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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, 2019

☐ **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	Trading Symbol(s)	**Name of exchange on which registered**
Common stock, par value $0.001	**BDSI**	**The Nasdaq Global Select 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 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 28, 2019 was approximately $359,814,864 based on the closing sale price of the company's common stock on such date of $4.65 per share, as reported by the NASDAQ Global Select Market.

As of March 6, 2020, there were 96,360,486 shares of company common stock issued and 96,344,995 shares of company common stock outstanding.

BioDelivery Sciences International, Inc.

Annual Report on Form 10-K

For the fiscal year ended December 31, 2019

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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.

From time to time, we may use our website, our Facebook page at Facebook.com/BioDeliverySI, on Twitter at @BioDeliverySI to distribute material information, and on LinkedIn at linkedin.com/company/biodeliverysciencesinternational/. Our financial and other material information is routinely posted to and accessible on the Investors section of our website, available at **www.bdsi.com**. Investors are encouraged to review the Investors section of our website because we may post material information on that site that is not otherwise disseminated by us. Information that is contained in and can be accessed through our website, our Facebook page and our Twitter posts are not incorporated into, and does not form a part of, this Annual Report.

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.

These forward-looking statements include, but are not limited to, statements about:

- our plans and expectations regarding the commercialization, manufacturing, marketing and distribution efforts relating to our BEMA (as defined below) drug delivery technology platform and any of our approved products;
- the domestic and international regulatory process and related laws, rules and regulations governing our technologies and our 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 commercialization, manufacturing and distribution of our products;
- our ability, or the ability of our commercial partners or licensors, to actually develop, commercialize, secure raw materials or active pharmaceutical ingredients in sufficient quantities, manufacture or distribute our products, including for BELBUCA and Symproic;
- 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;
- the protection and control afforded by our patents or other intellectual property, and any interest in 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 and any related commercial agreements of ours;
- the ability of our manufacturing partners to supply us or any 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 specialty pharmaceutical company dedicated to patients living with chronic pain and associated conditions. We have built a portfolio of products that includes utilizing our novel and proprietary BioErodible MucoAdhesive, or BEMA, drug-delivery technology to develop and commercialize new applications of proven therapies aimed at addressing important unmet medical needs. 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 serious and debilitating chronic conditions so they can experience life to the fullest. We commercialize in the U.S. using our own sales force while working in partnership with third parties to commercialize our products outside the U.S. We have made it a point to deeply understand the patients' journeys and are driven by recognizing the full impact of their conditions so we can deliver life-improving solutions. Our marketed products address serious and debilitating conditions, including chronic pain, opioid dependence and opioid-induced constipation.

Our Strategy

Our strategy is evolving with the establishment of our commercial footprint in the management of chronic pain. We seek to continue to build a well-balanced, diversified, high-growth specialty pharmaceutical company. Through our industry-leading commercialization infrastructure, we are 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 commercial strategy for BELBUCA is to further drive continued adoption in the large long-acting opioid (LAO) market based on its unique profile coupled with growing physician interest, policy tailwinds, and expanding payer access. We aim to leverage the specialized commercial infrastructure we established for BELBUCA as a vehicle to enable commercial growth in Symproic, which is being increasingly seen as a complementary asset.

Our Company

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

Background on Chronic Pain, Opioid Induced Constipation and Opioid Dependence

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 a National Health Interview Survey, there are over 25 million American adults experiencing daily chronic pain, with over 10 million of these experiencing severe pain on a daily basis.

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 2019, according to data from Symphony Health, the market for long-active opioids in the U.S. totaled over $3.1 billion in annual sales with almost 12 million prescriptions dispensed. However, prescription volume of long-acting opioids declined more than 13% in 2019 compared to 2018 amidst continuing 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 from Purdue Pharma L.P., or Purdue, 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, as well as Xtampza ER and Nucynta ER from Collegium Pharmaceutical, Inc., or Collegium, and multiple generic Schedule II oral opioid formulations, such as

morphine, hydrocodone, and fentanyl containing products. Approximately 70% 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 to cessation of manufacturing/promotion for products such as Arymo ER. This has led some manufacturers to reconsider launching an ADF product into the current market.

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. The FDA and other government agencies have taken an increasing number of actions to address the problem of opioid abuse and addiction.

- In July 2012, the Federal Drug Administration (or "FDA") approved a class-wide Risk Evaluation and Mitigation Strategy (or "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 its final ruling in the Federal Register 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, the U.S. Department of Health and Human Services, (or "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 non-pharmacologic therapy and non-opioid 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, or 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, or MME or greater and should avoid increasing total daily doses to 90 MME or greater. 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 was 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 May 2019, the Health and Human Services Pain Management Best Practices Inter-Agency Task Force issued their Final Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations. The report identifies that one of the barriers in pain management best practices "include lack of coverage and reimbursement for buprenorphine as well as the lack of education and training on the proper usage of buprenorphine. There has been a lack of access to buprenorphine treatment for chronic pain." The report then makes recommendations that third-party payers should provide coverage and reimbursement for buprenorphine treatment approaches. The report also encouraged the primary use of buprenorphine when opioids are appropriate for chronic pain. In October 2019, the HHS issued a guide for clinicians on how to appropriately reduce the dose for patients on long-term opioids. Within this guidance, it was noted that if patients on high opioid dosages are unable to taper despite worsening pain and/or function with opioids, clinicians should consider transitioning the patient to buprenorphine. The guide also noted that in addition to treating pain, buprenorphine has other properties that may be

helpful, including less opioid-induced hyperalgesia and easier withdrawal than full mu-agonist opioids, and less respiratory depression than other long-acting opioids.

- For 2019, the Centers for Medicare and Medicaid Services adopted a soft edit of 90 MME per day for patients, aligning with the 2016 CDC Guideline recommendation. A medication soft edit can be used to alert the pharmacist to a potential safety risk for the patient, but can often be overridden after consulting with the prescriber.

Opioid Induced Constipation

Opioid analgesics are an important therapeutic option for patients with moderate-to-severe chronic pain. However, a common side-effect of opioid therapy is opioid-induced constipation, or OIC, which is characterized by reduced bowel movement frequency, increased straining, sensation of incomplete evacuation, and hard stools after the initiation of opioid therapy. Unlike many other opioid-related adverse effects, opioid-induced constipation does not subside over time. According to the 2018 American Gastroenterological Association Institute Guideline on the Medical Management of Opioid-Induced Constipation, OIC is estimated to affect 40% to 80% of patients taking chronic opioid therapy. One-third of patients with OIC report skipping, reducing, or stopping use of opioids—despite experiencing an increase in pain—in an effort to have a bowel movement.

Treatment Landscape for Opioid Induced Constipation

First-line treatment for opioid-induced constipation typically involves a combination of pharmacological and non-pharmacological interventions such as laxatives and increased dietary fiber. However, these approaches are associated with sub-optimal efficacy and do not address the underlying mechanism of OIC. OIC results from the specific effects of opioids on the gastrointestinal tract, differing mechanistically from other forms of constipation. Therefore, medical management of this disorder requires targeted treatment.

In 2010, Relistor injectable was approved by the FDA as the first peripherally acting mu-opioid receptor antagonist, or PAMORA, for the treatment of OIC in adults with chronic non-cancer pain. The PAMORA mechanism of action targets the underlying cause of OIC, selectively blocking opioid actions at peripheral μ-opioid receptors, including those in the enteric nervous system, without affecting analgesia in the central nervous system (or "CNS"). In 2014, Movantik was the first oral PAMORA approved for the treatment of OIC, with the oral formulation of Relistor approved in mid-2016. In March 2017, Symproic was the third PAMORA approved for the treatment of OIC in adults with chronic non-cancer pain.

In addition to the PAMORA agents, Amitiza is also approved for the treatment of OIC in adults with chronic non-cancer pain. Amitiza is a chloride channel 2 activator in the gut, which increases intestinal fluid secretion and enhances transit through the gut without altering sodium and potassium serum concentrations.

In October 2018, the American Gastroenterological Association, or AGA issued guidelines for the medical management of OIC to help reduce practice variation and promote high quality and high-value care for patients suffering from OIC. For patients in whom traditional laxative therapy results in sub-optimal symptom control, the AGA recommends the use of PAMORAs. Of the PAMORAs, Symproic is the only OIC therapy with a strong recommendation and high quality of evidence from the AGA. Due to insufficient evidence, the AGA did not issue a recommendation regarding the use of Amitiza® in OIC.

In 2019, according to data from Symphony Health, the PAMORA market totaled $352 million in annual sales. There were over 585,000 PAMORA prescriptions dispensed, a slight decrease of 3% from 2018, driven by the decline in opioid prescribing.

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 National Survey on Drug Use and Health, in 2016, 2.1 million people in the U.S. 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 several 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.

In addition to BUNAVAIL, there are several buprenorphine containing products currently marketed for the treatment of opioid dependence including 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. In February 2019, generic equivalents of Suboxone entered the market, rapidly eroding the leadership position that Suboxone had maintained for several years.

