount that reflects the consideration expected to be received in exchange for transferring those goods. The Company accounts for a contract when it has approval and commitment from both parties, the rights of the parties are identified, payment terms are identified, the contract has commercial substance and collectability of consideration is probable. When determining whether the customer has obtained control of the goods, the Company considers any future performance obligations. Generally, there is no post-shipment obligations on product sold.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(U.S. DOLLARS IN THOUSANDS)

1. Nature of business and summary of significant accounting policies (continued):

Performance obligations

A performance obligation is a promise in a contract to transfer a distinct good or service to the customer and is the unit of account in Topic 606. A contract's transaction price is allocated to each distinct performance obligation and recognized as revenue when, or as, the performance obligation is satisfied. The majority of the Company's product sales contracts have a single performance obligation as the promise to transfer the individual goods is not separately identifiable from other promises in the contracts and, therefore, not distinct. The Company's performance obligations are satisfied at a point in time. The multiple performance obligations are not allocated based off of the obligations but based off of standard selling price.

Adjustments to product sales

The Company recognizes product sales net of estimated allowances for rebates, price adjustments, returns, chargebacks and prompt payment discounts. A significant majority of the Company's adjustments to gross product revenues are the result of accruals for its commercial contracts, retail consumer subsidy programs, and Medicaid rebates.

The Company establishes allowances for estimated rebates, chargebacks and product returns based on numerous qualitative and quantitative factors, including:

- the number of and specific contractual terms of agreements with customers;
- estimated levels of inventory in the distribution channel;
- historical rebates, chargebacks and returns of products;
- direct communication with customers;
- anticipated introduction of competitive products or generics;
- anticipated pricing strategy changes by the Company and/or its competitors;
- analysis of prescription data gathered by a third-party prescription data provider;
- the impact of changes in state and federal regulations; and
- the estimated remaining shelf life of products.

In its analyses, the Company uses prescription data purchased from a third-party data provider to develop estimates of historical inventory channel sell-through. The Company utilizes an internal analysis to compare historical net product shipments to estimated historical prescriptions written. Based on that analysis, management develops an estimate of the quantity of product in the channel which may be subject to various rebate, chargeback and product return exposures. To estimate months of ending inventory in the Company's distribution channel, the Company divides estimated ending inventory in the distribution channel by the Company's recent prescription data, not considering any future anticipated demand growth beyond the succeeding quarter. Monthly for each product line, the Company prepares an internal estimate of ending inventory units in the distribution channel by adding estimated inventory in the channel at the beginning of the period, plus net product shipments for the period, less estimated prescriptions written for the period. This is done for each product line by applying a rate of historical activity for rebates, chargebacks and product returns, adjusted for relevant quantitative and qualitative factors discussed above, to the potential exposed product estimated to be in the distribution channel. In addition, the Company receives daily information from the wholesalers regarding their sales and actual on hand inventory levels of the Company's products. This enables the Company to execute accurate provisioning procedures.

Product returns-Consistent with industry practice, the Company offers contractual return rights that allow its customers to return the products within an 18-month period that begins six months prior to and ends twelve months after expiration of the products.

Rebates- The liability for government program rebates is calculated based on historical and current rebate redemption and utilization rates contractually submitted by each program's administrator.

Price adjustments and chargebacks-The Company's estimates of price adjustments and chargebacks are based on its estimated mix of sales to various third-party payers, which are entitled either contractually or statutorily to discounts from the Company's listed prices of its products. If the sales mix to third-party payers is different from the Company's estimates, the Company may be required to pay higher or lower total price adjustments and/or chargebacks than it had estimated, and such differences may be significant.

The Company, from time to time, offers certain promotional product-related incentives to its customers. These programs include certain product incentives to pharmacy customers and other sales stocking allowances. The Company has voucher programs for

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(U.S. DOLLARS IN THOUSANDS)

1. Nature of business and summary of significant accounting policies (continued):

BELBUCA and BUNAVAIL whereby the Company offers a point-of-sale subsidy to retail consumers. The Company estimates its liabilities for these voucher programs based on the actual redemption rates as reported to the Company by a third-party claims processing organization. The Company accounts for the costs of these special promotional programs as price adjustments, which are a reduction of gross revenue.

Prompt payment discounts-The Company typically offers its wholesale customers a prompt payment discount of 2% as an incentive to remit payments within the first 30 to 37 days after the invoice date depending on the customer and the products purchased.

Gross to net accruals-A significant majority of the Company's gross to net adjustments to gross product revenues are the result of accruals for its voucher program and rebates related to Medicare Part D, Part D Coverage Gap, Medicaid and commercial contracts, with most of those programs having an accrual to payment cycle of anywhere from one to three months. In addition to this relatively short accrual to payment cycle, the Company receives daily information from the wholesalers regarding their sales of the Company's products and actual on hand inventory levels of its products. This enables the Company to execute accurate provisioning procedures. Consistent with the pharmaceutical industry, the accrual to payment cycle for returns is longer and can take several years depending on the expiration of the related products.

License and development agreements

The Company periodically enters into license and development agreements to develop and commercialize its products. The arrangements typically are multi-deliverable arrangements that are funded through upfront payments, milestone payments and other forms of payment. The Company currently has multiple license and development agreements that are described in notes 7, 9 and 10. Depending on the nature of the contract these revenues are classified as research and development reimbursements or contract revenue.

Cost of sales

Cost of sales includes the direct costs attributable to the production of BELBUCA and BUNAVAIL. It includes raw materials, production costs at the Company's three contract manufacturing sites, quality testing directly related to the products, and depreciation on equipment that the Company has purchased to produce BELBUCA and BUNAVAIL. It also includes any batches not meeting specifications and raw material yield losses. Yield losses and batches not meeting specifications are expensed as incurred. Cost of sales is recognized when sold to the wholesaler from our distribution center.

For BREAKYL and PAINKYL (the Company's out-licensed breakthrough cancer pain therapies), cost of sales includes all costs related to creating the product at the Company's contract manufacturing location in Germany. The Company's contract manufacturer bills the Company for the final product, which includes materials, direct labor costs, and certain overhead costs as outlined in applicable supply agreements. Cost of sales also includes royalty expenses that the Company owes to third parties.

Research and development expenses

Research and development expenses have historically consisted of product development expenses incurred in identifying, developing and testing product candidates. Product development expenses consist primarily of labor, benefits and related employee expenses for personnel directly involved in product development activities; fees paid to professional service providers for monitoring and analyzing clinical trials; regulatory costs; costs of contract research and manufacturing of inventory used in testing and clinical trials.

Product development expenses are expensed as incurred and reflect costs directly attributable to product candidates in development during the applicable period and to product candidates for which the Company has discontinued development. All indirect costs (such as salaries, benefits or other costs related to the Company's accounting, legal, human resources, purchasing, information technology and other general corporate functions) associated with individual product candidates are included in general and administrative expenses.

Advertising

Advertising costs, which include promotional expenses and the cost of placebo samples, are expensed as incurred. Advertising expenses were $4.5 million, $3.8 million and $4.2 million for the years ended December 31, 2018, 2017 and 2016, respectively, and are included in selling, general and administrative expenses in the accompanying consolidated statements of operations.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(U.S. DOLLARS IN THOUSANDS)

1. Nature of business and summary of significant accounting policies (continued):

Shipping and handling costs

Shipping and handling costs, which include expenses from our wholesalers, are expensed as incurred. Shipping and handling costs were $0.02 million, $0.01 and $0.01 million for the years ended December 31, 2018, 2017 and 2016, respectively, and are included in selling, general and administrative expenses in the accompanying consolidated statements of operations.

Stock-based compensation

The Company has a stock-based compensation plan under which various types of equity-based awards are granted, including stock options, restricted stock units (RSUs) and performance-based RSUs. The fair value of stock option and RSUs, which are subject only to service conditions with graded vesting, are recognized as compensation expense, generally on a straight-line basis over the service period, net of estimated forfeitures. Forfeitures are recognized as they occur. The fair values of performance-based RSUs are recognized as compensation expense from the grant date to the end of the performance period. The Company uses the fair-value based method to determine compensation for all arrangements under which employees and others receive shares of stock or equity instruments (warrants and options). The grant date fair value of an RSU equals the closing price of our common stock on the trading day preceding the grant date. The fair value of each option and warrant is estimated on the date of grant using the Black-Scholes valuation model that uses assumptions for expected volatility, expected dividends, expected term, and the risk-free interest rate. Expected volatility is based on historical volatility of the Company's Common Stock and other factors estimated over the expected term of the options. The expected term of options granted is derived using the "simplified method" which computes expected term as the average of the sum of the vesting term plus the contract term. The risk-free rate is based on the U.S. Treasury yield.

In applying the Black-Scholes options-pricing model, assumptions are as follows:

	2018	2017	2016
Expected price volatility	60.34%-68.77%	68.76%-78.79%	62.65%-80.78%
Risk-free interest rate	2.05%-3.00%	1.77%-2.05%	0.56%-1.70%
Weighted average expected life in years	6 years	6 years	6 years
Dividend yield	—	—	—

Fair Value of Financial Instruments

The Company measures the fair value of instruments in accordance with GAAP which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements.

GAAP defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. GAAP also establishes a fair value hierarchy, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. GAAP describes three levels of inputs that may be used to measure fair value:

Level 1 – quoted prices in active markets for identical assets or liabilities

Level 2 – quoted prices for similar assets and liabilities in active markets or inputs that are observable

Level 3 – inputs that are unobservable (for example cash flow modeling inputs based on assumptions)

Recent accounting pronouncements-adopted

The SEC has released SEC Final Rule Release No. 33-10532 Disclosure Update and Simplification, which adopts amendments to certain disclosure requirements that have become redundant, duplicative, overlapping, outdated, or superseded, in light of other SEC disclosure requirements, GAAP, or changes in the information environment. The amendments also refer certain SEC disclosure requirements that overlap with but require information incremental to GAAP to the Financial Accounting Standards Board ("FASB") for potential incorporation into GAAP. The amendments are intended to facilitate the disclosure of information to investors and simplify compliance without significantly altering the total mix of information provided to investors. These amendments are part of an initiative by the Division of Corporation Finance to review disclosure requirements applicable to issuers to consider ways to improve the requirements for the benefit of investors and issuers. The amendments became effective on November 5, 2018 and did not have a material impact to the Company.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(U.S. DOLLARS IN THOUSANDS)

1. Nature of business and summary of significant accounting policies (continued):

In the first quarter of 2018, the Company adopted Topic 606. Under the standard, revenue is recognized when a customer obtains control of promised goods or services in an amount that reflects the consideration the entity expects to receive in exchange for those goods or services. In addition, the standard requires disclosure of the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. The Company applied the five-step method outlined in the ASU to all revenue streams and elected the modified retrospective implementation method. The additional disclosures required by Topic 606 have been included in Note 2.

Recent accounting pronouncements-issued, not yet adopted

In November 2018, the FASB issued ASU "Collaborative Arrangements (Topic 808) – Clarifying the Interaction between Topic 808 and Topic 606" ("ASU 2018-18"). The amendments in ASU 2018-18 make targeted improvements to GAAP for collaborative arrangements by clarifying that certain transactions between collaborative arrangement participants should be accounted for as revenue under Topic 606 when the collaborative arrangement participant is a customer in the context of a unit of account. In those situations, all the guidance in Topic 606 should be applied, including recognition, measurement, presentation, and disclosure requirements. In addition, unit-of-account guidance in Topic 808 was aligned with the guidance in Topic 606 (that is, a distinct good or service) when an entity is assessing whether the collaborative arrangement or a part of the arrangement is within the scope of Topic 606. ASU 2018-18 is effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. Early adoption is permitted, including adoption in any interim period. The amendments in this Update should be applied retrospectively to the date of initial application of Topic 606. The Company is currently assessing the impact to its consolidated financial statements but believes there to be no material impact.

ASU 2016-02, issued on February 25, 2016, is intended to improve financial reporting about leasing transactions. The ASU affects all companies and other organizations that lease assets such as real estate, airplanes, and manufacturing equipment. The ASU will require organizations that lease assets referred to as "Lessees" to recognize on the balance sheet the assets and liabilities for the rights and obligations created by those leases. An organization is to provide disclosures designed to enable users of financial statements to understand the amount, timing, and uncertainty of cash flows arising from leases. These disclosures include qualitative and quantitative requirements concerning additional information about the amounts recorded in the financial statements. Under the new guidance, a lessee will be required to recognize assets and liabilities for leases; however, the Company has elected the short-term practical expedient which allows us not to recognize assets and liabilities for leases with lease terms of 12 months or less. Consistent with current GAAP, the recognition, measurement, and presentation of expenses and cash flows arising from a lease by a lessee primarily will depend on its classification as a finance or operating lease. The guidance also requires disclosures regarding the amount, timing and uncertainty of cash flows arising from leases. Effects such as changes in the categorization of rental costs, from rent expense to interest and depreciation expense should also be disclosed. Other effects may occur depending on the types of leases and on the specific terms that are utilized by particular lessees.

However, unlike current GAAP which requires only capital leases to be recognized on the balance sheet, the new ASU will require both types of leases (i.e., operating and finance leases) to be recognized on the balance sheet. The FASB lessee accounting model will continue to account for both types of leases. The finance lease will be accounted for in substantially the same manner as capital leases are accounted for under existing GAAP. The operating lease will be accounted for in a manner similar to operating leases under existing GAAP, except that lessees will recognize a lease liability and a right-of-use asset for all of those leases. The new standard requires a modified-retrospective approach to adoption and is effective for interim and annual periods beginning on January 1, 2019 but may be adopted earlier. In addition, the standard will require that the Company update its systems, processes and controls it uses to track, record and account for its lease portfolio.