The total U.S. market for buprenorphine containing products for opioid dependence exceeded $3.2 billion in 2019, an increase of 6% over 2018, 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. Due to the entrance of Suboxone generic equivalents, the dollar value of this market is anticipated to decline in 2020.

Breakthrough Cancer Pain

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 17,000 prescriptions in 2019, according to Symphony Health.

Our 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:

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.
Symproic	the treatment of opioid-induced constipation in adult patients with chronic non-cancer pain	Approval: U.S. in March 2017	BDSI markets in U.S.; licensed from Shionogi in April 2019
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.

* In March 2020, we announced that we were discontinuing marketing for BUNAVAIL in the U.S.

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 and marketed products 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 ONSOLIS (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.

Since 2016, we have utilized our own sales force, which provides us with significantly more control over commercialization efforts and greater flexibility to accommodate future strategic options. We have left commercialization of our ONSOLIS product in ex-U.S. markets with partners. As of January 2020, BELBUCA and Symproic are supported by a field force of approximately 121 sales representatives, 13 regional sales managers and two area directors.

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

BELBUCA is a buccal film that contains buprenorphine, a Schedule III opioid, and 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, fentanyl, 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 seven available strengths; and
- buccal administration to optimize buprenorphine delivery.

Because of the safety, tolerability and efficacy benefits associated with buprenorphine, we believe that BELBUCA should be the 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.

We believe that there are long-term growth opportunities for BELBUCA and we focus our commercial efforts primarily on 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/buprenorphine transdermal 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 2020, BELBUCA had formulary coverage for more than 96% of commercial lives. Approval rates within the commercial channel remained favorable throughout 2019 at about 85%. BELBUCA continues to have favorable approval rates over 90% within other Medicare plans, as we pursue improved access to BELBUCA for the senior population suffering with chronic pain.

In 2019, we also made significant improvements in patient access for BELBUCA, resulting in 100 million lives having preferred access and over 250 million lives having access to BELBUCA across all channels . BELBUCA total prescriptions in 2019, according to Symphony Health, totaled over 330,000, an increase of 103% over 2018. BELBUCA's share of total buprenorphine prescriptions (products for the treatment of chronic pain only) for 2019 totaled 38% compared to 23% for the prior year, and increased as high as 41% in December 2019. In addition to a steady increase in BELBUCA prescription volume through 2019, 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 2019, 41% of BELBUCA prescriptions were for doses of 450 mcg or greater, compared to 36% in 2018. Therefore, the weighted average price per prescription continued to increase in 2019.

Symproic (naldemedine), for Opioid Induced Constipation

Symproic was approved by the FDA on March 23, 2017 for the treatment of OIC in adult patients with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation. Compared to currently marketed products and products under development, we believe that Symproic is differentiated based on the following features:

- strong and durable efficacy observed in randomized, double-blind, placebo controlled clinical trials of 12 week and 52 week duration in OIC patients;
- OIC relief that was more frequent, more complete, with less straining than patients taking placebo;
- recommended by the American Gastroenterological Association for patients with laxative refractory OIC;
- adverse event profile comparable to placebo, with low rates of abdominal pain observed across the phase III program; and
- the only prescription OIC medication with the convenience of once daily dosing, with only a tablet strength, and that can be taken with or without food and with or without laxatives.

Because of the durable efficacy, tolerability and convenience benefits, we believe that Symproic is a best-in-class PAMORA that reliably provides durable relief of OIC, which frees both the patient and the healthcare provider to focus on treating the patient's chronic pain.

On April 4, 2019, we entered into an exclusive licensing agreement with Shionogi to commercialize Symproic in the U.S. and Puerto Rico for the treatment of OIC in adults with chronic non-cancer pain.

Symproic is a strong complementary product to BELBUCA, as patients requiring a PAMORA are by definition taking an opioid. Therefore, our sales force remains focused on high prescribers of long-acting opioids, BuTrans/buprenorphine transdermal and/or HCPs who prescribe short acting opioids around-the-clock for patients with chronic pain.

In 2019, we also focused on increasing market access for Symproic. As of January 2020, Symproic had formulary coverage for more than 95% of commercial lives. Approval rates within the commercial channel remained favorable throughout 2019 at about 80% and Medicare approval rates of over 70%.

In 2019, we also made significant improvements in patient access for Symproic, resulting in over 100 million lives having preferred access and over 240 million lives having access to Symproic across all channels. Symproic total prescriptions in 2019, according to Symphony Health, totaled over 60,000, an increase of 53% over 2018. Symproic share of PAMORA prescriptions in 2019 totaled 10.4% versus 6.6% for the prior year, ending 2019 with a 11.4% share in December.

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. 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.

As noted above, in January 2017 with the reacquisition of BELBUCA, we transitioned our primary commercial emphasis from BUNAVAIL to BELBUCA; and with the licensing of Symproic in April 2019, our commercial efforts are now focused on the continued growth of BELBUCA and Symproic. In March 2020, we announced that we are discontinuing marketing for BUNAVAIL.

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 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. We currently license ONSOLIS to TTY Biopharm Co., Ltd., or TTY, which markets the product as PAINKYL in Taiwan, and to Mylan N.V., which markets the product as BREAKYL in Europe.

Additional Overview Information

From our inception through December 31, 2019, we have recorded accumulated losses totaling approximately $366.6 million. Our historical operating losses have resulted principally from our prior research and development activities, including clinical trial activities for our products, sales, and general and administrative expenses. Ultimately, if we secure additional approvals from the FDA and other regulatory bodies throughout the world for other products 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 materially finance our commercialization and distribution efforts and our working capital needs primarily through:

- commercializing our approved products such as BELBUCA and Symproic;
- 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 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 our projected sales and similar metrics regarding BELBUCA, Symproic and ONSOLIS 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 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:

- *ARx*. Effective July 30, 2014, we entered into an agreement with ARx, LLC pursuant to which ARx acted as a supplier of BUNAVAIL laminate (bulk product) for the U.S. Our supply agreement with ARx was then amended July 14, 2017 through December 31, 2023. Upon the discontinued marketing of BUNAVAIL in March 2020, we have post-termination obligations with ARx of costs incurred pursuant to the binding portions of the rolling forecast.

  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 was extended by mutual agreement for subsequent one-year terms. Upon the discontinued marketing of BUNAVAIL in March 2020, we have post-termination obligations with Sharp minimal fees.

  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.

- *Shionogi*. Effective April 4, 2019, we entered into an agreement with Shionogi, Inc. pursuant to which Shionogi acts as a supplier of Symproic finished product. Our supply agreement with Shionogi runs until April 2021 and can be extended by written amendment up to two consecutive 6-month periods.

Relationship with CDC IV, LLC

On July 14, 2005, we entered into a Clinical Development and License Agreement, or CDLA, with the predecessor of CDC IV, LLC, or CDC IV, which provided funds to us for the development of ONSOLIS. Under the CDLA, as amended, we pay CDC IV a mid-single digit royalty, which shall not be less than $375,000 per quarter, on sales of ONSOLIS. The CDLA royalty term ends upon the latter of expiration of the patent for ONSOLIS or generic entry into any particular country, or the CDLA is terminated. We and CDC IV are also party to a Royalty Purchase and Amendment Agreement, or the RPAA, pursuant to which we pay CDC IV a 1% royalty on sales of BELBUCA. The RPAA royalty term shall terminate upon the earlier of (i) such time at which 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 or (ii) upon the last commercial sale of BELBUCA anywhere in the world.

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 U.S. It is possible, however, that a court of law in the U.S. 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 U.S. 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 U.S. 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 U.S. 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.

Government Regulation

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

In the U.S., 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.

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.

ONSOLIS (under different trade names and with a slightly different formulation) is approved in Europe and in Taiwan. In 2019, after learning that Purdue would no longer be marketing BELBUCA in Canada, BDSI requested that Purdue ask Health Canada to cancel its registration and approval there. BDSI has no plans at the moment to market BELBUCA outside of the U.S.

Other Regulation

In addition to regulations enforced by the FDA, we are also subject to U.S. 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. Although we believe that our safety procedures comply with the standards prescribed by state and federal regulations, the risk of injury 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.

Employees

As of March 6, 2020, we have 178 full-time employees. Of which, 128 handle our outside sales and training, 13 are involved in our medical affairs, clinical development program and regulatory, 26 handle our administration, finance, legal, human resources, operations, quality and supply chain management, and 11 handle our marketing and market access. Advanced degrees and certifications of our staff include four Ph.D., one M.D., three PharmDs, two CPAs, twenty-one MBAs, eleven MSs, ten MAs, four JDs, one MPA, one MEDU and three RNs. 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 in good standing. 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, 2019, we have recorded significant losses. Our accumulated deficit at December 31, 2019 was approximately $366.6 million. As of December 31, 2019, we had working capital of approximately $63.8 million. 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.

We have generated licensing-related revenue for ONSOLIS outside the US, and we have generated revenue from the commercial sales of our approved products, BELBUCA and BUNAVAIL. In the case of BELBUCA, our approval initially generated milestone revenue from our prior commercial partner Endo. However, in January 2017, we re-acquired the commercialization rights for BELBUCA and are utilizing our internal sales force to sell our product. In the case of Symproic, we acquired rights to the product in April 2019, and commenced the commercial launch of the product using our own sales force shortly thereafter. In the case of BUNAVAIL, sales have been challenging since we commenced the commercial launch of the product in November 2014 and, in March 2020, we announced that we are discontinuing marketing for BUNAVAIL. 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 suspension of manufacturing and marketing of ONSOLIS in the U.S. and Canada. As of the date of this report, we do not have any plans to launch ONSOLIS in the U.S.

We have limited experience commercializing Symproic.

We have limited experience commercializing Symproic, and our sales, marketing and distribution capabilities related to this product have only been recently established. As such, we may not achieve success in marketing and promoting Symproic, 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 Symproic, 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 Symproic as an appropriate therapy. In addition, we must provide our sales force with the highest quality training, support, guidance and oversight for them to effectively promote Symproic. If we fail to perform these commercial functions in the highest quality manner, Symproic may not achieve its maximum commercial potential or any level of success at all. 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 ability to obtain market acceptance of Symproic.

If our competitors are successful in obtaining approval for Abbreviated New Drug Applications for products that have the same active ingredients as BELBUCA or Symproic, sales of BELBUCA or Symproic 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 make patent certifications to the FDA, such as certification to the FDA that the new product that is 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 the past, we have initiated litigation with generic competitors that have filed Paragraph IV Certifications challenging certain of our patents. While we have entered in to settlement agreements with certain competitors, we are still pursuing litigation to defend against Patent IV Certifications related to BELBUCA. For more information, see Note 17, "Commitments and Contingencies" to our consolidated financial statements included in Part IV of this Report on Form 10-K. We believe that we will 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 need to raise substantial additional funding to fund our operations. If we fail to obtain additional financing, we may be unable to continue to spend on commercialization activities (including those relating to BELBUCA and Symproic) or complete the commercialization of other product candidates.

Our operations have required substantial amounts of cash since inception, and we expect to spend substantial amounts of our financial resources on our commercialization and development efforts going forward. Our business currently generates revenue from product sales , 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 Symproic) as well as potentially on other strategic initiatives, we may require additional capital to fund these activities. We may also need to raise additional funds sooner if we choose to expand more rapidly than we presently anticipate or due to other unanticipated factors. 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.

We cannot be certain that additional funding will be available on acceptable terms, or at all. We have no committed source of additional capital and if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the commercialization of our products. [Our collaboration and license agreements may also be terminated if we are unable to meet the payment or other obligations under the agreements.]

Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

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 addressing regulatory and other issues that may arise post-FDA approval (such as we have experienced with ONSOLIS and, to a lesser extent, with BELBUCA and Symproic);
- 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 term loan agreement with Pharmakon 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 loan

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 Pharmakon 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; and
- enter into material transactions with affiliates.

The restrictive covenants of the term loan agreement could prevent us from pursuing 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, Pharmakon 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 Pharmakon 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 commercialization efforts or grant to others rights to market our products 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 was March 8, 2018. We are assessing our commercial options for ONSOLIS. However, as of the date of this Report, we have no such plans to reintroduce ONSOLIS in the U.S., which indicates 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.

Opioid abuse in the U.S. is a significant healthcare issue, and the active ingredient in BELBUCA is an opioid. Media reports 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 abuse and misuse of opioids. Such efforts have challenged and could inhibit our ability to successfully market BELBUCA.

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 decrease the revenues we are able to generate from its sale.

Efforts by the FDA and other regulatory bodies to combat abuse of opioids may negatively impact the market for BELBUCA. 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. To the extent our company is named in such lawsuits, 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 candidates.

National and state level government agencies, professional and medical societies, and other groups may establish usage guidelines that apply to our products and drug candidates. 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 candidates.

Acceptance of our technologies 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 and products. Even if approved for marketing by the necessary regulatory authorities, our technologies and products may not achieve market acceptance.

The degree of market acceptance for our products 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 and BELBUCA 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 healthcare providers, patients, payers or the medical community in general may be unwilling to accept, utilize or recommend any of our approved products. 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 Symproic, which are our two products that we are commercializing ourselves.

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

Use of our products will require physicians to be informed regarding the intended benefits of our products. 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 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.

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 products, 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 Symproic. 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, with umbrella liability in the amount of an additional $5 million aggregate and $5 million per occurrence; product liability is $10 million for aggregate and $10 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, Symproic, and ONSOLIS, 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 related action is brought against us, or liability is found against us prior to our obtaining product liability insurance for any product, 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 U.S. 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 Aquestive Therapeutics, Inc. (formerly known as MonoSol Rx LLC, or Aquestive) relating to our BELBUCA product which was filed in January 2017. If the courts in these cases were to rule against us and our partner in these cases, we could be forced to license technology from Aquestive or be prevented from marketing BELBUCA, 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 BELBUCA.

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 Indivior 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 and products.

Key components of our drug delivery technologies and products, including for BELBUCA and Symproic, 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 ingredients, or API, 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 sufficient quantities of API and 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, extreme weather events, pandemics, labor issues and strikes, or any other factor beyond our reasonable control 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, API, 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.

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 marketing and distribution efforts around our products. 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, or 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.

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, 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 product 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 Regulation

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

The manufacture and marketing of our products are subject to extensive regulation for safety, efficacy and quality by numerous government authorities in the U.S. 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.

If users of our products are unable to obtain adequate reimbursement from third-party payers, or if new restrictive legislation is adopted, market acceptance of our 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 healthcare 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 U.S., given recent federal and state government initiatives directed at lowering the total cost of healthcare, the U.S. Congress and state legislatures will likely continue to focus on healthcare 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 Symproic, 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 healthcare in the U.S., which could control or significantly influence the purchase of healthcare services and drugs, as well as legislative proposals to reform healthcare 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.

In connection with 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. 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 and Symproic 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 U.S., 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 drug products. In addition, although the U.S. 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 has been seeking to repeal or replace all or portions of the ACA but to date no such legislation has been passed.

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 U.S. 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 issued by 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 the U.S. Congress, including the Sarbanes-Oxley Act of 2002 and, more 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 related to 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 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 the 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 our common stock. These fluctuations, as well as general economic and market conditions, may have a material and/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 have 2,709,300 issued and 2,093,155 outstanding shares of Series A Non-Voting Convertible Preferred Stock, or "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 have 5,000 issued and 618 outstanding shares of Series B Non-Voting Convertible Preferred Stock, or "Series B", which is convertible into 3,433,335 shares of our 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, 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 6, 2020, there are 96,360,486 shares of common stock issued and 96,344,995 shares of common stock outstanding.

On July 25, 2019, our stockholders approved an amendment to our certificate of incorporation to increase the number of authorized shares of common stock, par value $0.001, of our common stock from 125,000,000 to 175,000,000 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.

We currently have an effective shelf registration which registered up to $125 million of our securities for potential future issuance. To the extent we issue such shares of stock under this registration statement, the current holders of our common stock may experience further dilution.

Anti-takeover provisions under our organizational documents and Delaware law could delay or prevent a change of control, which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.

Our certificate of incorporation, as amended, our amended and restated bylaws 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 may 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 with 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 feet of space and has remaining base rent of $0.9 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.

Refer to Note 17, "Commitments and Contingencies" to our consolidated financial statements included in Part IV of this Report on Form 10-K, which is incorporated into this item by reference.

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.

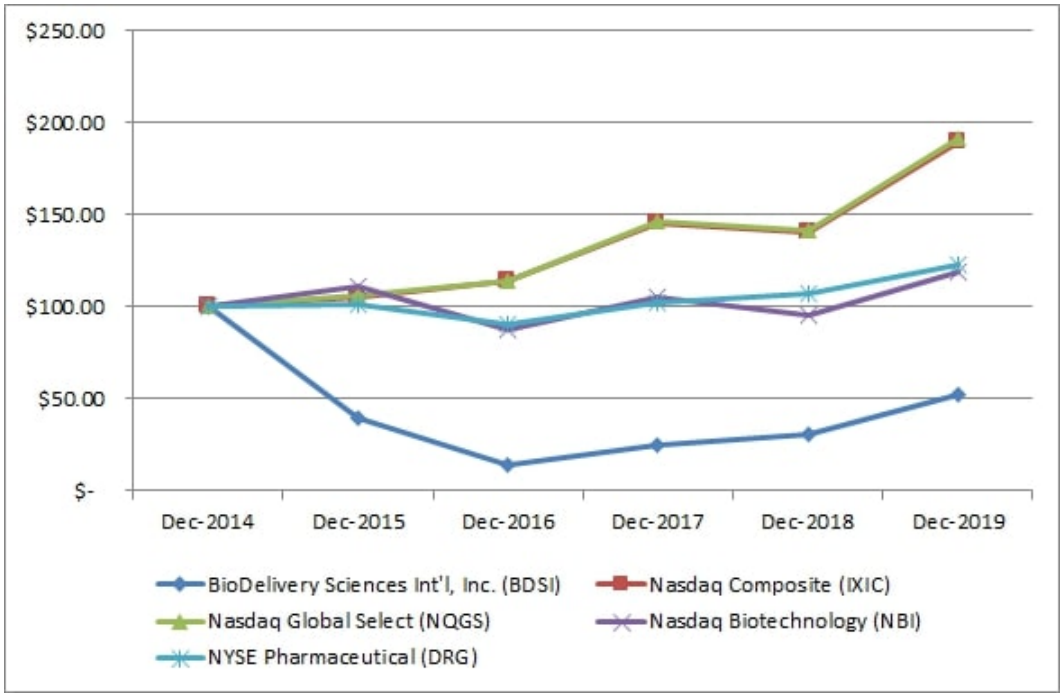
Beginning November 1, 2019, our common stock is listed for quotation on the NASDAQ Global Select Market under the symbol "BDSI". Prior to November, our common stock was listed on the NASDAQ Capital Market.