The Company will adopt and implement this standard on January 1, 2019, using the required modified-retrospective approach as of the effective date. The Company will elect the package of practical expedients permitted under the transition guidance within the new standard, which among other things, allows us to carryforward the historical lease classification. The Company will make an accounting policy election to account for leases with an initial term of 12 months or less similar to existing guidance for operating leases today. The Company will recognize those lease payments in the Consolidated Statements of Operations on a straight-line basis over the lease term. The Company is substantially complete with its implementation to the new leasing standard and believes that the transition will not have a material impact on its consolidated balance sheet. As disclosed in Note 18 – Commitments and Contingencies, the Company has approximately $1.3 million in future minimum lease commitments as of the year ended December 31, 2018. Upon adoption, the Company's lease liability will generally be based on the present value of such payments and the related right-of-use asset will generally be based on the lease liability.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(U.S. DOLLARS IN THOUSANDS)

1. Nature of business and summary of significant accounting policies (continued):

The Company has estimated the right-of-use lease assets of $0.9 million and liabilities of $1.0 million that will be required to be recorded as an adjustment to retained earnings upon adoption beginning January 1, 2019. The Company does not believe that adoption of the standard will materially affect consolidated net income.

2. Revenue from contracts with customers:

Effective January 1, 2018, the Company adopted Topic 606. The Company elected to apply the standard using the modified retrospective method beginning January 1, 2018. The Company applied this guidance only to those contracts that were not completed at the date of adoption. As a result of adoption, the cumulative impact to the Company's retained earnings at January 1, 2018 was $0.135 million. The comparative information has not been restated and continues to be reported under the accounting standards in effect for those periods.

There were no significant changes in the timing or amount of revenue recognized for the Company's product sales and related gross-to-net adjustments under Topic 606. The Company's net product sales continue to be recognized when delivery has occurred, and its gross-to-net adjustments are estimated and recorded in the accounting period related to when sales occur in the manner fundamentally consistent with the Company's prior accounting methodology.

Under the new standard, timing for recognition of certain contract revenue may be accelerated such that a portion of revenue will be estimated and recognized in revenue earlier than the previous accounting standards. During the year ended December 31, 2018, the Company recorded financing revenue for a milestone that is not due until 2020.

The main types of revenue contracts are:

- *Product sales*-Product sales amounts relate to sales of BELBUCA and BUNAVAIL. These sales are recognized as revenue when control is transferred to the wholesaler in an amount that reflects the consideration expected to be received.
- *Product royalty revenues*-Product royalty revenue amounts are based on sales revenue of BELBUCA under the Company's license agreement with Purdue Pharma ("Purdue"), the PAINKYL™ product under the Company's license agreement with TTY and the BREAKYL™ product under the Company's license agreement with Meda AB, which was acquired by Mylan N.V. (which we refer to herein as Mylan). Product royalty revenues are recognized when control of the product is transferred to the license partner in an amount that reflects the consideration expected to be received. Supplemental sales-based product royalty revenue may also be earned upon the subsequent sale of the product at agreed upon contractual rates.
- *Contract revenue*-Contract revenue amounts are related to milestone payments under the Company's license agreements with its partners including any associated financing component.

The impact of adoption of Topic 606 on the Company's consolidated balance sheet as of December 31, 2018 follows (in thousands):

	Consolidated Balance Sheet December 31, 2018		
	As reported	Balances without adoption of Topic 606	Effect of Adoption
Accounts receivable, net	$ 13,627	$ 13,462	$ 165
Accumulated deficit	$(351,288)	$(351,453)	$ 165

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2. Revenue from contracts with customers (continued):

The impact of adoption of Topic 606 on the Company's consolidated statement of operations for the year ended December 31, 2018 follows (in thousands):

	Consolidated Statement of Operations Year ended December 31, 2018		
	As reported	Balances without adoption of Topic 606	Effect of Adoption
Product sales	$ 51,410	$ 51,410	$ —
Product royalty revenues	3,389	3,389	—
Contract revenues	841	811	30
Total revenues	$ 55,640	$ 55,610	$ 30
Net loss	$(33,867)	$ (33,897)	$ 30

The beginning and ending balances of the Company's accounts receivables with customers from contracts during the periods presented is as follows (in thousands):

	Balance at January 1, 2018	Year ended December 31, 2018	Balance at December 31, 2018
Accounts receivable with customers	$ 8,987	$ 4,640	$ 13,627

On January 8, 2019, Purdue terminated their license agreement with the Company which was effective March 11, 2019 (See Note 10, Other license agreements and acquired product rights). Therefore, all previously presented contract revenue for future milestones related to the Purdue agreement as a result of the adoption of Topic 606 during the year ended December 31, 2018 has been reversed. The total amount reversed is $0.2 million and is recorded in the accompanying consolidated statement of operations for the year ended December 31, 2018.

3. Liquidity:

At December 31, 2018, the Company had cash of approximately $43.8 million. The Company used $24.1 million of cash in operations during the year ended December 31, 2018 and had stockholders' equity of $29.7 million, versus stockholders' equity of $8.9 million at December 31, 2017. The Company believes that it has sufficient current cash, along with expected proceeds from sales to manage the business as currently planned.

The Company's cash on hand estimation assumes that the Company does not otherwise face unexpected events, costs or contingencies, any of which could affect the Company's cash requirements from time to time. Available resources may be consumed more rapidly than currently anticipated, potentially resulting in the need for additional funding. Additional funding, capital or loans (including, without limitation, milestone or other payments from commercialization agreements) may be unavailable on favorable terms, if at all, which could leave the Company without adequate capital resources.

4. Accounts payable and accrued liabilities:

The following table represents the components of accounts payable and accrued liabilities as of December 31:

	2018	2017
Accounts payable	$ 3,166	$12,236
Accrued rebates	12,261	5,648
Accrued compensation and benefits	3,814	3,472
Accrued acquisition costs	318	2,311
Accrued returns	715	915
Accrued royalties	159	488
Accrued clinical trial costs	464	234
Accrued legal	70	216
Accrued other	572	629
Total accounts payable and accrued expenses	$21,539	$26,149

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4. Accounts payable and accrued liabilities (continued):

As of December 31, 2018, three vendors comprised 37% of the accounts payable balance. As of December 31, 2017, three vendors comprised 39% of the accounts payable balance.

5. Property and equipment:

Property and equipment, summarized by major category, consist of the following as of December 31:

	2018	2017
Machinery & equipment	$ 5,635	$ 5,428
Computer equipment & software	406	399
Office furniture & equipment	155	169
Leasehold improvements	43	44
Idle equipment	679	766
Total	6,918	6,806
Less accumulated depreciation	(3,846)	(3,028)
Total property, plant & equipment, net	$ 3,072	$ 3,778

Depreciation expense for years ended December 31, 2018, 2017 and 2016 was approximately $1.0 million, $0.7 million and $0.4 million, respectively.

6. Other intangible assets:

Other intangible assets, net, consisting of product rights and licenses are summarized as follows:

December 31, 2018	Gross Carrying Value	Accumulated Amortization	Intangible Assets, net	Weighted average Useful Life
Product rights	$ 6,050	$ (5,442)	$ 608	1.08
BELBUCA license and distribution rights	45,000	(9,000)	36,000	7.65
Licenses	1,900	(1,805)	95	0.50
Total intangible assets	$ 52,950	$ (16,247)	$ 36,703	9.23

December 31, 2017	Gross Carrying Value	Accumulated Amortization	Intangible Assets, net	Weighted average Useful Life
Product rights	$ 6,050	$ (4,881)	$ 1,169	1.21
BELBUCA license and distribution rights	45,000	(4,500)	40,500	8.50
Licenses	1,900	(1,709)	191	0.54
Total intangible assets	$ 52,950	$ (11,090)	$ 41,860	10.25

The Company incurred amortization expense on other intangible assets of approximately $5.2 million, $5.4 million and $1.0 million for the years ended December 31, 2018, 2017 and 2016, respectively. Estimated aggregate future amortization expenses for other intangible assets for each of the next five years and thereafter are as follows:

Years ending December 31,	
2019	$ 5,157
2020	4,546
2021	4,500
2022	4,500
2023	4,500
Thereafter	13,500
	$36,703

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7. License and development agreements:

The Company periodically enters into license and development agreements to develop and commercialize its products. The arrangements typically are multi-deliverable arrangements that are funded through upfront payments, milestone payments, royalties and other forms of payment to the Company. The Company's most significant license and development agreements are as follows:

Endo license and development agreement

In January 2012, the Company entered into a License and Development Agreement with Endo Pharmaceuticals, Inc. ("Endo") pursuant to which the Company granted Endo an exclusive commercial world-wide license to develop, manufacture, market and sell the Company's BELBUCA product and to complete U.S. development of such product candidate for purposes of seeking FDA approval (the "Endo Agreement").

Pursuant to the Endo Agreement, Endo had obtained all rights necessary to complete the clinical and commercial development of BELBUCA and to sell the product worldwide.

Pursuant to the Endo Agreement, the Company has received the following payments:

- $50 million upon regulatory approval, earned in October 2015 and received in November 2015. Of the $50 million received in November 2015, $20 million related to a patent extension and was recorded as deferred revenue because all or a portion of such $20 million was contingently refundable to Endo if a third party generic product was introduced in the U.S. during the patent extension period from 2020 to 2027. However, due to the Company and Endo entering into a Termination Agreement on December 7, 2016 which terminated the BELBUCA license to Endo effective January 6, 2017, the deferred $20 million was recognized as revenue in January 2017. (See note 8, Business Combinations and BELBUCA Acquisition).

Collegium license and development agreement

On May 11, 2016, the Company and Collegium executed a License Agreement under which the Company granted Collegium the exclusive rights to develop and commercialize ONSOLIS in the U.S.

Under the terms of the License Agreement, Collegium was responsible for the manufacturing, distribution, marketing and sales of ONSOLIS in the U.S. The Company was obligated to use commercially reasonable efforts to continue the transfer of manufacturing to the anticipated manufacturer for ONSOLIS and to submit a corresponding Prior Approval Supplement (the "Supplement") to the FDA with respect to the current NDA for ONSOLIS. Following approval of the Supplement, the NDA and manufacturing responsibility for ONSOLIS (including the manufacturing relationship with the Company's manufacturer, subject to the Company entering into an appropriate agreement with such manufacturer that is acceptable and assignable to Collegium) would have been transferred to Collegium.

On December 8, 2017, the Company received the required 90-day notice from Collegium regarding termination of the License Agreement and the effective date of termination was March 8, 2018. The Company is assessing its commercial options for ONSOLIS.

Pursuant to the Collegium Agreement, the Company has received the following payments:

- a $2.5 million upfront non-refundable payment, payable to the Company within 30 days of execution of the License Agreement (received June 2016);
- reimbursement to the Company for a pre-determined amount of the remaining expenses associated with the ongoing transfer of the manufacturing of ONSOLIS;

8. Business combination and BELBUCA acquisition:

On December 7, 2016, the Company and Endo entered into the Termination Agreement to terminate Endo's licensing rights for BELBUCA. The transaction closed on January 6, 2017. At the closing date, the Company purchased from Endo the following net assets (the "net assets"): (i) current BELBUCA product inventory and work-in-progress, (ii) material manufacturing contracts related to BELBUCA, (iii) BELBUCA-related domain names and trademarks (including the BELBUCA trademark), (iv) BELBUCA -related manufacturing equipment, and (v) all pre-approval regulatory submissions, including any INDs and NDAs, regulatory approvals and post-approval regulatory submissions concerning BELBUCA. In addition to the Purchase Price, pursuant to the terms of the Termination Agreement, the Company also paid to Endo a fee in the amount of $5 million in consideration for (i) Endo's agreement not to compete for a period of two years from the closing date of the termination

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8. Business combination and BELBUCA acquisition (continued):

agreement and (ii) Endo's waiver of its right to sell product for twelve months following the closing of the termination agreement.

At the closing date, the Company accepted transfer of the net assets and assumed and agreed to discharge when due all applicable liabilities assumed by the Company, which consisted of post-closing obligations for liabilities and payments associated with the net assets, the assumed contracts related to the net assets and applicable taxes (with the obligation for pre-closing and other certain liabilities resulting from the acts or omissions of Endo being retained by Endo). The Purchase Price, together with all other payments (including a non-compete covenant payment) due to Endo under the Termination Agreement, was payable to Endo in cash in four quarterly installments on the last calendar day of each quarter in 2017.

The BELBUCA acquisition was accounted for as a business combination in accordance with ASC No. 805, Business Combinations which, among other things, requires assets acquired and liabilities assumed to be measured at their acquisition date fair values. Determining the fair value of certain acquired assets and liabilities is subjective in nature and often involves the use of significant estimates and assumptions, including, but not limited to, the selection of appropriate valuation methodology, projected revenue, expenses and cash flows, weighted average cost of capital, discount rates, and estimates of terminal values. The Company believes the estimates used are reasonable and the significant effects of the BELBUCA acquisition are properly reflected.

The following table summarizes the consideration paid to acquire BELBUCA and the estimated values of assets acquired and liabilities assumed in the accompanying consolidated balance sheet based on their fair values on January 6, 2017 (the date of the Endo Closing):

Asset purchase price:	
Deferred cash consideration to Endo	$ 7,536
Total asset purchase price	$ 7,536
Estimated fair value of assets acquired:	
BELBUCA product inventory and work-in process	$ 5,412
BELBUCA-related manufacturing equipment	432
License and distribution rights intangible assets	45,000
Deferred tax liability	(15,972)
Amount attributable to assets acquired	$ 34,872
Bargain purchase gain	$(27,336)

Inventories acquired included raw materials, work-in-progress and finished goods. The fair value of the acquired finished goods inventory was estimated by adjusting the anticipated selling price costs to sell and an appropriate profit on selling activities. For work-in-process, in addition to those inputs used to estimate the fair value of finished goods, the cost and estimated profit on completing the manufacturing are also included. The fair value of the raw materials represent cost to acquire the materials from suppliers.