As of March 6, 2020, we had approximately 112 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, 2014 in (i) our common stock (ii) the Nasdaq Composite Index (iii) the Nasdaq Global Select Index (iv) the Nasdaq Biotechnology Index and (v) 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, 2014:



	12/31/2014	12/31/2015	12/31/2016	12/31/2017	12/31/2018	12/31/2019
BioDelivery Sciences Int'l, Inc.	$ 100.00	$ 39.85	$ 14.56	$ 24.54	$ 30.78	$ 52.58
Nasdaq Composite (U.S. Companies)	100.00	105.73	113.66	145.76	140.10	189.45
Nasdaq Global Select	100.00	106.11	114.16	146.62	141.23	191.51
Nasdaq Biotechnology	100.00	111.42	87.26	105.64	95.79	119.17
NYSE Pharmaceutical	100.00	101.62	90.38	102.28	106.76	122.68

Item 6. Selected Financial Data.

The statements of operations data and statements of cash flows data for the years ended December 31, 2019, 2018 and 2017 and the balance sheet data as of December 31, 2019 and 2018 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, 2016 and 2015 and the balance sheet data as of December 31, 2017, 2016 and 2015 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.

	2019	2018	2017	2016	2015
Statements of Operations Data:					
Total revenue (1)	$ 111,389	$ 55,640	$ 61,985	$ 15,546	$ 48,231
Operating income (loss)	3,736	(23,648)	(29,420)	(63,935)	(35,179)
Net (loss) income (2) (3)	(15,305)	(46,367)	5,285	(67,138)	(37,672)
Diluted net (loss) income per share	(0.18)	(0.73)	0.09	(1.25)	(0.72)
Balance Sheet Data:					
Cash, short-term and long-term investments	$ 63,888	$ 43,822	$ 21,195	$ 32,019	$ 83,560
Total assets (4) (5)	182,905	108,533	88,101	51,720	102,772
Long-term liabilities	59,148	57,252	53,075	50,097	42,993
Accumulated deficit	(366,593)	(351,288)	(305,056)	(310,341)	(243,203)
Total stockholders' equity (deficit)	69,764	29,742	8,877	(17,665)	31,696
Statements of Cash Flows Data:					
Net cash flows from operating activities	$ 11,072	$ (24,113)	$ (32,451)	$ (53,982)	$ (3,732)

(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 BDSI 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, 2019 includes the value of the BELBUCA license and distribution rights intangible asset, net, totaling $31.5 million.and the value of the Symproic license and distribution rights intangible asset, net, totaling $28.8 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. All amounts and percentages are approximate due to rounding. When we cross-reference to a "Note," we are referring to our "Notes to Consolidated Financial Statements," unless the context indicates otherwise. 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 continue to build a well-balanced, diversified, high-growth specialty pharmaceutical company. Through our industry-leading commercialization infrastructure, we are 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 commercial strategy for BELBUCA is to further drive continued adoption in the large long-acting opioid (LAO) market based on its unique profile coupled with growing physician interest, policy tailwinds, and expanding payer access. We aim to leverage the specialized commercial infrastructure we established for BELBUCA as a vehicle to enable commercial growth in Symproic, which is being increasingly seen as a complementary asset.

Recent Highlights

- On April 4, 2019, we entered into an exclusive licensing agreement with Shionogi to commercialize Symproic in the U.S. and Puerto Rico, for the treatment of OIC in adults with chronic non-cancer pain.
- On April 15, 2019, we completed an underwritten public offering by us and a selling stockholder of 12,000,000 shares of common stock at a public offering price of $5.00 per share. The gross proceeds from our portion of the offering (10,000,000 shares), before deducting the underwriter discounts and commission and other offering expenses, were $50.0 million, or $47.6 million net proceeds.
- On May 23, 2019, we refinanced our existing debt agreement with a new facility from Pharmakon. The new facility consists of a $60.0 million term loan and is expected to result in an estimated $1.5 million in annual interest cost savings compared to the previous debt facility.
- On July 1, 2019, we were added to the broad-market Russell 3000® Index as well as the Russell 2000® Index at the conclusion of the 2019 Russell indexes annual reconstitution.
- On July 9, 2019, we announced that several regional healthcare plans improved patient access to BELBUCA during the second quarter of this year. The regional U.S. insurance plans enhanced BELBUCA's coverage to preferred status or initiated coverage for BELBUCA, which means that an additional six million covered lives now have access to BELBUCA. These six million covered lives brings the total number of commercial lives with access to BELBUCA to more than 165 million, representing more than 90% of the U.S. commercial insurance market.
- On August 28, 2019, we reported the acceptance of five scientific abstracts highlighting data supporting our portfolio of products that address the unmet need of chronic conditions at the PAINWeek® 2019 National Conference on Pain for Frontline Practitioners which took place in September in Las Vegas, NV.
- On October 1, 2019, we announced that a major pharmacy benefits manager, or "PBM", began providing improved patient access to BELBUCA and Symproic, with full plan adoption on January 1, 2020. The addition of this large national PBM increased the number of covered lives to approximately 14 million covered lives within both commercial and health exchange plans that have access to BELBUCA as either the preferred or preferred exclusive buprenorphine product within their respective plans and Symproic as the preferred exclusive product within its class. Also, on January. 13, 2020, we announced that a large PBM, along with various healthcare insurance companies, have expanded access for Symproic to more than 25 million additional commercial covered lives by placing Symproic in preferred formulary position beginning on January 1, 2020. As of January 1, 2020, this brings the total number of covered lives with preferred access to BELBUCA is approximately 100 million (out of more than 250 million with access to coverage) and the total number of covered lives with preferred access to Symproic is more than 100 million, (out of more than 240 million with access to coverage).
- On November 22, 2019, our Board of Directors appointed Dr. Vanila Singh to join the Board and to serve on the Compensation Committee of the Board.
- On December 11, 2019, we announced the launch of *This Is Pain*, a long-term initiative that aims to improve the lives of over 10 million American adults living with chronic pain. As part of the initiative, actress Kristin Chenoweth is sharing her personal experience with chronic pain to help spread awareness around the disease.
- On December 19, 2019, we announced we had been selected for addition to the NASDAQ Biotechnology Index.
- On January 6, 2020, we announced the appointment of Kevin Ostrander as Senior Vice President of Business Development and member of the Company Executive Leadership Team.
- On February 27, 2020, we presented at the American Academy of Pain Medicine's (AAPM) 36th Annual Meeting, positive results of a study titled, "A Phase I Placebo-Controlled Trial Comparing the Effect of Buprenorphine Buccal Film and Oral Oxycodone Hydrochloride on Respiratory Drive".

- On March 09, 2020, we announced that we had appointed Jeffrey A. Bailey to our Board of Directors.

Our Products and Related Trends

Our current product portfolio currently consists of four products that are approved by the FDA. Three of our products utilize our patented BEMA thin film drug delivery technology.

BELBUCA

BELBUCA (buprenorphine buccal film) is a buccal film that contains buprenorphine, a Schedule III opioid, and was approved by the FDA in October 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. 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 to Schedule II opioids, which include oxycodone, hydrocodone and morphine;
- in published studies, investigators observed that respiratory depression from buprenorphine administration reached a plateau, and we believe 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 seven available strengths; and
- buccal administration to optimize buprenorphine delivery.

We believe that there are long-term growth opportunities for BELBUCA and we focus our commercial efforts primarily on BELBUCA. Our sales force is focused on current BELBUCA prescribers, chronic pain management specialists, and clinicians we believe have the greatest opportunity to be adopters of BELBUCA. As of January 2020, BELBUCA had formulary coverage for more than 96% of commercial lives.

The risks to our company associated with BELBUCA include: (i) inability to continue to manufacture adequate supplies for commercial use; (ii) unexpected product safety issues; (iii) failure of our sales force to effectively sell the product and, (iv) inadequate reimbursement. A technical or commercial failure of BELBUCA would have a material adverse effect on our future revenue potential and would negatively affect investor confidence in our company and our public stock price.

SYMPROIC

Symproic is a peripherally acting mu-opioid receptor antagonist, or PAMORA, and was approved by the FDA on March 23, 2017 for the treatment of opioid-induced constipation in adult patients with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation. OIC occurs primarily via activation of enteric mu-receptors in the small intestine and proximal colon, which results in harder stool and less frequent and less effective defecation. Because OIC results from the specific effects of opioids, it differs mechanistically from other forms of constipation, and deserves dedicated medical management. Compared to currently marketed products and products under development for OIC, we believe that Symproic is differentiated based on the following features:

- strong and durable efficacy observed in randomized, double-blind, placebo controlled clinical trials of 12 week and 52 week duration in OIC patients;
- OIC relief that was more frequent, more complete, with less straining than patients taking placebo
- recommended by the American Gastroenterological Association for patients with laxative refractory OIC;
- adverse event profile comparable to placebo, with low rates of abdominal pain observed across the phase III program; and
- the only prescription OIC medication with the convenience of once daily dosing, with only a tablet strength, and that can be taken with or without food and with or without laxatives.

Because of the durable efficacy, tolerability and convenience benefits, we believe that Symproic is a best-in-class PAMORA that reliably provides durable relief of OIC, which frees both the patient and the healthcare provider to focus on treating the patient's chronic pain.

We believe that there are long-term growth opportunities for Symproic. According to data from Symphony Health, in 2019 Symproic prescription volume grew over 60%, capturing 10% of the PAMORA market. In 2019 the PAMORA market declined by 3%, with over 585,000 PAMORA prescriptions dispensed. The growth rate of the PAMORAs has slowed, driven by a decline in opioid prescription rates. As of January 2020, Symproic had formulary coverage for more than 95% of commercial lives.

The risks to our company associated with Symproic include: (i) unexpected product safety issues; (ii) inability to continue to supply product in adequate quantities to meet the commercial demand; (iii) inability to manufacture adequate supplies for commercial use; (iv) failure of our sales force to effectively sell the product and, (v) inadequate reimbursement.

BUNAVAIL

In June 2014, BUNAVAIL (buprenorphine and naloxone buccal film) 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. BUNAVAIL contains the partial opioid agonist buprenorphine, which binds to the same receptors as opiate drugs but has a higher affinity, and naloxone, an opioid antagonist and an abuse deterrent. In March 2020, we announced that we are discontinuing marketing for BUNAVAIL.

ONSOLIS

In July 2009, ONSOLIS (fentanyl buccal soluble film) was approved for the management of pain that "breaks through" the effects of other medications being used to control persistent pain, or 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. We refer to breakthrough pain in opioid tolerant patients with cancer as 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. We are not currently assessing options for U.S. commercialization of ONSOLIS. Given current declining market conditions, we have no plans to introduce the product in the U.S. at this time. The product is no longer a strategic asset for the Company.

We will continue to seek additional license agreements. We anticipate that funding for the next several years will come primarily from earnings from sales of BELBUCA and Symproic, and milestone payments and royalties from Mylan and TTY.

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 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, inventory, fixed assets, 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 2019, 2018 or 2017.

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 2019, 2018 or 2017.

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. Refer to Note 1, “Nature of business and summary of significant accounting policies” for more information related to assumptions in applying the Black-Scholes option pricing model.

Fair Value of Financial Instruments

We 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. We consider the carrying amount of our cash and cash equivalents to approximate fair value due to short-term nature of this instrument.

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. Under the new guidance, we are required to evaluate the impact of estimating variable consideration related to our product sales and licensing contracts. We 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.

Refer to Note 1, “Nature of business and summary of significant accounting policies” for more information related to, (i) product sales, (ii) performance obligations, (iii) adjustments to product sales and (iv) gross to net accruals.

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 sales revenue of the PAINKYL product under the Company’s license agreement with TTY and the BREAKYL product under the Company’s 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. TTY and Mylan have the right to reject products that do not comply with product, packaging, or regulatory specifications. Defective product must be identified by TTY and Mylan within 10 days after inspection at their respective distribution sites. We bill TTY and Mylan immediately upon receipt by them of product (FOB manufacturer). On a quarterly basis, a reconciliation is prepared that reflects the difference between actual net sales by TTY and 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 TTY and Mylan). The parties “true-up” the differences within 45 days of each quarter-end.

Cost of Sales

Cost of sales in 2019 includes direct costs attributable to the production of BELBUCA, Symproic, BUNAVAIL, BREAKYL and PAINKYL. Cost of sales also includes royalty expenses owed to third parties.

For BELBUCA, Symproic 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, Symproic and BUNAVAIL. It also includes any batches not meeting specifications and raw material yield loss. Cost of sales for BELBUCA, Symproic and BUNAVAIL are recognized when sold to the wholesaler from our distribution center. There was no deferred cost of sales for the years ended December 31, 2019 nor 2018. Yield losses and batches not meeting specifications are expensed as incurred. For the year ended December 31,2019, depreciation expense included accelerated depreciation for BUNAVAIL specific equipment due to the March 2020 announcement to discontinue marketing of BUNAVAIL.

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

Refer to Note 13, “Income taxes” for more information related to (i) the impact of the Tax Act to our Company, (ii) reconciliation of the Federal statutory income tax rate to the effective rate, (iii) the tax effects of temporary differences and net operating losses that give rise to significant components of deferred tax assets and liabilities and (iv) our federal and state net operating loss carry forward (“NOLs”).

Results of Operations

For the Year Ended December 31, 2019 Compared to the Year Ended December 31, 2018

Product Sales. We recognized $107.9 million and $51.4 million in product sales during the years ended 2019 and 2018, respectively, from our products BELBUCA, Symproic and BUNAVAIL. The increase in 2019 is principally due to increased BELBUCA product sales and the acquisition of Symproic, which was partially offset by lower BUNAVAIL product sales, as well as additional reserves recorded in connection with the discontinuation of the marketing of BUNAVAIL.

Product Royalty Revenues. We recognized $3.3 million and $3.4 million in product royalty revenue during the years ended 2019 and 2018, respectively, which are composed of BREAKYL sales from Mylan and PAINKYL sales from TTY.

Contract Revenues. We recognized $0.2 million in contract revenue during the year ended 2019 related to milestone revenues associated with PAINKYL from TTY. We recognized $0.8 million in contract revenue during the year ended 2018, which was composed of $1.0 million in contract revenue related to our former license agreement with Purdue, offset by the reversal of $0.2 million in milestone revenue as a result of the termination of the aforementioned license agreement in March 2019.

Cost of Sales. We incurred $21.6 million and $15.8 million in cost of sales during the years ended 2019 and 2018, respectively. Cost of sales includes product cost, royalties paid, depreciation and yield adjustments. The increase in cost of sales is driven by the overall increase in gross sales as well as a one time acceleration of depreciation expense for certain BUNAVAIL specific equipment.

Selling, General and Administrative Expenses. During the years ended December 31, 2019 and 2018, selling, general and administrative expenses totaled $86.1 million and $58.6 million, respectively. Selling, general and administrative costs include BELBUCA, Symproic and BUNAVAIL sales, marketing, and commercial expenses. These costs also include legal expenses, professional fees, wages and stock-based compensation expense. The increase in selling, general and administrative expenses during 2019 is due primarily to the increase in compensation expense related to our expansion efforts, medical affairs expenses, increased marketing efforts and expenses related to the acquisition of Symproic.

Research and Development. We recognized $4.9 million of research and development expense during the year ended December 31, 2018 related to allocated wages and compensation for approved products and product candidates. There was no such research and development expense during the year ended December 31, 2019 due to the Company focusing entirely on commercialization of products beginning in 2019.

Interest Expense, Net. During the year ended December 31, 2019, we had net interest expense of $19.0 million, consisting of $11.9 million of one-time costs associated with the refinancing of our debt, $6.8 million of scheduled interest payments relating to both loans, $0.8 million of related amortization of discount and loan costs for both the old and new debt arrangements, and $0.4 million of warrant interest expense associated with the former CRG loan. The one-time expenses related to the payoff of the CRG loan consisted of $5.2 million in unamortized deferred loan fees, $3.9 million in unamortized warrant discount costs and $2.8 million in loan prepayment fees and realized losses, for a cumulative total of $11.9 million in one-time costs.

During the year ended December 31, 2019, we also had interest income of $0.9 million.

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, $3.0 million of related amortization of discount and loan costs and $1.1 million of warrant interest expense all related to the former debt arrangement.

Information pertaining to fiscal year 2017 was included in the Company's Annual Report on Form 10-K for the year ended December 31, 2018 on page 43 under Part II, Item 7, "Management's Discussion and Analysis of Financial Position and Results of Operations," which was filed with the SEC on March 14, 2019.