The fair value of the equipment was determined by consideration of replacement cost and equipment condition and was assigned a useful life of seven years. The fair value of the license and distribution rights intangible assets as amortized in the accompanying consolidated balance sheets were estimated primarily using the "income method," which starts with a forecast of all expected future cash flows. Some of the more significant assumptions inherent in the development of intangible asset values, from the perspective of a market participant, include: the amount and timing of projected future cash flows (including net revenue, cost of sales, commercial expenses, research and development costs and working capital requirements) as well as estimated contributory asset charges; the discount rate selected to measure the risks inherent in the future cash flows; and the assessment of the asset's life cycle and the competitive trends impacting the asset, among other factors. The license and distribution rights intangible assets will be amortized over ten years, which approximates the current, remaining patent life of the BELBUCA -related intellectual property.

As a result of the business combination, the Company recognized a deferred tax liability of $16.0 million. This deferred tax liability was netted against its deferred tax assets as of December 31, 2017. Because a full valuation allowance has been provided against the Company's deferred tax assets as it is considered more likely than not that they will not be utilized, the Company released a corresponding amount of its valuation allowance during the year ended December 31, 2017 and recognized a $16.0 million tax benefit in the accompanying consolidated statement of operations.

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8. Business combination and BELBUCA acquisition (continued):

Pro forma impact of acquisition of BELBUCA

The following pro forma combined results of operations are provided for the year ended December 31, 2016, as though the BELBUCA acquisition had been completed as of January 1, 2016. These supplemental pro forma results of operations are provided for illustrative purposes only and do not purport to be indicative of the actual results that would have been achieved by the combined company for the period presented or that may be achieved by the combined company in the future. The pro forma results of operations do not include any cost savings or other synergies that resulted, or may result, from the BELBUCA acquisition or any estimated costs that will be incurred to integrate the BELBUCA product line, nor do they reflect the bargain purchase gain recognized. Future results may vary significantly from the results in this pro forma information because of future events and transactions, as well as other factors.

(in thousands, except per share data)	December 31, 2016 (unaudited)
Revenue	$ 25,010
Net loss	$ (201,769)
Pro forma net loss per common share	
Basic	$ (3.76)
Diluted	$ (3.76)

The Company's historical financial information was adjusted to give effect to the pro forma events that were directly attributable to the BELBUCA acquisition and factually supportable. The unaudited pro forma consolidated results include historical revenues and expenses of assets acquired in the acquisition with the following adjustments:

- Adjustment to recognize incremental amortization expense based on the fair value of intangibles acquired;
- Adjustment to recognize incremental depreciation expense for equipment acquired in the acquisition.

9. Other license agreements and acquired product rights:

Purdue license and supply agreement:

On July 12, 2017, the Company, along with Purdue, an Ontario limited partnership, announced that they had executed an exclusive agreement granting to Purdue the licensing, distribution, marketing and sale rights related to BELBUCA in Canada. Financial terms of the Purdue agreement include: (i) total upfront and other cash milestone payments (relating to marketing authorization transfer and certain other marketing- and sales-related milestones) of up to an aggregate of CAD 4.5 million, including approximately CAD 1.5 million (0.5 million CAD and 1.0 million CAD received August 2017 and October 2017, respectfully); (ii) a low double digit percent royalty payable quarterly by Purdue to the Company based on Canadian net sales of BELBUCA, which royalty rate is subject to adjustment in certain circumstances; (iii) an annual royalty fee commencing a period of time after the commercial launch of BELBUCA in Canada, which fee is creditable against royalties payable by Purdue and subject to reduction in certain circumstances; and (iv) payment by Purdue of certain costs incurred to obtain and transfer the marketing authorization for BELBUCA in Canada, a portion of which will be reimbursed by the Company as a reduction of royalties payable by Purdue.

On September 12, 2017, the Company announced Health Canada had granted market authorization to formally transfer the Drug Identification Number (DIN) ownership of BELBUCA in Canada to Purdue. This approval triggered a milestone payment to the Company in the amount of CAD 1 million, which was received October 2017.

On January 30, 2018, the Company and Purdue announced that BELBUCA was now commercially available in Canada. The first commercial sale of BELBUCA in Canada triggered a milestone payment to the Company from Purdue in the amount of CAD 1 million, which the Company received March 2018.

On January 8, 2019, the Company received the required 60-day notice from Purdue regarding termination of the License Agreement and the effective date of termination was March 11, 2019. Given these developments, the Company is taking steps to discontinue the sale of BELBUCA in Canada.

TTY license and supply agreement

On October 7, 2010, the Company announced a license and supply agreement with TTY Biopharm Co., Ltd. ("TTY") for the exclusive rights to develop and commercialize BEMA Fentanyl in the Republic of China, Taiwan. The agreement results in potential milestone payments to the Company of up to $1.3 million, which include an upfront payment of $0.3 million that was

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9. Other license agreements and acquired product rights:

received in 2010. In addition, the Company will receive an ongoing royalty based on net sales. TTY will be responsible for the regulatory filing of BEMA Fentanyl in Taiwan as well as future commercialization in that territory. The term of the agreement with TTY is for the period from October 4, 2010 until the date fifteen years after first commercial sale unless the agreement is extended in writing or earlier terminated as provided for in the agreement.

On July 29, 2013, the Company announced the regulatory approval of BEMA Fentanyl in Taiwan, where the product will be marketed under the brand name PAINKYL. The approval in Taiwan resulted in a milestone payment of $0.3 million to the Company, which was received in the third quarter 2013.

The Company received cumulative payments totaling $1.5, $1.2 million and $0.9, all which related to royalties based on product purchased in Taiwan by TTY of PAINKYL. Such amounts are recorded as contract revenue in the accompanying consolidated statement of operations for the years ended December 31, 2018, 2017 and 2016, respectively.

10. Notes payable:

On February 21, 2017, the Company entered into a term loan agreement (the "Term Loan Agreement") with CRG, as administrative agent and collateral agent, and the lenders named in the Term Loan Agreement (the "Lenders"). The Company utilized approximately $29.4 million of the initial loan proceeds under the Term Loan Agreement to repay all the amounts owed by the Company under the 2015 MidCap Credit Agreement. Upon the repayment of all amounts owed by the Company under the MidCap Credit Agreement, all commitments under the MidCap Credit Agreement were terminated and all security interests granted by the Company and its subsidiary guarantors under the MidCap Credit Agreement were released. Certain warrants issued to MidCap and its affiliates in May 2016 related to the extension of the interest only period under the MidCap Credit Agreement remain outstanding as of December 31, 2018 and will expire, if not earlier exercised in May 2021. Such warrants are exercisable for 84,986 shares of Common Stock at an exercise price of $3.53 per share. During the year ended December 31, 2017, $0.7 million of deferred loan costs arising out of the MidCap Credit Agreement were expensed and recorded as interest expense in the accompanying consolidated statement of operations.

Pursuant to the Term Loan Agreement, the Company borrowed $45.0 million from the Lenders as of the Closing Date, and was eligible to borrow up to an additional $15.0 million contingent upon achievement of certain conditions, including: (i) in the case of the first tranche, representing the second potential draw under the Loan Agreement (the "Second Draw"), satisfying both (a) certain minimum net revenue thresholds on or before September 30, 2017 or December 31, 2017 and (b) a certain minimum market capitalization threshold for a period of time prior to the funding of the Second Draw (provided, that if the Company does not achieve the minimum net revenue thresholds necessary for the Second Draw but does achieve a certain minimum market capitalization threshold for a period of time prior to December 31, 2017, the Company would be eligible for a Second Draw funding in the amount of $5.0 million). On December 26, 2017, the Company was eligible and elected to receive the Second Draw for gross proceeds of $15.0 million.

After the payoff of the MidCap Credit Agreement, the Company utilized the initial proceeds under the Term Loan Agreement (after deducting loan origination costs and broker and other fees) of approximately $13.7 million, plus any additional amounts borrowed in the future, for general corporate purposes and working capital. The original Term Loan Agreement had a six-year term with three years of interest-only payments, (from 2017-2019). On May 16, 2018, the Company entered into an amendment to its Term Loan Agreement with CRG. Pursuant to the amendment: (i) the interest only period of the Loan Agreement was extended by one year, and certain milestones previously required for the extended interest only period have been removed; (ii) the "PIK" period (under which a portion of the interest accrued under the Loan Agreement can be deferred to maturity) will also be extended for a year, (through 2020); (iii) amortization of the loan principal can be deferred until maturity (making the payment of the loan a "balloon" payment) if the Company achieves and maintains a market capitalization of $200 million prior to the conclusion of the interest only period (provided that if the Company achieves, and thereafter falls below a $200 million market capitalization, amortization of the loan principal will resume); and (iv) certain Company revenue targets, the failure of which would create an event of default under the loan, have been recalculated. Interest on the amounts borrowed under the Term Loan Agreement accrues at an annual fixed rate of 12.50%, 3.5% of which may be deferred during the interest-only period by adding such amount to the aggregate principal loan amount. On each borrowing date (including the Closing Date), the Company is required to pay CRG a financing fee based on the loan drawn on that date. The Company is also required to pay the Lenders a final payment fee equivalent to 9% of the original loan amount upon repayment of the loans in full, in addition to prepayment amounts described below.

The Company may prepay all or a portion of the outstanding principal and accrued unpaid interest under the Term Loan Agreement at any time upon prior notice to the Lenders subject to a certain prepayment fees during the first five years of the term (which fees are lowered over time) and no prepayment fee thereafter. In certain circumstances, including a change of

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10. Notes payable (continued):

control and certain asset sales or licensing transactions, the Company is required to prepay all or a portion of the loan, including the applicable prepayment premium on the amount of the outstanding principal to be prepaid.

As security for its obligations under the Term Loan Agreement, on the funding date of the initial borrowing, the Company and the Subsidiary Guarantors entered into a security agreement with CRG whereby the Company and the subsidiary guarantors of the Company under the Term Loan Agreement (the "Subsidiary Guarantors") granted to CRG, as collateral agent for the Lenders, a lien on substantially all of its assets including intellectual property (subject to certain exceptions). The Term Loan Agreement requires the Company to maintain minimum cash and cash equivalents balance and, each year through the end of 2022, to meet a minimum net annual revenue threshold. The Company is in compliance as of December 31, 2018. In the event that the Company does not meet the minimum net annual revenue threshold, then the Company can satisfy the requirement for that year by raising two (2) times the shortfall by way of raising equity or subordinated debt.

The Term Loan Agreement also contains customary affirmative and negative covenants for a credit facility of this size and type, including covenants that limit or restrict the Company's ability to, among other things (but subject in each case to negotiated exceptions), incur indebtedness, grant liens, merge or consolidate, dispose of assets, make investments, make acquisitions, enter into transactions with affiliates, pay dividends or make distributions, license intellectual property rights on an exclusive basis or repurchase stock.

The Term Loan Agreement includes customary events of default that include, among other things, non-payment, inaccuracy of representations and warranties, covenant breaches, a material adverse change (as defined in the Term Loan Agreement), cross default to material indebtedness or material agreements, bankruptcy and insolvency, material judgments and a change of control. The occurrence and continuance of an event of default could result in the acceleration of the obligations under the Term Loan Agreement. Under certain circumstances, a default interest rate of an additional 4.00% per annum will apply on all outstanding obligations during the existence of an event of default under the Term Loan Agreement.

The following table represents future maturities of the CRG obligation as of December 31, 2018:

2019	$ —
2020	—
2021	30,892
2022	30,892
Total maturities	$ 61,784
Unamortized discount and loan costs	(10,132)
Total notes payable obligation	$ 51,652

In connection with the initial borrowing made under the Term Loan Agreement, the Company issued to CRG and certain of its affiliates five separate warrants to purchase an aggregate of 1,701,583 shares of the Common Stock (the "CRG Warrants"). The CRG Warrants are exercisable any time prior to February 21, 2027 at a price of $2.38 per share, with typical provisions for cashless exercises. The exercise of the CRG Warrants could have a dilutive effect to the Common Stock to the extent that the market price per share of the Common Stock, as measured under the terms of the CRG Warrants, exceeds the exercise price of the CRG Warrants.

In connection with the Second Draw, the Company issued to CRG and certain of its affiliates warrants to purchase an aggregate of 349,452 shares of the Company's common stock (the "CRG Second Draw Warrants"). The CRG Second Draw Warrants are exercisable any time prior to December 26, 2027, at a price of $3.42 per share, with typical provisions for cashless exercise and stock-based anti-dilution protection. The exercise of the CRG Second Draw Warrants could have a dilutive effect to the Company's common stock to the extent that the market price per share of the Company's common stock, as measured under the terms of the CRG Second Draw Warrants, exceeds the exercise price of the CRG Warrants.

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11. Net sales by product:

The Company operates in a single industry engaging in the commercialization of pharmaceutical products principally in the areas of pain management and addiction. Accordingly, the Company's business is classified as a single reportable segment.