Refer to Note 12, "Net sales by product" for more information related to (i) net product sales for BELBUCA, Symproic and BUNAVAIL, and (ii) the percentages related to each product.

Medical Affairs Initiatives

In 2019, 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 clinical 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;
- Planning public policy initiatives and developing policy expertise in order to capitalize on federal and state tailwinds that focus on safer opioid options in chronic pain;
- Continuing to progress post-marketing requirements, or PMRs, and plans for BELBUCA, Symproic and BUNAVAIL; and
- Providing regulatory, pharmacovigilance, PV, and drug safety support for BELBUCA, Symproic, and ONSOLIS.

Our estimates of medical affairs initiatives, and our projected sales associated with each of our products 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 products at December 31, 2019:

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 (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 and possibly beyond. In addition, during the past year, we have completed a Phase 1 study looking at the change in minute ventilation between BELBUCA, oxycodone and placebo. Those results are being analyzed and interpreted and will be made publicly available in 2020. Additionally, three scientific manuscripts were submitted (and accepted) to tier-one pain journals in 2019 and will be published in 2020. Finally, four scientific abstracts regarding BELBUCA were submitted, accepted, and presented at PAINWeek 2019.

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. In March 2020, we announced that we were discontinuing marketing for BUNAVAIL.

SYMPROIC. In 2019 we submitted a scientific abstract to PAINWeek 2019 which was accepted and presented. In addition, we continued to advance an FDA post-marketing requirement (PMR) which is an observational study to access the risk of major adverse cardiovascular events (MACE) in naldemedine users.

Non-GAAP Financial Information:

We report our consolidated financial results in accordance with GAAP; however, we believe that earnings before interest, taxes, depreciation and amortization ("EBITDA") and other non-GAAP results should not be considered in isolation of or as an alternative for, earnings measures prepared in accordance with GAAP. Management uses these non-GAAP measures internally to measure the ongoing operating performance of our Company along with other metrics, and for planning and forecasting purposes. In addition, when evaluating non-GAAP results, we exclude certain items that are considered to be non-cash and if applicable, non-recurring, in nature.

EBITDA and Non-GAAP Income/(Loss):

We have presented EBITDA because it is a key measure used by our management and board of directors to understand and evaluate our operating performance and to develop operational goals for managing our business. We believe this financial

measure helps identify underlying trends in our business that could otherwise be masked by the effect of the expenses that we exclude. In particular, we believe that the exclusion of the expenses eliminated in calculating EBITDA can provide a useful measure for period-to-period comparisons of our core operating performance. Accordingly, we believe that EBITDA provides useful information to investors and others in understanding and evaluating our operating results, enhancing the overall understanding of our past performance and future prospects, and allowing for greater transparency with respect to key financial metrics used by our management in its financial and operational decision-making.

EBITDA is not prepared in accordance with GAAP, and should not be considered in isolation of, or as an alternative to, measures prepared in accordance with GAAP. There are a number of limitations related to the use of adjusted EBITDA rather than net income/(loss), which is the nearest GAAP equivalent. Some of these limitations are:

- EBITDA excludes depreciation and amortization and, although these are non-cash expenses, the assets being depreciated or amortized may have to be replaced in the future, the cash requirements for which are not reflected in EBITDA;
- EBITDA does not reflect provision for (benefit from) income taxes or the cash requirements to pay taxes; and
- EBITDA excludes net interest, including both interest expense and interest income.

Non-GAAP net income/(loss) is an alternative view of our performance that we are providing because management believes this information enhances investors' understanding of our results as it permits investors to better understand the ongoing operations of the business, the impact of any non-recurring one-time events, the cash results of the organization and is an additional measure used by management to assess performance.

Non-GAAP net income/(loss) is not prepared in accordance with GAAP, and should not be considered in isolation of, or as an alternative to, measures prepared in accordance with GAAP. There are a number of limitations related to the use of non-GAAP net income/(loss) rather than net income/(loss), which is the nearest GAAP equivalent. Some of these limitations are:

- Non-GAAP income/(loss) excludes certain one-time items because of the nature of the items and the impact that those have on the analysis of underlying business performance and trends. Specifically, in the presentation of non-GAAP income/(loss) for the year ended December 31, 2019, we have excluded the financial impact of our debt refinancing which closed in May 2019, as it is non-recurring. This excluded item is a significant component in understanding and assessing ongoing financial performance. The one-time expenses related to the payoff of the CRG loan consisted of $5.2 million in unamortized deferred loan fees, $3.9 million in unamortized warrant discount costs and $2.8 million in loan prepayment fees and realized losses, for a cumulative total of $11.9 million in one-time costs. Also during 2019, we have excluded the non-recurring financial impact of the BUNAVAIL discontinuation, for a cumulative total of $3.8 million. In the presentation of non-GAAP income/(loss) for the year ended December 31, 2017, we have excluded the financial impact of the fair value of the bargain purchase price of the BELBUCA acquisition which closed in January 2017, as it is non-recurring. This excluded item is also a significant component in understanding and assessing ongoing financial performance. The one-time gain related to the asset purchase price and fair value of assets acquired for a cumulative total of $27.3 million in a one-time gain;
- The expenses and other items that we exclude in our calculation of non-GAAP net income/(loss) may differ from the expenses and other items, if any, that other companies may exclude from non-GAAP net income/(loss) when they report their operating results since non-GAAP income/(loss) is not a measure determined in accordance with GAAP, and it has no standardized meaning prescribed by GAAP;
- We exclude stock-based compensation expense from non-GAAP net income/(loss) although (a) it has been, and will likely continue to be for the foreseeable future, a significant recurring expense for our business and an important part of our compensation strategy and (b) if we did not pay out a portion of our compensation in the form of stock-based compensation, the cash salary expense included in operating expenses would likely be higher, which would affect our cash position;
- We exclude amortization of intangible assets from non-GAAP net income/(loss) due to the non-cash nature of this expense and although it has been and will continue to be for the foreseeable future a recurring expense for our business, these expenses do not affect our cash position; and

- Amortization of warrant discount costs associated with the CRG loan which was dissolved in May 2019 are excluded given these expenses did not affect our cash position;

Reconciliations of non-GAAP metrics to most directly comparable U.S. GAAP financial measures:

The following tables reconcile net income/(loss)earnings and computations (in thousands) under GAAP to a Non-GAAP basis.

	Year Ended December 31,		
Reconciliation of GAAP net income/(loss) to EBITDA (non-GAAP)	**2019**	**2018**	**2017**
GAAP net income/(loss)	$ (15,305)	$ (33,867)	$ 5,285
Add back:			
Provision for income taxes	5	14	(15,972)
Net interest expense	19,036	10,206	(18,733)
Depreciation and amortization	8,748	6,188	6,119
EBITDA	$ 12,484	$ (17,459)	$ (23,301)
Reconciliation of GAAP net income/(loss) to Non-GAAP net income/(loss)			
GAAP net income/(loss)	(15,305)	(33,867)	5,285
Non-GAAP adjustments:			
Stock-based compensation expense	5,416	5,941	14,800
Amortization of intangible assets	6,981	5,157	5,425
Amortization of warrant discount	448	1,076	832
Non-recurring financial impact of debt refinance	11,866	—	—
Non-recurring financial impact of BUNAVAIL discontinuation	3,750	0	0
Non-recurring financial impact of bargain purchase gain	0	0	(27,336)
Non-GAAP net income/(loss)	$ 13,156	$ (21,693)	$ (994)

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 and the commercialization of our BELBUCA, Symproic and BUNAVAIL products. We intend to finance our commercialization and working capital needs from existing cash, earnings from the commercialization of BELBUCA and Symproic, 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.

At December 31, 2019, we had cash of approximately $63.9 million. We generated $11.1 million of cash in operations during the year ended December 31, 2019 and had stockholders' equity of $69.8 million, versus stockholders' equity of $29.7 million at December 31, 2018. 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 Symproic products, or other products which may be acquired or licensed by us, and for general working capital requirements. Based on agreements with our partners, the ability to scale up or reduce personnel and associated costs are factors considered throughout the product life cycle. Available resources may be consumed more rapidly than currently anticipated, potentially resulting in the need for additional funding.

Accordingly, while we don't anticipate that we will be required to raise additional capital in the near term, in the event funding is required, we believe it may be available to us through a variety of sources, including:

- public equity markets;
- private equity financings;
- commercialization agreements and collaborative arrangements;
- 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 2020 and beyond. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of such securities could result in ownership dilution to existing stockholders.

Term Loan Agreement

Refer to Note 11, “Notes payable” for more information related to (i) the 2017 CRG Servicing, LLC ("CRG") term loan agreement and payoff (ii) the 2019 Biopharma Credit plc ("Pharmakon") loan agreement, and (iii) the future maturities of notes payable obligations.