The following table presents net sales by product for each of the years ended December 31 (in thousands):

	Year ended December 31,		
	2018	2017	2016
BELBUCA	$45,988	$ 26,980	$ —
BUNAVAIL	5,422	7,942	8,266
Net product sales	$51,410	$ 34,922	$8,266

12. Income taxes:

On December 22, 2017, the United States enacted major tax reform legislation, Public Law No. 115-97, commonly referred to as the Tax Cuts and Jobs Act (or 2017 Tax Act). The 2017 Tax Act, among other changes, lowers the general corporate income tax rate to 21% for tax years beginning after December 31, 2017, transitions U.S. international taxation from a worldwide tax system to a territorial system, and provides for a one-time transition tax on the mandatory deemed repatriation of cumulative foreign earnings as of December 31, 2017, which is not applicable to the Company. The Company has calculated its impact of the 2017 Tax Act in its income tax provision during the year ended December 31, 2018, in accordance with its understanding of the 2017 Tax Act and guidance available as of the date of this filing.

The Company recorded federal income tax benefit during 2018 due to the impact of the 2018 Tax Cuts and Jobs Act. For years beginning after December 31, 2017, the Act repeals corporate AMT. The credit becomes refundable in an amount equal to 50% of the excess of the credit for the tax year over the amount of the credit allowable for the year against regular tax liability. The Company recorded state income tax expense of $0.05 million due to state audit findings related to prior periods. The Company has recognized valuation allowances for all deferred tax assets for years ending 2018 and 2017. Reconciliation of the Federal statutory income tax rate of 21% to the effective rate is as follows:

	2018	2017	2016
Federal statutory income (benefit) tax rate	21.00%	(34.00%)	34.00%
2017 Tax Act, net deferred tax remeasurement	—	(626.73)	—
State taxes, net of federal benefit	(0.11)	(2.01)	2.88
Stock compensation	(4.74)	(5.18)	(0.61)
Permanent differences-other	(1.33)	(13.39)	(1.00)
North Carolina tax rate change	—	(32.75)	—
Research and development ("R&D") credit	—	5.54	0.98
Valuation release for bargain purchase gain	—	(302.23)	—
Other	(2.07)	(1.36)	(0.47)
Decrease (increase) in valuation allowance	(12.65)	709.88	(35.78)
	0.10%	(302.23%)	0.00%

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12. Income taxes (continued):

The tax effects of temporary differences and net operating losses that give rise to significant components of deferred tax assets and liabilities consist of the following:

	December 31,	
Deferred tax assets (liabilities)	**2018**	**2017**
Deferred revenue	$ —	$ —
Basis difference in equipment	(459)	(587)
Basis difference in intangibles	(6,045)	(8,288)
Accrued liabilities and other	2,246	654
R&D credit	10,980	11,882
AMT credit	—	79
Stock options	4,360	6,115
Net operating loss carry-forward	64,376	61,660
	75,458	71,515
Less: valuation allowance	(75,458)	(71,515)
	$ —	$ —

The Company is required to reduce any deferred tax asset by a valuation allowance if, based on an assessment of positive and negative evidence, including estimates of future taxable income necessary to realize future deductible amounts, it is more likely than not (a likelihood of more than 50 percent) that some portion or all of the deferred tax assets will not be realized. The valuation allowance should be sufficient to reduce the deferred tax asset to the amount, which is more likely than not to be realized. As a result, the Company recorded a valuation allowance with respect to all of the Company's deferred tax assets.

The Company has a federal net operating loss carry forward ("NOLs") of approximately $279 million as of December 31, 2018. Under Section 382 and 383 of the Internal Revenue Code, if an ownership change occurs with respect to a "loss corporation", as defined, there are annual limitations on the amount of the NOLs and other deductions, which are available to the Company. The portion of the NOLs incurred prior to May 16, 2006 is subject to this limitation. As such, the use of these NOLs to offset taxable income is limited to approximately $1.5 million per year. The Company's State NOLS are approximately $264 million as of December 31, 2018. These loss carryforwards expire between 2024 and 2037 for federal NOL and 2030 for state NOL generated prior to December 31, 2017. The federal NOL generated in 2018 of $3.28 million will have an indefinite carryforward life due to tax reform. Management has evaluated all other tax positions that could have a significant effect on the financial statements and determined that the Company has no uncertain income tax positions at December 31, 2018.

One or more of the Company's legal entities file income tax returns in the U.S. federal jurisdiction and various U.S. state jurisdictions. The Company's income tax returns are subject to audit by the tax authorities in those jurisdictions. Significant disputes may arise with authorities involving issues of the timing and amount of deductions, the use of tax credits and allocations of income and expenses among various tax jurisdictions because of differing interpretations of tax laws, regulations and the interpretation of the relevant facts. The Company is no longer subject to U.S. federal or state tax examinations for years ended on or before December 31, 2014.

13. Stockholders' equity:

Common Stock

On August 23, 2017, the Company and Dr. Mark Sirgo entered into a retirement agreement (the "Sirgo Retirement Agreement"). Pursuant to the Sirgo Retirement Agreement, all unvested RSUs previously issued under the Company's equity incentive plans and held by Dr. Sirgo as of the retirement date were cancelled and, in lieu thereof, Dr. Sirgo was awarded a one-time issuance of shares of Common Stock based upon a net present valuation of the cancelled RSUs in January 2018 of 795,730 shares of Common Stock.

On January 12, 2018, the Company and Dr. Niraj Vasisht entered into a retirement agreement (the "Vasisht Retirement Agreement"). Pursuant to the Vasisht Retirement Agreement, all unvested RSUs previously issued under the Company's equity incentive plans and held by Dr. Vasisht as of the retirement date were cancelled and, in lieu thereof, Dr. Vasisht was awarded a one-time issuance of shares of Common Stock based upon a net present valuation of the cancelled RSUs in March and December 2018 of 309,162 and 65,000 shares of Common Stock, respectively.

The Compensation Committee of the Board of Directors approved in early 2018, equity awards for 2017 in the form of RSUs to its named executive officers (including Drs. Sirgo and Vasisht) and other senior executives. Dr. Sirgo, received 285,305 and Dr. Vasisht received 198,129, respectively, shares of Common Stock in fulfillment of the Company's contractual obligations. Such shares were issued in 2018.

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13. Stockholders' equity (continued):

On August 2, 2018, in connection with the Company's 2018 Annual Meeting of Stockholders, the Company's stockholders approved, among other matters, to amend the Company's Certificate of Incorporation to increase the number of authorized shares of Common Stock from 75,000,000 to 125,000,000.

On November 9, 2018, The Company filed a shelf registration statement (as amended on January 18, 2019) which registered up to $150 million of the Company's securities for potential future issuance and such registration statement was effective on February 7, 2019.

Preferred Stock and Series A Preferred

The Company had authorized five million "blank check" shares of $.001 par value convertible preferred stock. In the event of the Company's liquidation, dissolution or winding up, holders of the Series A Preferred will receive a payment equal to $.001 per share of Series A Preferred before any proceeds are distributed to the holders of common stock. After the payment of this preferential amount, and subject to the rights of holders of any class or series of capital stock hereafter created specifically ranking by its terms senior to the Series A Preferred, the holders of Series A Preferred will participate ratably in the distribution of any remaining assets with the common stock and any other class or series of our capital stock hereafter created that participates with the common stock in such distributions.

At December 31, 2018, 2,093,155 shares of Series A Preferred were outstanding and 2,285,700 shares of "blank check" preferred stock remain authorized but undesignated. There were no conversions of Series A Preferred during the years ended December 31, 2018, 2017 or 2016.

Series B Preferred stock financing

In May of 2018, the Company closed on the sale of an aggregate of 5,000 shares of the Company's authorized preferred stock that the Board of Directors of the Company has designated as Series B Non-Voting Convertible Preferred Stock, par value $0.001 per share (the "Series B Preferred Stock") at a purchase price of $10,000 per share.

Each share of Series B Preferred Stock is convertible into a number of shares of the Company's common stock at a conversion price of $1.80 per share (subject to adjustment for stock splits and stock dividends as provided in the Certificate of Designation). At the time of closing the then outstanding shares of Series B Preferred Stock were convertible into an aggregate 27,777,778 shares of Common Stock. The Series B Preferred Stock does not contain any price-based anti-dilution protection. The Series B Preferred Stock is convertible at any time at the option of the holder, subject to certain limitations related to beneficial ownership.

The Company has the right to deliver a notice to the holders of the Series B Preferred Stock to require conversion of the Series B Preferred Stock into Common Stock. Following an initial forced conversion of the Series B Preferred Stock, every ninety (90) days thereafter, the Company has the right to require the forced conversion of the still outstanding shares of Series B Preferred Stock, subject to certain limitations related to beneficial ownership.

During the year ended December 31, 2018, a cumulative total of 1,900 shares of Series B Preferred Stock from various holders were converted into 10,555,556 shares of Common Stock. As of December 31, 2018, 3,100 shares of Series B Preferred Stock are outstanding.

The Series B Preferred Stock issued in May 2018 contained a contingent beneficial conversion feature ("BCF") that was recognized during the year ending December 31, 2018 upon the August 2018 stockholder approval, which eliminated the contingency. The Company evaluated its convertible preferred stock in accordance with provisions of ASC 815, Derivatives and Hedging, including consideration of embedded derivatives requiring bifurcation. The issuance of the Series B Preferred Stock generated a BCF, which arises when a debt or equity security is issued with an embedded conversion option that is beneficial to the investor or in the money at inception because the conversion option has an effective strike price that is less than the market price of the underlying stock at the commitment date. As a result, the intrinsic value of the conversion option , totaling $12.5 million, was recorded as a reduction to additional paid-in capital, increasing net loss attributable to the Company Common stockholders.

Restricted stock units

During the year ended December 31, 2018, 2,034,261 RSUs, were granted to members of the Company's executive officers, board of directors, certain employees and retiring officers, with a fair market value of approximately $4.7 million. The fair value of restricted units is determined using quoted market prices of the Common Stock and the number of shares expected to vest.

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13. Stockholders' equity (continued):

These RSUs were issued under the Company's 2011 Equity Incentive Plan, as amended, and vest as following: (i) For executive officers, half of the grant vests in equal installments over three years and the remaining half vests subject to performance criteria over three years, (ii) for employees, the grants immediately vested in full October 2018, (iii) for the board of directors grants vest ratably from August 2018 to August 2022, and (iv) and for retiring officers, the grants vested immediately vested in full February and March 2018.

Restricted stock activity during the year ended December 31, 2018 was as follows:

	Number of Restricted Shares	Weighted Average Fair Market Value Per RSU
Outstanding at January 1, 2018	4,706,895	$ 5.20
Granted:		
Executive officers	1,183,750	2.25
Directors	469,261	2.59
Employees	381,250	2.28
Vested	(1,863,731)	2.57
Forfeitures	(591,398)	2.46
Conversions	(2,119,925)	2.72
Outstanding at December 31, 2018	2,166,102	$ 2.59

Performance Long Term Incentive Plan

In December 2012, the Company's Board of Directors (the "Board") approved the BDSI Performance Long Term Incentive Plan ("LTIP"). The LTIP is designed as an incentive for the Company's senior management to generate revenue for the Company. The LTIP consists of RSUs (which are referred to in this context as Performance RSUs) which are rights to acquire shares of Common Stock. All Performance RSUs granted under the LTIP will be granted under the Company's 2011 Equity Incentive Plan (as the same may be amended, supplemented or superseded from time to time) as "Performance Compensation Awards" under such plan. The participants in the LTIP are either named executive officers or senior officers of the Company.

The term of the LTIP began with the Company's fiscal year ended December 31, 2012 and lasts through the fiscal year ending December 31, 2019. The total number of Performance RSUs covered by the LTIP is 1,078,000, of which 978,000 were awarded in 2012 (with 100,000 Performance RSUs being reserved for future hires and of that reserve, 35,000 Performance RSUs were awarded in 2015). No additional Performance RSUs were awarded in 2017 or 2018. The Performance RSUs under the LTIP did not vest upon granting, but instead are subject to potential vesting each year over the 8-year term of the LTIP depending on the achievement of pre-defined revenue amounts by the Company, as reported in its Annual Report on Form 10-K. During the years ended December 31, 2018, 2017 and 2016, a total of 31,036, 9,958 and 13,347 RSUs vested, respectively, subject to performance criteria.

Stock options

The Company has a 2011 Equity Incentive Plan. During the 2017 Annual Meeting of Stockholders (the "Annual Meeting"), stockholders approved an amendment to the Company's 2011 Equity Incentive Plan to increase the number of shares of common stock authorized for issuance under the plan by 7,100,000 shares from 11,050,000 to 18,150,000.

An additional 523,854 shares of Common Stock underlying options previously granted under the Company's Amended and Restated 2001 Incentive Plan remain outstanding and exercisable as of December 31, 2018. The Company's Amended and

Restated 2001 Incentive Plan expired in July 2011 and no new securities may be issued thereunder. Options may be awarded during the ten-year term of the 2011 Equity Incentive Plan to Company employees, directors, consultants and other affiliates.

During the years ended December 31, 2018, 2017 and 2016, Company employees, directors and affiliates exercised approximately 0.4 million, 0.2 million and 0.1 million stock options, respectively, with net proceeds to the Company of approximately $0.7 million, 0.4 million and $0.3 million, respectively.