Contractual Obligations and Commercial Commitments

Our non-cancellable contractual obligations as of December 31, 2019 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	$ 949	$ 360	$ 589	$ —	$ —
Secured loan facility	60,000	—	13,846	46,154	—
Interest on secured loan facility	23,932	5,997	11,614	6,321	—
Minimum royalty expenses*	11,250	1,500	3,000	3,000	3,750
Purchase obligations**	1,885	1,363	522	—	—
Total contractual cash obligations	$ 98,016	$ 9,220	$ 29,571	$ 55,475	$ 3,750

* 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 U.S. The Federal Deposit Insurance Corporation covers $0.25 million for substantially all depository accounts. As of December 31, 2019, we had approximately $65.1 million, which exceeded these insured limits.

Foreign currency exchange risk

We currently have, and may in the future have increased, commercial, manufacturing and clinical agreements which are denominated in Euros 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 or Euro or other applicable currencies, or by weak economic

conditions in Europe or elsewhere in the world. Such amounts are currently immaterial to our financial position or results of operations. We are not currently engaged in any foreign currency hedging activities.

Market Risk

We do not engage in speculative transactions nor do we hold or issue financial instruments for trading purposes. In connection with the recapitalization of our business, we have entered into a secured credit facility consisting of a term loan. Our term loan note bears interest which includes fluctuating interest rates based on LIBOR.

There is currently uncertainty around whether LIBOR will continue to exist after 2021. However, if LIBOR ceases to exist, we will not be required to renegotiate our loan documents with our current lender.

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-37 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

The Company has established disclosure controls and procedures designed to ensure that information required to be disclosed in the reports that the Company files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and is accumulated and communicated to management, including the principal executive officer (our Chief Executive Officer) and principal financial officer (our Chief Financial Officer), to allow timely decisions regarding required disclosure.

Our management, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Annual Report on Form 10-K. Management recognizes that any disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives. Our disclosure controls and procedures have been designed to provide reasonable assurance of achieving their objectives. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2019.

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, 2019 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, 2019. 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, 2019.

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 6, 2020 are as follows:

Name	Age	Position(s) Held
Peter S. Greenleaf	50	Chairman of the Board and Director
Mark A. Sirgo, Pharm.D.	66	Vice Chairman of the Board and Director
Herm Cukier	53	Chief Executive Officer and Director
Scott M. Plesha	55	President and Chief Commercial Officer
Mary Theresa Coelho	58	Chief Financial Officer and Treasurer
Thomas B. Smith, M.D.	59	Chief Medical Officer
James Vollins	51	General Counsel, Chief Compliance Officer and Corporate Secretary
Frank E. O'Donnell, Jr., M.D.	70	Director
W. Mark Watson	69	Director
Todd C. Davis	59	Director
Kevin Kotler	48	Director
Vanila Singh, M.D., MAMC	49	Director

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

Peter S. Greenleaf, age 50, has been our Chairman of the Board and Director since May 2018. He has served as the Chief Executive Officer of Aurinia Pharmaceuticals, Inc., since April 2019. Previously, he served as the Chief Executive Officer of Cerecor, Inc., since March 2018 and 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 has been a member of the board of directors of Antares Pharma since December 2018. Mr. Greenleaf chairs the Maryland Venture Fund Authority and served as 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 66, has been our Director since August 2005 and Vice Chairman of the Board since October 2016. He has served as Chief Executive Officer of ArunA Bio since January 2019. Formerly, he served as 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, which includes clinical drug development, marketing, sales, and business development, and executive management positions. Prior to Arius Pharmaceuticals, from 2003 to 2004, he spent 16 years in a variety of positions of increasing responsibility in both clinical development and marketing at Glaxo, Glaxo Wellcome, and GlaxoSmithKline, including Vice President of International OTC Development and Vice President of New Product Marketing. Dr. Sirgo was responsible for managing the development and FDA approval of Zantac 75 while at Glaxo Wellcome, among other accomplishments. From 1996 to 1999, Dr. Sirgo was Senior Vice President of Global Sales and Marketing at Pharmaceutical Product Development, Inc. Dr. Sirgo served on the Board of Directors of Salix Pharmaceuticals, Inc., from 2008 until its sale in 2015. Dr. Sirgo was added to the Board of Directors of Biomerica, Inc., a diagnostics and therapeutic company, in July 2016 and as Chairman of the Board of RDD Pharma, Ltd., in April 2018. 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 53, 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 55, 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 58, has been our Chief Financial Officer and Treasurer 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 from October 2017 to October 2018. From September 2017 to October 2017, she served as Chief Operating Officer 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 October 2014 through August 2017, including as Chief Financial Officer for Diversey Care. 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 59, has been our 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., from January 2017 to July 2018 and from October 2014 to January 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 51, 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 70, 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 served as a Manager of The Hopkins Capital Group, an affiliation of limited liability companies that 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 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.

W. Mark Watson, CPA, age 69, joined our Board of Directors as an independent member in December 2017 and is Chairman of the Audit Committee. 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, the multinational professional services network, 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. 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 the American Institute of Certified Public Accountants and the Florida Institute of Certified Public Accountants. Mr. Watson is a member of the Board of Directors of Sykes Enterprises, Inc., and is a member of the Audit Committee. He is also Chairman of the Board of Directors and Chairman of the Audit Committee of Inhibitor Therapeutics, Inc. He received his undergraduate degree in Accounting from Marquette University.

Todd C. Davis, age 59, 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., Vaxart Inc., and Ligand Pharmaceuticals. He is also a board member of the Harvard Business School Healthcare Alumni Association.

Kevin Kotler, age 48, 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 served as a Director of Avadel Pharmaceuticals from December 2018 to October 2019 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 December 2016 to September 2018. Mr. Kotler earned a BS in Economics from the Wharton School at the University of Pennsylvania in 1993.

Vanila M. Singh, M.D., MAMC, age 49, joined our Board of Directors as an independent director in November 2019. Dr. Singh is currently a Clinical Associate Professor of Anesthesiology, Pain and Peri-operative Medicine at Stanford University School of Medicine and is a teaching mentor at Walter Reed National Military Medical Center. Dr. Singh is the immediate past Chief Medical Officer of the United States Department of Health and Human Services (HHS) and served as Chairperson of the Inter-Agency Pain Management Best Practices Task Force, chartered by Congress and involving multiple federal health agencies, professional medical organizations, and patient advocacy groups to guide the medical community and key stakeholders in optimal patient care in a growing and complex national health matter. Dr. Singh, board-certified in both anesthesiology and pain medicine, specializes in treating patients with complex chronic pain issues. She graduated from the University of California at Berkeley with a B.S. in both molecular and cell biology and economics. She received her M.D. from the George Washington University School of Medicine & Health Sciences. Dr. Singh completed her internal medicine internship at Yale University School of Medicine and her anesthesiology residency and pain medicine fellowship at Weill-Cornell New York Presbyterian Hospital, which included training at Memorial Sloan Kettering and the Hospital for Special Surgery.

Key Employees

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

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.

Kevin Ostrander joined our company in January 2020 as Senior Vice President, Business Development. Drawing on nearly 30 years of pharmaceutical industry experience in the areas of business development, licensing, regulatory affairs, marketing, project management and formulation/process development, Kevin leads our business development function with experience in closing more than 75 transactions across brand, generic and OTC markets. Prior to joining our company, Mr. Ostrander served in the role of Vice President of Business Development for Glenmark Pharmaceuticals Inc. USA, whereby he developed several strategic product partnerships for the US generics division, as well as, having closed multiple transactions in the branded prescription area to expand the company's US presence. Before joining Glenmark, Mr. Ostrander held positions of increasing responsibility with Sandoz Inc. (Division of Novartis), Mylan Specialty, Watson Pharmaceuticals, Cardinal Health, Elan Drug Delivery and Nycomed. Mr. Ostrander has been involved in the issuance of several US patents for his previous contributions in research and development. Mr. Ostrander received a Master of Business Administration degree in International Business from St. Joseph's University in Philadelphia, Pennsylvania, a Master of Science degree in Pharmaceutical Regulatory Affairs and Quality Assurance from Temple University School of Pharmacy, Philadelphia, Pennsylvania and a Bachelor of Science degree in Biology from the State University of New York at Albany.

Director Independence

We believe that Peter S. Greenleaf, W. Mark Watson, Todd C. Davis, Kevin Kotler and Dr. Vanila Singh 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 2019 and also acted by unanimous written consent. Each member of our board of directors was present 100% 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 2019 Annual Meeting of Stockholders.

Board Committees

Our board of directors has established three standing committees: Audit, Compensation, and Nominating and Corporate Governance. 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 seven times during 2019. Each member of the Audit Committee was present at 100% of the Audit Committee meetings held during such director's tenure in 2019 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 registered public accounting firm and engages such independent registered public accounting firm;
- 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 registered public accounting firm;

- monitors the independence of the independent registered public accounting firm and the rotation of partners of the independent registered public accounting firm 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 registered public accounting firm 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, W. Mark 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 five times in 2019 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 2019, we did not pay any fees to any third parties to assist in the identification of nominees.