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13. Stockholders' equity (continued):

Stock option activity for the years ended December 31, 2018, 2017 and 2016 is as follows:

	Number of Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value
Outstanding at January 1, 2016	3,397,529	$ 5.42	$ 3,124
Granted in 2016:			
Officers and Directors	95,000	$ 2.34	
Others	558,373	3.12	
Exercised	(147,425)	2.01	
Forfeitures	(434,486)	13.17	
Outstanding at December 31, 2016	3,468,991	$ 4.14	$ 0
Granted in 2017:			
Officers and Directors	83,658	$ 2.64	
Others	873,017	1.96	
Exercised	(202,519)	2.17	
Forfeitures	(1,510,193)	5.13	
Outstanding at December 31, 2017	2,712,954	$ 2.98	$ 1,190
Granted in 2018:			
Officers and Directors	1,249,817	$ 2.49	
Others	1,299,360	2.60	
Exercised	(350,441)	2.00	
Forfeitures	(502,186)	3.48	
Outstanding at December 31, 2018	4,406,004	$ 3.19	$ 4,172

Options outstanding at December 31, 2018 are as follows:

Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value
$1.00 – 5.00	3,948,887	7.72	$ 2.70	
$5.01 – 10.00	387,361	4.78	$ 5.91	
$10.01 – 15.00	38,756	6.15	$ 13.09	
$15.01 – 20.00	31,000	6.00	$ 16.20	
	4,406,004			$ 4,172

Options exercisable at December 31, 2018 are as follows:

Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Aggregate Intrinsic Value
$1.00 – 5.00	1,196,693	4.07	$ 3.15	
$5.01 – 10.00	375,722	4.71	$ 6.10	
$10.01 – 15.00	38,756	6.15	$ 13.09	
$15.01 – 20.00	31,000	5.80	$ 16.20	
	1,642,171			$ 653

The weighted average grant date fair value of options granted during the years ended December 31, 2018, 2017 and 2016 was $1.57, $1.46 and $1.75, respectively. There were no options granted during the years ended December 31, 2018, 2017 or 2016 whose exercise price was lower than the estimated market price of the stock at the grant date.

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13. Stockholders' equity (continued):

Nonvested stock options as of December 31, 2018, and changes during the year then ended, are as follows:

Nonvested Shares	Shares	Weighted Average Grant Date Fair Value	Intrinsic Value
Nonvested at January 1, 2018	885,484		
Granted	2,549,177		
Vested	(209,500)		
Forfeited	(461,328)		
Nonvested at December 31, 2018	2,763,833	$ 1.54	$ 5,979

As of December 31, 2018, there was approximately $6.9 million of unrecognized compensation cost related to unvested share-based compensation awards granted. These costs will be expensed over the next four years.

Stock-based compensation

During the year ended December 31, 2018, a total of 2,549,177 options to purchase Common Stock, with an aggregate fair market value of approximately $3.9 million, were granted to Company employees and directors. The options granted have a term of 10 years from the grant date and vest ratably between a one and three-year period. The fair value of each option is amortized as compensation expense evenly through the vesting period.

Warrants:

The Company has granted warrants to purchase shares of Common Stock. Warrants may be granted to affiliates in connection with certain agreements.

During the year ended December 31, 2016, the Company granted warrants to purchase 84,986 shares of Common Stock at an exercise price of $3.53 per share to Midcap and its affiliates in connection with the Company's extension agreement with MidCap. The warrants were valued using the Black-Scholes Model, which fair value is approximately $0.05 million. As of December 31, 2018, 84,986 warrants remain outstanding.

In February 2017, the Company granted warrants to purchase 1,701,583 shares of Common Stock at an exercise price of $2.38 per share to CRG and certain of its affiliates in connection with the Company's term loan agreement with CRG. The warrants were valued using the Black-Scholes Model, which fair value is approximately $4.5 million.

In December 2017, the Company granted warrants to purchase 349,451 shares of Common Stock at an exercise price of $3.42 per share to CRG and certain of its affiliates in connection with the Company's 2nd tranche funding from its term loan agreement with CRG. The warrants were valued using the Black-Scholes Model, which fair value is approximately $1.5 million. As of December 31, 2018, a cumulative of 2,051,034 to CRG and affiliates remain outstanding.

14. Earnings per common share:

The following is a reconciliation of the numerators and denominators of the basic and diluted earnings per common share computations for the years ended December 31, 2018, 2017 and 2016.

	December 31,		
	2018	2017	2016
Basic:			
Net (loss) income	$ (33,867)	$ 5,285	$ (67,138)
Less deemed dividend related to beneficial conversion feature on Series B Preferred Stock	(12,500)	—	—
Net (loss) income attributable to common stockholders, basic	$ (46,367)	$ 5,285	$ (67,138)
Weighted average common shares outstanding	63,165,063	55,355,802	53,679,134
Basic (loss) income per common share	**$ (0.73)**	**$ 0.10**	**$ (1.25)**

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	December 31,		
	2018	2017	2016
Diluted:			
Effect of dilutive securities:			
Net (loss) income attributable to common stockholders, diluted	$ (46,367)	$ 5,285	$ (67,138)
Weighted average common shares outstanding	63,165,063	55,355,802	53,679,134
Effect of dilutive options and warrants	—	1,046,677	—
Diluted weighted average common shares outstanding	63,165,063	56,402,479	53,679,134
Diluted (loss) income per common share	**$ (0.73)**	**$ 0.09**	**$ (1.25)**

Basic earnings per common share is calculated using the weighted average shares of Common Stock outstanding during the period. Common equivalent shares from stock options, RSUs, warrants and convertible preferred stock using the treasury stock method, are also included in the diluted per share calculations unless the effect of inclusion would be antidilutive. During the years ended December 31, 2018, 2017 and 2016, outstanding stock options, RSUs, warrants and convertible preferred stock of 28,424,998, 6,531,346 and 10,228,929, respectively, were not included in the computation of diluted earnings per common share, because to do so would have had an antidilutive effect because the outstanding exercise prices were greater than the average market price of the common shares during the relevant periods. Included in the year ended December 31, 2018 are the Series B shares as converted to common stock.

The following is the total outstanding options, RSUs and warrants for the years ended December 31, 2018, 2017 and 2016, respectively.

	2018	2017	2016
Options, RSUs, warrants and convertible preferred stock to purchase Common Stock	10,739,378	9,555,869	10,228,929

15. Retirement plan:

The Company sponsors a defined contribution retirement plan under Section 401(k) of the Internal Revenue Code. The plan covers all employees who meet certain eligibility and participation requirements. Participants may contribute up to 90% of their eligible earnings, as limited by law. The Company makes a matching contribution equal to 100% on the first 5% of participant contributions to the plan. The Company made contributions of approximately $0.8 million, $0.5 million and $0.4 million in years, 2018, 2017 and 2016.

16. Separation agreement:

De Paolantonio separation agreement

On January 23, 2019, the Company entered into a Transitional Service and Separation Agreement (the "Separation Agreement") with Mr. De Paolantonio, the Company's former Chief Financial Officer and Treasurer. Unless Mr. De Paolantonio resigns or his employment is terminated earlier, Mr. De Paolantonio will continue as a senior advisor to the Company until April 30, 2019, at which time his employment with the Company will end (the "Retirement Date").

The Separation Agreement provides for, among other things, Mr. De Paolantonio to (i) continue to receive his current base salary, (ii) remain eligible to participate in the Company's group employee benefit plans as a regular full-time employee, and (iii) continue to vest in his outstanding equity awards until his Retirement Date. At the termination of his employment with the Company, provided that, among other things, Mr. De Paolantonio is not terminated by the Company for "cause," Mr. De Paolantonio will be entitled to receive (a) a one-time cash payment of $0.36 million, subject to applicable deductions and withholdings, representing one full year of his current base salary, provided that Mr. De Paolantonio has not breached any of his continuing obligations, including that he signs and does not revoke a general release of claims against the Company, (b) his target annual incentive compensation for 2018 (subject to determination by the board of directors of the Company), and (c) a monthly cash payment for three months in an amount equal to the actual costs of continuation of Mr. De Paolantonio's group health and dental insurance under the Consolidated Omnibus Reconciliation Act of 1985.

17. Commitments and contingencies:

Operating leases

Since November 2007, the Company has leased space for their corporate office. Lease expense for the corporate office was $0.3 million for each of the years ended December 31, 2018, 2017 and 2016, respectively. The Company leased new space for their corporate offices, which began March 2015 for 89 months.

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17. Commitments and contingencies (continued):

The future minimum commitment on the new operating lease at December 31, 2018 is as follows:

Years ending December 31,	
2019	$ 351
2020	360
2021	370
2022	219
	$1,300

Indemnifications

The Company's directors and officers are indemnified against costs and expenses related to stockholder and other claims (i.e., only actions taken in their capacity as officers and directors) that are not covered by the Company's directors' and officers' insurance policy. This indemnification is ongoing and does not include a limit on the maximum potential future payments, nor are there any recourse provisions or collateral that may offset the cost.

Post marketing requirements

On October 5, 2017, the Company entered a subsequent party acknowledgement relating to its participation in the Opioid PMR Consortium (the "OPC"). The participants are member companies, collectively undertaking various observational and clinical studies to satisfy certain post-marketing requirements by the FDA as holders of a NDA for extended-release and long-acting opioid analgesics. As a requirement of joining the OPC, the Company was required to pay its share of the previous expenses incurred and funded by the existing member companies. The Company's pro-rata share of such expenses totaled approximately $4.3 million, which was paid during the fourth quarter of 2017. Ongoing expenses will be shared equally by the member companies and paid monthly from 2019 through 2020.

Certain rights of CDC IV

The Company and CDC IV are parties to the CDLA pursuant to which CDC IV has previously provided funds to the Company for the development of the Company's ONSOLIS product. CDC IV is entitled to receive a mid-single digit royalty based on net sales of ONSOLIS, including minimum royalties of $375,000 per quarter beginning in the second full year following commercial launch. The royalty term expires upon the latter of expiration of the patent or generic entry into a particular country.

In September 2007, in connection with CDC IV's consent to the North American Mylan transaction, the Company, among other transactions with CDC IV, granted CDC IV a 1% royalty on net sales of the next BEMA product, which was BUNAVAIL. CDC IV's right to the royalty shall immediately terminate at any time if annual net sales of BUNAVAIL equal less than $7.5 million in any calendar year following the third anniversary of initial launch of the product and CDC IV receives $0.02 million in three (3) consecutive quarters as payment for CDC IV's one percent (1%) royalty during such calendar year.

The Company records such royalties as costs of sales occur.

In April 2016, CDC IV exercised its right pursuant to the Royalty Purchase and Amendment Agreement to exchange its royalty rights to the next BEMA product which was BUNAVAIL, in favor of royalty rights to the Substitute BEMA product which is BELBUCA (the CDC IV Option).

Indivior PLC (formerly RB Pharmaceuticals Ltd.) and Aquestive Therapeutics (formerly MonoSol Rx)

Litigation related to BUNAVAIL

Reckitt Benckiser, Inc., RB Pharmaceuticals Limited, and Aquestive (collectively, the RB Plaintiffs) (and the Company's commercial partner) relating to the Company's BUNAVAIL product in the United States District Court for the District of New Jersey for alleged patent infringement. The RB Plaintiffs claim that BUNAVAIL, whose formulation and manufacturing processes have never been disclosed publicly, infringes its patent U.S. Patent No. 8,765,167 (the '167 Patent. As with prior actions by the RB Plaintiffs, the Company believes this is another anticompetitive attempt by the RB Plaintiffs to distract our efforts from commercializing BUNAVAIL. The Company strongly refutes as without merit the RB Plaintiffs' assertion of

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18. Commitments and contingencies (continued):

patent infringement. On the Company's motion, this case was transferred to the Eastern District of North Carolina. A Joint Motion to Stay the case was granted and the case is now stayed until a final resolution of the '167 IPRs discussed directly below. The Company will continue to vigorously defend this case.

On October 28, 2014, the Company filed multiple IPR petitions on certain claims of the '167 Patent. The USPTO instituted three of the four IPR petitions. The PTAB upheld the claims and denied collateral estoppel applied to the PTAB decisions in March 2016. The Company appealed to Court of Appeals for the Federal Circuit. The USPTO intervened with respect to whether collateral estoppel applied to the PTAB. On June 19, 2018, the Company filed a motion to remand the case for further consideration by the PTAB in view of intervening authority. On July 31, 2018, the Federal Circuit vacated the decisions, and remanded the '167 Patent IPRs for further consideration on the merits.

Litigation related to BELBUCA

On January 13, 2017, Aquestive filed a complaint in the United States District Court for the District of New Jersey alleging BELBUCA infringes the '167 Patent. In lieu of answering the complaint, the Company filed motions to dismiss the complaint and, in the alternative, to transfer the case to the EDNC. On July 25, 2017, the New Jersey Court administratively terminated the case pending the parties submission of a joint stipulation of transfer because the District of New Jersey was an inappropriate venue. This case was later transferred to the Delaware District Court. On October 31, 2017 the Company filed motions to dismiss the complaint and, in the alternative, to transfer the case to the EDNC. On October 16, 2018, denying the motion to dismiss as moot, the Delaware District Court granted the Company's motion to transfer the case to the EDNC. The case is now pending in the EDNC. The Company strongly refutes as without merit Aquestive's assertion of patent infringement and will vigorously defend the lawsuit.

Teva Pharmaceuticals USA (formerly Actavis)

On February 8, 2016, the Company received a notice relating to a Paragraph IV certification from Teva Pharmaceuticals USA ("Teva") (formerly Actavis) seeking to find invalid three Orange Book listed patents relating specifically to BUNAVAIL. The Paragraph IV certification related to an Abbreviated New Drug Application (the "ANDA") filed by Teva with the U.S Food and Drug Administration ("FDA") for a generic formulation of BUNAVAIL. The patents subject to Teva's certification were U.S. Patent No. 7,579,019 (the "'019 Patent"), U.S. Patent No. 8,147,866 (the "'866 Patent") and 8,703,177 (the "'177 Patent").

On October 12, 2017, the Company announced that it had entered into a settlement agreement with Teva that resolved the Company's BUNAVAIL patent litigation against Teva pending in the U.S. District Court for the District of Delaware. As part of the Settlement Agreement, which is subject to review by the U.S. Federal Trade Commission and the U.S. Department of Justice, the Company had entered into a non-exclusive license agreement with Teva that permits Teva to first begin selling its generic version of BUNAVAIL in the U.S. on July 23, 2028 or earlier under certain circumstances. Other terms of the agreement are confidential.

The Company received notices regarding Paragraph IV certifications from Teva on November 8, 2016, November 10, 2016, and December 22, 2016, seeking to find invalid two Orange Book listed patents relating specifically to BELBUCA. The Paragraph IV certifications relate to three ANDAs filed by Teva with the FDA for a generic formulation of BELBUCA. The patents subject to Teva's certification were the '019 Patent and the '866 Patent. The Company filed complaints in Delaware against Teva on December 22, 2016 and February 3, 2017 in which the Company asserted against Teva the '019 Patent and the '866 Patent. Teva did not contest infringement of the claims of the '019 Patent and did not contest infringement of the claims of the '866 Patent.

In February 2018, the Company announced that it had entered into a settlement agreement with Teva that resolved the Company's BELBUCA patent litigation against Teva pending in the U.S. District Court for the District of Delaware. As part of the settlement agreement, which is subject to review by the U.S. Federal Trade Commission and the U.S. Department of Justice, the Company had granted Teva a non-exclusive license (for which the Company will receive no current or future payments) that permits Teva to first begin selling the generic version of the Company's BELBUCA product in the U.S. on January 23, 2027 or earlier under certain circumstances (including, for example, upon (i) the delisting of the patents-in-suit from the U.S. FDA Orange Book, (ii) the granting of a license by the Company to a third party to launch another generic form of BELBUCA at a date prior to January 23, 2027, or (iii) the occurrence of certain conditions regarding BELBUCA market share). Other terms of the Agreement are confidential.

Alvogen

On September 7, 2018, the Company filed a complaint for patent infringement in Delaware against Alvogen Pb Research & Development LLC, Alvogen Malta Operations Ltd., Alvogen Pine Brook LLC, Alvogen, Incorporated, and Alvogen Group,

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18. Commitments and contingencies (continued):

Incorporated (collectively, "Alvogen"), asserting that Alvogen infringes the Company's Orange Book listed patents for BELBUCA, including U.S. Patent Nos. 8,147,866 and 9,655,843, both expiring in July of 2027, and U.S. Patent No. 9,901,539, expiring in December of 2032. This complaint follows receipt by the Company on July 30, 2018 of a Paragraph IV Patent Certification from Alvogen stating that Alvogen had filed an ANDA with the FDA for a generic version of BELBUCA Buccal Film (75 mcg, 150 mcg, 300 mcg, 450 mcg, 600 mcg, 750 mcg and 900 mcg). Because the Company initiated a patent infringement suit to defend the patents identified in the Paragraph IV notice within 45 days after receipt of the Paragraph IV Certification, the FDA is prevented from approving the ANDA until the earlier of 30 months or a decision in the case that each of the patents is not infringed or invalid. Alvogen's notice letter also does not provide any information on the timing or approval status of its ANDA.

In its Paragraph IV Certification, Alvogen does not contest infringement of at least several independent claims of each of the '866, '843, and '539 patents. Rather, Alvogen advances only invalidly arguments for these independent claims. The Company believes that it will be able to prevail on the Company's claims of infringement of these patents, particularly as Alvogen does not contest infringement of certain claims of each patent. Additionally, as the Company has done in the past, it intends to vigorously defend its intellectual property against assertions of invalidity. Each of the three patents carry a presumption of validity, which can only be overcome by clear and convincing evidence.

2018 Arkansas Opioid Litigation

On March 15, 2018, the State of Arkansas, and certain counties and cities in that State, filed an action in the Circuit Court of Arkansas, Crittenden County against multiple manufacturers, distributors, retailers, and prescribers of opioid analgesics, including our Company. The Company was served with the complaint on April 27, 2018. The complaint specifically alleged that

the Company licensed its branded fentanyl buccal soluble film ONSOLIS to Collegium, and Collegium is also named as a defendant in the lawsuit. ONSOLIS is not presently sold in the United States and the license agreement with Collegium was terminated prior to Collegium launching ONSOLIS in the United States. Therefore, on June 28, 2018, the Company moved to dismiss the case against it and most recently, on July 6, 2018, the plaintiffs filed a notice to voluntarily dismiss the Company from the Arkansas case, without prejudice.

Chemo Research, S.L

On March 1, 2019, the Company filed a complaint for patent infringement in Delaware against Chemo Research, S.L., Insud Pharma S.L., IntelGenx Corp., and IntelGenx Technologies Corp. (collectively, "Defendants"), asserting that the Defendants infringe its Orange Book listed patents for BELBUCA, including U.S. Patent Nos. 8,147,866 and 9,655,843, both expiring in July of 2027, and U.S. Patent No. 9,901,539 expiring December of 2032. This complaint follows a receipt by the Company on January 31, 2019, of a Notice Letter from Chemo Research S.L. stating that it has filed with the FDA an ANDA containing a Paragraph IV Patent Certification, for a generic version of BELBUA Buccal Film in strengths 75 mcg, 150 mcg, 300 mcg, 450 mcg, and 900 mcg. Because the Company initiated a patent infringement suit to defend the patents identified in the Notice Letter within 45 days after receipt, the FDA is prevented from approving the ANDA until the earlier of 30 months or a decision in the case that each of the patents is not infringed or invalid. Chemo Research S.L.'s Notice Letter also does not provide any information on the timing or approval status of its ANDA.

The Company believes that it will be able to prevail in this lawsuit. As it has done in the past, the Company intends to vigorously defend its intellectual property against assertions of invalidity.

18. Subsequent events:

On January 15, 2019, the Company announced the appointment of Terry Coelho as Chief Financial Officer. Ms. Coelho will also serve as the Company's principal financial officer and principal accounting officer. Ms. Coelho replaced Ernest De Paolantonio in these positions effective as of January 15, 2019. Mr. De Paolantonio will remain at the Company past such date in order to allow for an orderly transition.

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(U.S. DOLLARS IN THOUSANDS)

SELECTED QUARTERLY RESULTS (UNAUDITED)

The following table sets forth certain quarterly financial data for the periods indicated (in thousands, except per share data):

	Quarter Ended			
	March 31, 2018	June 30, 2018	September 30, 2018	December 31, 2018
Revenue	$ 11,281	$12,175	$ 14,156	$ 18,028
Gross profit	7,866	7,609	10,377	14,005
Loss from operations	(8,123)	(7,266)	(3,811)	(4,448)
Net loss	(10,709)	(9,770)	(18,880)	(7,008)
Basic loss per share	(0.18)	(0.16)	(0.29)	(0.13)
Diluted loss per share	(0.18)	(016)	(0.29)	(0.13)

	Quarter Ended			
	March 31, 2017	June 30, 2017	September 30, 2017	December 31, 2017
Revenue	$ 29,478	$ 8,744	$ 11,253	$ 12,510
Gross profit	23,833	4,573	6,808	7,275
Income (loss) from operations	7,903	(12,987)	(10,045)	(14,291)
Net income (loss)	48,325	(14,879)	(11,951)	(16,210)
Basic income (loss) per share	0.89	(0.27)	(0.21)	(0.31)
Diluted income (loss) per share	0.87	(0.27)	(0.21)	(0.30)

	Quarter Ended			
	March 31, 2016	June 30, 2016	September 30, 2016	December 31, 2016
Revenue	$ 3,040	$ 5,004	$ 3,571	$ 3,931
Gross profit	490	910	1,257	1,631
Loss from operations	(17,942)	(15,594)	(15,199)	(15,200)
Net loss	(18,733)	(16,486)	(15,977)	(15,942)
Basic loss per share	(0.35)	(0.31)	(0.30)	(0.29)
Diluted loss per share	(0.35)	(0.31)	(0.30)	(0.29)

BIODELIVERY SCIENCES INTERNATIONAL, INC. AND SUBSIDIARIES

SCHEDULE II – VALUATION AND QUALIFYING ACCOUNTS AND RESERVES

Description	Balance at beginning of the period	Charged to income	Charged to other accounts	Deductions	Balance at the end of the period
			(In thousands)		
Valuation allowance for deferred tax assets					
Year ended December 31, 2018:	$ 71,515	$ 3,943	$ —	$ —	$ 75,458
Year ended December 31, 2017:	$ 109,030	$(37,515)	$ —	$ —	$ 71,515
Year ended December 31, 2016:	$ 84,960	$ 24,070	$ —	$ —	$109,030
Allowance for rebates					
Year ended December 31, 2018:	$ 5,648	$ 37,071	$ 813	$ (31,270)	$ 12,261
Year ended December 31, 2017:	$ 3,842	$ 17,236	$ (132)	$ (15,298)	$ 5,648
Year ended December 31, 2016:	$ 4,470	$ (1,204)	$ 11,501	$ (10,925)	$ 3,842
Allowance for price adjustments and chargebacks					
Year ended December 31, 2018:	$ 3,925	$ 13,033	$ —	$ (12,940)	$ 4,018
Year ended December 31, 2017:	$ 602	$ 6,738	$ (3)	$ (3,412)	$ 3,925
Year ended December 31, 2016:	$ 383	$ 36	$ 1,711	$ (1,528)	$ 602
Allowance for inventory obsolescence					
Year ended December 31, 2018:	$ 243	$ (56)	$ —	$ —	$ 187
Year ended December 31, 2017:	$ —	$ 243	$ —	$ —	$ 243
Year ended December 31, 2016:	$ —	$ —	$ —	$ —	$ —

SIGNATURES

In accordance with Section 13 or 15(d) of the Exchange Act, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

BIODELIVERY SCIENCES INTERNATIONAL, INC.

Date: March 14, 2019

By: /S/ HERM CUKIER
Name: **Herm Cukier**
Title: **Chief Executive Officer and Director**
(Principal Executive Officer)

By: /S/ MARY THERESA COELHO
Name: **Mary Theresa Coelho**
Title: **Chief Financial Officer**
(Principal Financial Officer and Principal Accounting Officer)

In accordance with the Exchange Act, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Person	Capacity	Date
/S/ PETER S. GREENLEAF Peter S. Greenleaf	Chairman of the Board	March 14, 2019
/S/ MARK A. SIRGO **Mark A. Sirgo**	Vice Chairman	March 14, 2019
/S/ HERM CUKIER **Herm Cukier**	Chief Executive Officer and Director	March 14, 2019
/S/ FRANK E. O'DONNELL, JR. **Francis E. O'Donnell, Jr.**	Director	March 14, 2019
/S/ WILLIAM M. WATSON **William M. Watson**	Director	March 14, 2019
/S/ TODD C. DAVIS **Todd C. Davis**	Director	March 14, 2019
/S/ KEVIN KOTLER **Kevin Kotler**	Director	March 14, 2019

EXHIBIT 10.59

October 25, 2018

James Vollins
105 Lake Ridge Place
Chapel Hill, NC 27516

Re: Offer of Employment *Revised Start Date to November 5, 2018 (V2)*
Section 16 Officer, Title Change & Annual Bonus Target 40% (V3)

BioDelivery Sciences International, Inc. (BDSI) is pleased to extend to you a conditional offer of employment as General Counsel, Chief Compliance Officer & Corporate Secretary, reporting to me, CEO. Please note that this offer is subject to you satisfying our criteria in a pre-employment background and reference check. In this role it is anticipated that you will be responsible for the following:

- You will be a member of BDSI's management team and will be expected to play a full part in the strategic leadership of the company.
- As a Section 16 officer, you will serve as the legal advisor to the CEO and to the board of directors.
- You will serve as the Corporate Secretary to the board of directors which will include taking minutes at meetings, maintaining documentation and review of pertinent organizational documents.
- You will provide counsel on all major legal and compliance initiatives including advising on all corporate and commercial transactions (including mergers, acquisitions, joint ventures and other strategic alliances), litigation, employment matters, BDSI's patent, trademark and other intellectual property portfolio including overseeing strategic IP guidance for BDSI's global business, manufacturing operations and research and development centers.
- You will be responsible for developing and operationalizing a proactive and integrated compliance function and will implement, monitor and manage programs and internal controls to comply with applicable legal and regulatory standards to ensure that BDSI develops and consistently maintains an effective, best-in-class compliance program.

This position will be based in the Raleigh, NC office, provided you will be required to travel as needed to perform the role.

Your starting date will be November 5, 2018, unless another date it agreed to by you and the CEO. You will be paid an initial annual base salary at the rate of $310,000 per year (equivalent to $11,923.08 payable bi-weekly). You will be entitled to a one-time starting bonus of $35,000, payable on the first regular payroll date for executives after the start date.

You will also be awarded stock options that equate to one (1) times your starting annual base salary in value. The strike price of these options will be based on the 30-day VWAP preceding your start date. The options will vest annually in 1/3 increments over 3 years, beginning on the one-year anniversary of your start date.

Your annual bonus target will be 40% of annual base salary, provided the actual bonus amount will be in the discretion of the CEO. You must be employed on the date a bonus is paid to earn any part of a bonus.
Annual adjustments to salary, as well as bonus and additional stock option awards or RSUs are at the discretion of the CEO and/or BDSI's Board of Directors.

BioDelivery Sciences International, Inc.
4131 ParkLake Avenue, Suite 225
Raleigh, NC 27612
Tel 919 582 9050 • www.bdsi.com

You will also be eligible to accrue 4 weeks paid vacation according to BDSI's Vacation Policy in addition to 11 company-paid holidays each year. Additionally, as a regular, full-time employee, you would be entitled to six paid sick days due to illness in accordance with BDSI's Sick Leave Policy. The Company's time off policies may be modified from time to time.

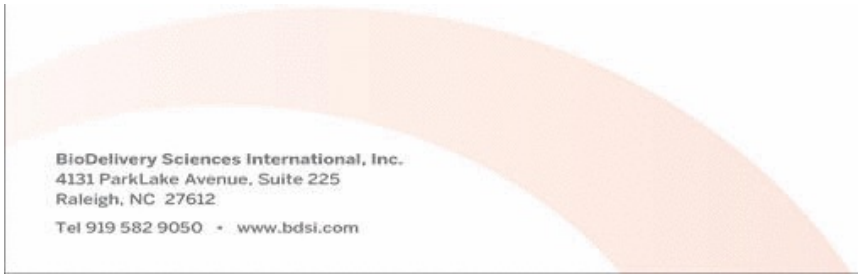
You will be eligible to participate in the following benefits, in accordance with our policies as they may change from time to time, and after meeting the applicable eligibility requirement of 30 days of continued employment (Insurance benefits begin on the 1st of the month):

- Health insurance
- Dental Insurance
- Basic Life & Accidental Death & Dismemberment Insurance
- Long and Short-Term Disability Insurance
- 401(k) Plan (after 60 days) with up to 5% Employer match
- Employee Stock Options Plan

Your employment with BDSI will be "at will", which means you or BDSI may end the employment relationship at any time and with or without notice. However, if BDSI terminates your employment other than for "Cause" (as defined below) or if your employment terminates as a result of your death or permanent disability, provided you (and/or your beneficiaries) enter into a release agreement in a form provided by the Company at the time of such termination (a "Release"), BDSI will pay you a one-time cash severance payment equal to 100% of annual base salary if the date of termination occurs after you have been continuously employed for greater then one (1) year. As used herein, the term "Cause" means (i) a material breach or material default (including, without limitation, any material dereliction of duty) by you of any agreement between you and BDSI or your continuing failure to follow the direction of BDSI's Chief Executive Officer or BDSI's Board of Directors; (ii) your gross negligence, willful misfeasance or breach of fiduciary duty; (iii) your commission of an act of fraud, embezzlement or any felony or crime of dishonesty in connection with your duties with BDSI; or (iv) your conviction of a felony or any other crime that would materially and adversely affect: (a) BDSI's business reputation, or (b) the performance of your duties for BDSI. In the event of a termination of your employment for Cause, BDSI will pay your salary and expenses reimbursable incurred through the date of termination, and thereafter BDSI shall have no further responsibility for termination or other payments to you.

In addition, if your employment with BDSI is terminated by BDSI or its successor without Cause within six (6) months following the occurrence of a "Change of Control" (as defined below) (a "CIC Severance

Triggering Event"), then, in lieu of the Severance Payment: (i) you will be entitled to a one-time cash severance payment equal to your then current annual base salary; (ii) you shall maintain any rights that you may have been specifically granted pursuant to any of BDSI's or its successor's retirement plans, supplementary retirement plans, profit sharing and savings plans, healthcare, 401(k) and any other employee benefit plans sponsored by BDSI or its successor; and (iii) all unvested time-based options, RSUs or other equity securities to acquire shares of BDSI common stock granted to you under BDSI's 2011 Equity Incentive Plan or any similar plan (the "Plan") shall immediately become fully vested and shall be exercisable to the extent provided for in the Plan (collectively the "Change in Control Benefits"). Following BDSI or its successor's compliance with clauses (i), (ii) and (iii) above, BDSI or its successor shall have no



further obligations to you following termination. In addition, as a condition to the Change in Control Benefits you must enter into a Release. All such payments shall comply with Section 409A of the Internal Revenue Code of 1986, as amended, and all regulations promulgated thereunder.

For purposes of the foregoing, the term "Change of Control" means the occurrence of any one or more of the following events (it being agreed that, with respect to paragraphs (i) and (iii) of this definition below, a '(Change of Control" shall not be deemed to have occurred if the applicable third party acquiring party is an "affiliate" of BDSI within the meaning of Rule 405 promulgated under the Securities Act of 1933, as amended): (i) an acquisition (whether directly from BDSI or otherwise) of any voting securities of BDSI (the "Voting Securities") by any "Person" (as the term person is used for purposes of Section 13(d) or 14(d) of the Securities and Exchange Act of 1934, as amended (the "1934 Act")), immediately after which such Person has "Beneficial Ownership" (within the meaning of Rule 13d-3 promulgated under the 1934 Act) of forty percent (40%) or more of the combined voting power of the BDSl's then outstanding Voting Securities; (ii) the individuals who, as of the date hereof, are members of BDSl's Board of Directors cease, by reason of a financing, merger, combination, acquisition, takeover or other non-ordinary course transaction affecting BDSI, to constitute at least fifty-one percent (51%) of the members of BDSl's Board of Directors; or (iii) the consummation of: (A) a merger, consolidation or reorganization involving BDSI, where either or both of the events described in clauses (i) or (ii) above would be the result; (B) a liquidation or dissolution of or appointment of a receiver, rehabilitator, conservator or similar person for, or the filing by a third party of an involuntary bankruptcy against, BDSI; or (C) an agreement for the sale or other disposition of all or substantially all of the assets of BDSI to any Person (other than a transfer to a subsidiary of BDSI).

All forms of compensation referred to in this Agreement are subject to reduction to reflect applicable withholding and payroll taxes and other deductions required by law. You hereby acknowledge that the Company does not have a duty to design its compensation policies in a manner that minimizes your tax liabilities, and you will not make any claim against the Company or its board of directors related to tax liabilities arising from your compensation. Anything in this Agreement to the contrary notwithstanding, if at the time of your separation from service within the meaning of Section 409A of the Code, the Company determines that you are a "specified employee" within the meaning of Section 409A(a)(2)(B)(i) of the Code, then to the extent any payment or benefit that you becomes entitled to under this Agreement on account of your separation from service would be considered deferred compensation subject to the 20% additional tax imposed pursuant to Section 409A(a) of the Code as a result of the application of Section 409A(a)(2)(B)(i) of the Code, such payment shall not be payable and such benefit shall not be provided until the date that is the earlier of (A) six months and one day after your separation from service, or (B) your death. If any such delayed cash payment is otherwise payable on an installment basis, the first payment shall include a catch-up payment covering amounts that would otherwise have been paid during the six-month period but for the application of this provision, and the balance of the installments shall be payable in accordance with their original schedule. All in-kind benefits provided and expenses eligible for reimbursement under this Agreement shall be provided by the Company or incurred by you during the time periods set forth in this Agreement. All reimbursements shall be paid as soon as administratively practicable, but in no event shall any reimbursement be paid after the last day of the taxable year following the taxable year in which the expense was incurred. The amount of in-kind benefits provided or reimbursable expenses incurred in one taxable year shall not affect the in-kind benefits to be provided or the expenses eligible for reimbursement in any other taxable year. Such right to reimbursement or in-

kind benefits is not subject to liquidation or exchange for another benefit. To the extent that any payment or benefit described in this Agreement constitutes "non-qualified deferred compensation" under Section 409A of the Code, and to the extent that such payment or benefit is payable upon your termination of employment, then such payments or benefits shall be payable only upon your "separation from service." The determination of whether and when a separation from service has occurred shall be made in accordance with the presumptions set forth in Treasury Regulation Section 1.409A-1(h). The Company and you intend that this Agreement will be administered in accordance with Section 409A of the Code. To the extent that any provision of this Agreement is ambiguous as to its compliance with Section 409A of the Code, the provision shall be read in such a manner so that all payments hereunder comply with Section 409A of the Code. The Company makes no representation or warranty and shall have no liability to you or any other person if any provisions of this Agreement are determined to constitute deferred compensation subject to Section 409A of the Code but do not satisfy an exemption from, or the conditions of, such Section.

Please note that this offer is contingent upon:

(i) Confirmation of employee-provided information regarding prior work history, education, personal and professional references. A formal background investigation will be undertaken; employment is contingent pending the validation of satisfactory results by the investigating agency; and

(ii) Approval by the Compensation Committee of BDSI's Board of Directors of the compensation terms of this letter;

(iii) Execution and delivery to BDSI of agreements concerning Confidentiality, Intellectual Property and Non-Competition Agreements, the terms of which are incorporated herein; and

(iv) Review and acknowledgement of BDSI Code of Ethics and Insider Training Policy; and

(v) Compliance with requirements of the Immigration Reform and Control Act. (Completion of I-9 form and copies of appropriate documents must be provided on your first day of employment).

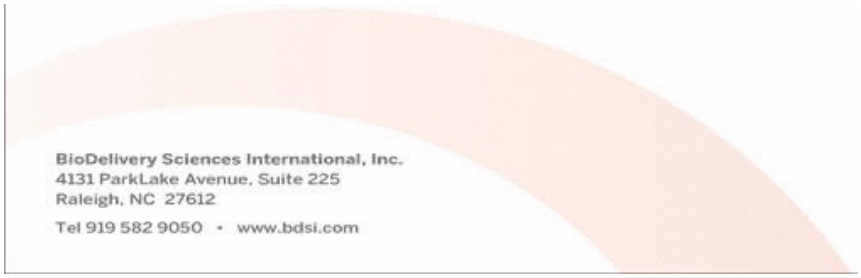
This Offer Letter contains all of the terms of your employment with the Company and supersedes any prior agreements, representations or understandings (whether written, oral or implied) between you and the Company. If the above terms are acceptable, please contact me at your earliest convenience regarding acceptance of our contingent offer of employment. To formally accept this offer, please sign in the appropriate place below and return an executed copy of this letter to me. Please retain an executed copy of this letter for your own records.

We are excited about the future of BDSI and your contribution to our success. I look forward to hearing from you regarding this offer.

Regards,

/s/ Herm Cukier

Herm Cukier
Chief Executive Officer
BioDelivery Sciences International, Inc.



[Signature Page Follows]

(V3) Offer Letter of Employment Acknowledged and agreed as of the date set forth below:

/s/ James Vollins
James Vollins

October 25, 2018
Date

BioDelivery Sciences International, Inc.
4131 ParkLake Avenue, Suite 225
Raleigh, NC 27612
Tel 919 582 9050 • www.bdsi.com

EXHIBIT 10.60

January 10, 2019

Terry Coelho
8904 Woodhall Lake Drive Waxhaw, NC 28173

Re: Offer of Employment

Dear Terry,

BioDelivery Sciences International, Inc. (BDSI) is pleased to extend to you a conditional offer of employment as Chief Financial Officer, reporting to me, CEO. Please note that this offer is subject to you satisfying our criteria in a pre-employment background and reference checks. In this role it is anticipated that you will be responsible for the following:

- Overseeing the global financial strategy and financial organization of this independent NASDAQ-listed corporation by working with senior executives and the Board of Directors to establish financial and strategic goals for the company, and financial and investing strategies to meet specific business objectives in addition to legal, regulatory, and securities reporting requirements.
- Serve as a strategic business partner to the CEO, Board and BDSI management team, and will maintain responsibility for all corporate financial functions, including treasury, financial operations and audit, risk management, tax and investor relations.
- Play a key role in the development and execution of BDSI corporate strategy, including participation in closing key partnership deals.
- Comply with all legal and reporting obligations of a public corporation and will help BDSI maintain the highest level of ethics, profitability, financial strength, and operating efficiency as we develop our current pipeline and lay the groundwork for further corporate development.
- This position will be based in the Raleigh, NC office, provided you will be required to travel as needed to perform the role.

Your starting date will be January 15, 2019, unless another date it agreed to by you and the CEO. You will be paid an initial annual base salary at the rate of $385,000.00 per year (equivalent to $14,807.70 payable bi-weekly). You shall be eligible to earn annual merit increases in base salary based upon your performance and subject to the same considerations and conditions as other C-suite level employees reporting directly to the CEO in the discretion of the Board.

You will also be awarded stock options with a value equated to $400,000.00 and 55,000 restricted stock units (RSUs) and the stock options strike price will be based on the 30-day VWAP preceding your start date. The options and RSUs will vest annually in 1/3 increments over 3 years, beginning on the one-year anniversary of your start date. You shall be eligible to earn and receive future annual stock grants upon the same considerations and conditions as other C-suite level executives reporting to the CEO.

Your annual bonus target will be 45% of annual base salary and determined on the basis of fulfillment of personal and management objectives set in the discretion of the CEO and after prior consultation with yourself, provided the actual bonus amount will be in the discretion of the CEO. You must be employed on the date a bonus is paid to earn any part of a bonus. Any annual bonus your earn and become entitled to receive under the bonus plan shall be paid on the same date such bonus is paid to other C-suite level executives who have earned a bonus. For 2019, you shall be eligible for an annual bonus as if you were employed by the Company on January 1, 2019, provided that you actually commence employment on or before January 15, 2019.

Annual adjustments to salary, as well as bonus and additional stock option awards or RSUs are at the discretion of the CEO and/or BDSI's Board of Directors.

You will also be eligible to accrue 4 weeks paid vacation according to BDSI's Vacation Policy in addition to 11 company-paid holidays each year. Additionally, as a regular, full-time employee, you will receive six paid sick days due to illness in accordance with BDSI's Sick Leave Policy. The Company's time off policies may be modified from time to time. Upon separation, you shall be entitled to payment for any accrued and unused paid vacation according to NC law.

You will be eligible to participate in the following benefits that begin upon your hire date, in accordance with our policies as they may change from time to time.

- Health Insurance
- Dental Insurance
- Basic Life & Accidental Death & Dismemberment Insurance
- Long and Short-Term Disability Insurance
- 401(k) Plan (after 60 days) with up to 5% Employer match
- Employee Stock Options Plan

Your employment with BDSI will be "at will", which means you or BDSI may end the employment relationship at any time. Except in the event of a termination of your employment by the Company for "Cause" (as defined below), you and the Company agree to provide the other party with a minimum of (30) days advance written notice of any other termination of employment.

If BDSI terminates your employment other than for "Cause", if your employment terminates as a result of your death or permanent disability, or by your for "Good Reason" and you comply with the terms stated below, provided you (and/or your beneficiaries) enter into a release agreement in a form provided by the Company at the time of such termination (a "Release"), BDSI will pay you a one-time cash severance payment equal to 100% of annual base salary plus the pro-rata share of any earned annual bonus. As used herein, the term "Cause" means (i) a material breach or material default (including, without limitation, any material dereliction of duty) by you of any agreement between you and BDSI or your continuing failure to follow any valid and legal direction of BDSI's Chief Executive Officer or BDSI's Board of Directors; (ii) your gross negligence, willful misfeasance or breach of fiduciary duty; (iii) your commission of an act of fraud, embezzlement or any felony or crime of dishonesty in connection with your duties with BDSI; or (iv) your conviction of a felony or any other crime that would materially and adversely affect: (a) BDSI's business reputation, or (b) the performance of your duties for BDSI. In the event of a termination of your employment for Cause, BDSI will pay your salary and expenses reimbursable incurred through the date of termination, and thereafter BDSI shall have no further responsibility for termination or other payments to you.

For purposes of this Agreement, "Good Reason" shall mean the occurrence of any of the following in each case during the Term without your consent: (i) a reduction in your Base Salary; (ii) a reduction in in your annual target bonus opportunity; (iii) a relocation of your principal place of employment by more than thirty-five (35) miles; (iv) any material breach by the Company of any material provision of this Agreement or of any other agreement between the Company and you, including any representation, warranties or covenants set forth herein; (v) the Company's failure to obtain an agreement from any successor to the Company following a Change of Control to assume and agree to perform this Agreement in the same manner and to the same extent that the Company would be required to perform if no succession had taken place, except where such assumption occurs by operation of law; (vi) a material, adverse change in your authority, duties, or responsibilities (other than temporarily while you are physically or mentally incapacitated or as required by applicable law).

You shall not terminate your employment for Good Reason unless you have first provided written notice to the Company of the existence of the circumstances providing grounds for termination for Good Reason within sixty (60) days of the date Executive learns of the initial existence of such grounds and the Company has had at least thirty (30) days from the date on which such notice is provided to cure such circumstances. If you do not terminate your employment for Good Reason within ninety (90) days after the date Executive learns of the first occurrence of the applicable grounds, then Executive will be deemed to have waived her right to terminate for Good Reason with respect to such grounds.

In addition, if your employment with BDSI is terminated by BDSI or its successor without Cause within twelve (12) months following the occurrence of a "Change of Control" (as defined below) (a "CIC Severance Triggering Event"), then, in lieu of the Severance Payment: (i) you will be entitled to a one-time cash separation payment equal to 150% of your then current annual base salary and a one-time cash payment of 100% of you annual bonus target; (ii) you shall maintain any rights that you may have been specifically granted pursuant to any of BDSI's or its successor's retirement plans, supplementary retirement plans, profit sharing and savings plans, healthcare, 401(k) and any other employee benefit plans sponsored by BDSI or its successor; and (iii) all unvested time-based options, RSUs or other equity securities to acquire shares of BDSI common stock granted to you under BDSI's 2011 Equity Incentive Plan or any similar plan (the "Plan") shall immediately become fully vested and shall be exercisable to the extent provided for in the Plan (collectively the "Change in Control Benefits"). Following BDSI or its successor's compliance with clauses (i), (ii) and (iii) above, BDSI or its successor shall have no further obligations to you following termination. In addition, as a condition to the Change in Control Benefits you must enter into a Release. All such payments shall comply with Section 409A of the Internal Revenue Code of 1986, as amended, and all regulations promulgated thereunder.

For purposes of the foregoing, the term "Change of Control" means the occurrence of any one or more of the following events (it being agreed that, with respect to paragraphs (i) and (iii) of this definition below, a '(Change of Control" shall not be deemed to have occurred if the applicable third party acquiring party is an "affiliate" of BDSI within the meaning of Rule 405 promulgated under the Securities Act of 1933, as amended): (i) an acquisition (whether directly from BDSI or otherwise) of any voting securities of BDSI (the "Voting Securities") by any "Person" (as the term person is used for purposes of Section 13(d) or 14(d) of the Securities and Exchange Act of 1934, as amended (the "1934 Act")), immediately after which such Person has "Beneficial Ownership" (within the meaning of Rule 13d-3 promulgated under the 1934 Act) of fifty percent (50%) or more of the combined voting power of the BDSI's then outstanding Voting Securities; (ii) the individuals who, as of the date hereof, are members of BDSI's Board of Directors cease, by reason of a financing, merger, combination, acquisition, takeover or other non-ordinary course transaction affecting BDSI, to constitute at least fifty-one percent (51%) of the members of BDSI's Board of Directors; or (iii) the consummation of: (A) a merger, consolidation or reorganization involving BDSI, where either or both of the events described in clauses (i) or (ii) above would be the result; (B) a liquidation or dissolution of or appointment of a receiver, rehabilitator, conservator or similar person for, or the filing by a third party of an involuntary bankruptcy against, BDSI; or (C) an agreement for the sale or other disposition of all or substantially all of the assets of BDSI to any Person (other than a transfer to a subsidiary of BDSI).

All forms of compensation referred to in this Agreement are subject to reduction to reflect applicable withholding and payroll taxes and other deductions required by law. You hereby acknowledge that the Company does not have a duty to design its compensation policies in a manner that minimizes your tax liabilities, and you will not make any claim against the Company or its board of directors related to tax liabilities arising from your compensation. Anything in this Agreement to the contrary notwithstanding, if at the time of your separation from service within the meaning of Section 409A of the Code, the Company determines that you are a "specified employee" within the meaning of Section 409A(a)(2)(B)(i) of the Code, then to the extent any payment or benefit that you becomes entitled to under this Agreement on

account of your separation from service would be considered deferred compensation subject to the 20% additional tax imposed pursuant to Section 409A(a) of the Code as a result of the application of Section 409A(a)(2)(B)(i) of the Code, such payment shall not be payable and such benefit shall not be provided until the date that is the earlier of (A) six months and one day after your separation from service, or (B) your death. If any such delayed cash payment is otherwise payable on an installment basis, the first payment shall include a catch-up payment covering amounts that would otherwise have been paid during the six-month period but for the application of this provision, and the balance of the installments shall be payable in accordance with their original schedule. All in-kind benefits provided and expenses eligible for reimbursement under this Agreement shall be provided by the Company or incurred by you during the time periods set forth in this Agreement. All reimbursements shall be paid as soon as administratively practicable, but in no event shall any reimbursement be paid after the last day of the taxable year following the taxable year in which the expense was incurred. The amount of in-kind benefits provided, or reimbursable expenses incurred in one taxable year shall not affect the in-kind benefits to be provided or the expenses eligible for reimbursement in any other taxable year. Such right to reimbursement or in-kind benefits is not subject to liquidation or exchange for another benefit. To the extent that any payment or benefit described in this Agreement constitutes "non-qualified deferred compensation" under Section 409A of the Code, and to the extent that such payment or benefit is payable upon your termination of employment, then such payments or benefits shall be payable only upon your "separation from service." The determination of whether and when a separation from service has occurred shall be made in accordance with the presumptions set forth in Treasury Regulation Section 1.409A-1(h). The Company and you intend that this Agreement will be administered in accordance with Section 409A of the Code. To the extent that any provision of this Agreement is ambiguous as to its compliance with Section 409A of the Code, the provision shall be read in such a manner so that all payments hereunder comply with Section 409A of the Code. The Company makes no representation or warranty and shall have no liability to you or any other person if any provisions of this Agreement are determined to constitute deferred compensation subject to Section 409A of the Code but do not satisfy an exemption from, or the conditions of, such Section.

You may serve on the Boards of one (1) or more organizations or entities provided that such work does not interfere with your responsibilities for BDSI (which shall take precedence over such other activities) and with the consent and preapproval of the CEO and the Board, which shall not be unreasonably withheld.

The Company hereby represents, warrants and covenants to you that: (i) it will not direct or instruct you to take any action or engage in any activities that you have informed the Company in writing may violate any commitment or violate any confidentiality or trade secret duty between you and any previous employer; and (ii) except for any matters that have been disclosed in filings with the U.S. Securities and Exchange Commission or otherwise in writing to you on or prior to the Effective Date, there is no pending or, to the Company's knowledge, threatened materially adverse civil (including administrative) or criminal litigation; material disciplinary or regulatory (including self-regulatory) proceeding or investigation; or material regulatory (including self-regulatory) or congressional or governmental inquiry of any sort against or involving the Company or its affiliates, in whole or in part.

Please note that this offer is contingent upon:

(i) Confirmation of employee-provided information regarding prior work history, education, personal and professional references. A formal background investigation will be undertaken; employment is contingent pending the validation of satisfactory results by the investigating agency; and

(ii) Approval by the Compensation Committee of BDSI's Board of Directors of the compensation terms of this letter;

(iii) Execution and delivery to BDSI of agreements concerning Confidentiality, Intellectual Property and Non-Competition Agreements, the terms of which are incorporated herein; and

(iv) Review and acknowledgement of BDSI Code of Ethics and Insider Training Policy; and

(v) Compliance with requirements of the Immigration Reform and Control Act. (Completion of I-9 form and copies of appropriate documents must be provided on your first day of employment).

This Offer Letter contains all of the terms of your employment with the Company and supersedes any prior agreements, representations or understandings (whether written, oral or implied) between you and the Company. If the above terms are acceptable, please contact me at your earliest convenience regarding acceptance of our contingent offer of employment. To formally accept this offer, please sign in the appropriate place below and return an executed copy of this letter to me. Please retain an executed copy of this letter for your own records.

We are excited about the future of BDSI and your contribution to our success. I look forward to hearing from you regarding this offer.

Regards,

/s/ Herm Cukier

Herm Cukier
Chief Executive Officer
BioDelivery Sciences International, Inc.

Offer Letter of Employment Acknowledged and agreed as of the date set forth below:

/s/ Terry Coelho
Terry Coelho

January 10, 2019
Date

Exhibit 21.1

Subsidiaries of the Registrant

1. Arius Pharmaceuticals, Inc., a Delaware corporation
2. Arius Two, Inc., a Delaware corporation
3. Bioral Nutrient Delivery, LLC, a Delaware limited liability company

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in each of the Registration Statements on Form S-3 (Nos. 333-133629, 333-133630, 333-135746, 333-143247, 333-149671, 333-156839, 333-157173, 333-160121, 333-173261, 333-179257, 333-192618, 333-205483, and 333-228292) and on Form S-8 (Nos. 333-143590, 333-176476, 333-190796, 333-206326, and 333-222734) of our report dated March 14, 2019 included in this Annual Report on Form 10-K of BioDelivery Sciences International, Inc. (the "Company"), relating to the consolidated balance sheets of the Company as of December 31, 2018 and 2017, the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for each of the years in the three-year period ended December 31, 2018, and Schedule II – Valuation and Qualifying Accounts and Reserves for each of the years in the three-year period ended December 31, 2018, and the effectiveness of internal control over financial reporting for the Company as of December 31, 2018.

/s/ Cherry Bekaert LLP

Raleigh, North Carolina

March 14, 2019

Exhibit 31.1

Certification Pursuant to Rule 13a-14(a)

I, Herm Cukier, hereby certify that:

1. I have reviewed this Annual Report on Form 10-K of BioDelivery Sciences International, Inc.

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 14, 2019

/s/ Herm Cukier
Herm Cukier
Chief Executive Officer and Director

Exhibit 31.2

Certification Pursuant to Rule 13a-14(a)

I, Mary Theresa Coelho, hereby certify that:

1. I have reviewed this Annual Report on Form 10-K of BioDelivery Sciences International, Inc.

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 14, 2019

/s/ Mary Theresa Coelho
Mary Theresa Coelho
Chief Financial Officer

Exhibit 32.1

CERTIFICATION

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(18 U.S.C. 1350)

Pursuant to Section 906 of the Sarbanes-Oxley Act of (18 U.S.C. 1350), the undersigned officer of BioDelivery Sciences International, Inc., a Delaware corporation (the "Company"), does hereby certify, to the best of such officer's knowledge and belief, that:

(1) The Annual Report on Form 10-K for the year ended December 31, 2018 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Form 10-K fairly presents, in all materials respects, the financial condition and results of operations of the Company.

Date: March 14, 2019

/s/ Herm Cukier
Herm Cukier, Chief Executive Officer and Director

This certification shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act, or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act or the Securities Exchange Act.

Exhibit 32.2

CERTIFICATION

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(18 U.S.C. 1350)

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350), the undersigned officer of BioDelivery Sciences International, Inc., a Delaware corporation (the "Company"), does hereby certify, to the best of such officer's knowledge and belief, that:

(1) The Annual Report on Form 10-K for the year ended December 31, 2018 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Form 10-K fairly presents, in all materials respects, the financial condition and results of operations of the Company.

Date: March 14, 2019

/s/ Mary Theresa Coelho
Mary Theresa Coelho, Chief Financial Officer

This certification shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act, or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act or the Securities Exchange Act.