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 four members: Todd C. Davis, Peter S. Greenleaf, Kevin Kotler and Dr. Vanila Singh. Todd C. Davis serves as chairman of this committee. The Compensation Committee met five times during 2019.

On November 22, 2019, upon the recommendation of its Nominating and Corporate Governance Committee, the Board appointed Dr. Vanila Singh to join the Board, effective as of November 22, 2019. The Board determined that Dr. Singh is independent under the listing standards of Nasdaq. Dr. Singh was also appointed to serve on the Compensation Committee of the Board. Effective as of November 22, 2019, the Compensation Committee of the Board is composed of Dr. Singh, Todd C. Davis, Peter S. Greenleaf and Kevin Kotler.

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 2019, the Compensation Committee engaged Willis Towers Watson (or "WTW") 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 WTW of $0.009 million in 2019.

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 2019, all Forms 3, 4 and 5 were timely filed with the SEC by such reporting person, with the exception of Dr. Vanila Singh, who filed a Form 3, which was due December 2, 2019 on December 3, 2019, and a Form 4, which was due on November 26, 2019, on December 9, 2019.

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.

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, 2019, 2018 and 2017. Individuals we refer to as our "named executive officers" include our Chief Executive Officer, our Chief Financial Officer, our former Chief Financial Officer who served as Principle Accounting 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, 2019.

Summary Compensation Table

Name and principal position	Year	Salary ($)	Bonus ($)	Stock Awards ($)(10)	Option Awards ($)(10)	Non-Equity Incentive Plan Compensation ($)	Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Herm Cukier, Chief Executive Officer and Director	2019	582,496	—	433,125	1,549,800	—	355,135 (1)	16,966 (2)	2,937,522
	2018	359,539	50,000 (3)	526,000	1,288,000	—	231,050	14,459	2,469,048
Terry Coelho, Chief Financial officer and Treasurer	2019	362,022	—	235,400	282,768	—	190,575 (1)	34,198 (4)	1,104,963
Scott M. Plesha, President and Chief Commercial Officer	2019	375,669	—	184,800	703,150	—	205,200 (1)	35,040 (5)	1,503,859
	2018	371,080	—	332,813	—	—	180,675	34,423	918,991
	2017	296,920	—	92,500	—	—	83,138	32,466	505,024
Thomas Smith, M.D., Chief Medical Officer	2019	352,564	—	106,260	373,100	—	156,200 (1)	25,326 (6)	1,013,450
	2018	139,327	25,000 (3)	—	165,944	—	50,094	3,441	383,806
James Vollins, General Counsel, Chief Compliance Officer and Corporate Secretary	2019	310,714	—	53,130	186,550	—	148,800 (1)	29,563 (7)	728,757
	2018	41,731	35,000 (3)	—	210,269	—	—	351	287,351
Ernest DePaolantonio, Former Principle Accounting Officer (8)	2019	127,385	—	120,500	—	—	—	410,250 (9)	658,135
	2018	370,000	162,800	294,000	—	—	—	32,790	859,590
	2017	350,000	98,000	351,500	—	—	—	32,632	832,132

(1) The bonus represents 2019 earned amounts but paid in 2020.

(2) Includes: $2,615 of health insurance premiums paid, $351 telephone reimbursement and 401(k) matching of $14,000 paid in 2019.

(3) The bonus represents paid sign-on amounts.

(4) Includes: $18,037 of health insurance premiums paid, $2,161 telephone reimbursement and 401(k) matching of $14,000 paid in 2019.

(5) Includes: $18,760 of health insurance premiums paid, $2,280 telephone reimbursement and 401(k) matching of $14,000 paid in 2019.

(6) Includes: $9,045 of health insurance premiums paid, $2,280 telephone reimbursement and 401(k) matching of $14,000 paid in 2019.

(7) Includes: $23,706 of health insurance premiums paid, $2,280 telephone reimbursement and 401(k) matching of $14,000 paid in 2019.

(8) Mr. DePaolantonio served as Principle Accounting Officer until January 2019. He served as a consultant during the transition to our new CFO, and he officially retired on April 30, 2019.

(9) Includes $360,000 severance paid, $23,426 vacation paid, $12,009 of health insurance premiums paid. $814 telephone reimbursement and 401(k) matching of $14,000 paid in 2019.

(10) 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 2019

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 ($) (4)	Maximum ($)	Threshold (#)	Target (#)	Maximum (#)					
	1/31/2019 (1)								540,000	$ 3.90	$ 4.62	$ 1,549,800
Herm Cukier	1/31/2019 (2)							93,750				$ 433,125
			322,905									
	1/17/2019 (1)								107,109	$ 3.73	$ 4.28	$ 282,768
Terry Coelho	1/17/2019 (2)							55,000				$ 235,400
			173,250									
	1/31/2019 (1)								245,000	$ 3.90	$ 4.62	$ 703,150
Scott Plesha	1/31/2019 (2)							40,000				$ 184,800
			170,820									
	1/31/2019 (1)								130,000	$ 3.90	$ 4.62	$ 373,100
Thomas Smith, M.D.	1/31/2019 (2)							23,000				$ 106,260
			142,140									
	1/31/2019 (1)								65,000	$ 3.90	$ 4.62	$ 186,550
James Vollins	1/31/2019 (2)							11,500				$ 53,130
			124,000									
Ernest DePaolantonio	2/28/2019 (3)							25,000				$ 120,500

(1) The stock awards disclosed in this item consist of options, as issued under our 2011 Equity Incentive Plan, which vest ratably in thirds beginning January 2020.

(2) The stock awards disclosed in this item consist of time-based restricted stock units, as issued under our 2011 Equity Incentive Plan, which vest ratably in thirds beginning January 2020.

(3) The stock awards disclosed in this item consist of time-based restricted stock units, as issued under our 2011 Equity Incentive Plan, which immediately vested upon Mr. DePaolantonio's retirement April 30, 2019.

(4) This column sets forth the target bonus amount for each NEO for the year ended December 31, 2019 under the performance bonus plan. There are no thresholds or maximum bonus amounts for each individual officer established under the performance bonus plan. Target bonuses were set as a percentage of each NEO's base salary earned for the fiscal year ended December 31, 2019. The dollar value of the actual bonus award earned for the year ended December 31, 2019 for each NEO is set forth in the Summary Compensation Table above. As such, the amounts set forth in this column do not represent either additional or actual compensation earned by the NEOs for the year ended December 31, 2019.

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 included 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. During 2020, the Compensation Committee approved to adjust Mr. Cukier's base salary to $608,719, which was a 3.7% increase from 2019 and an amount consistent with our compensation philosophy.

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 (as defined in the agreement), we cannot terminate Mr. Cukier for cause unless we have 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 (as defined in the agreement) 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 of the date Mr. Cukier learns 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 (i) 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), (ii) his pro-rated bonus through the date of termination and (iii) 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; provided that, in that event, Mr. Cukier (or his estate, as applicable) shall be entitled to receive a prorated bonus at target for the year in which such termination occurs and any earned but unpaid bonus for the fiscal year prior to the fiscal year in which such termination occurred.

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). We shall also pay Mr. Cukier 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 RSUs and other performance-based equity awards shall accelerate and vest in full.

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).

Terry Coelho, Chief Financial Officer – Ms. Coelho’s employment agreement, dated January 10, 2019 includes a base salary of $385,000, target bonus of up to 45% of her base salary (which is subject to modification by our Compensation Committee), and other employee benefits. During 2020, the Compensation Committee approved to adjust Ms. Coelho's base salary to $399,245, which was a 3.7% increase from 2019 and an amount consistent with our compensation philosophy.

Except in the event of a termination by us for Cause (as defined in the agreement), we or Ms. Coelho may terminate her agreement for any reason or no reason upon thirty (30) days prior written notice to the other. Ms. Coelho cannot terminate her employment for Good Reason (as defined in the agreement) unless she has provided written notice to us of the existence of the circumstances providing grounds for termination for Good Reason within sixty (60) days of the date Ms. Coelho learns 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 Ms. Coelho does not terminate her employment for Good Reason within ninety (90) days after the date Ms. Coelho learns of the first occurrence of the applicable grounds, then Ms. Coelho will be deemed to have waived her right to terminate for Good Reason with respect to such grounds.

In the event of a termination by us for Cause or Ms. Coelho’s resignation without Good Reason, we will pay Ms. Coelho (i) the base salary earned and expenses reimbursable incurred through the date of Ms. Coelho’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 Ms. Coelho.

In the event of a termination by us without Cause, as a result of her death or disability or resignation by Ms. Coelho for Good Reason: We shall pay Ms. Coelho a one-time cash severance payment equal to one (1) times the amount of her then current annual base salary (or, in the event of a resignation by Ms. Coelho for Good Reason as a result of a reduction in Ms. Coelho's base salary, one (1) times the amount of her annual base salary prior to the reduction that gave rise to grounds for Good Reason). We shall pay Ms. Coelho on the payment date her pro-rated bonus through the date of termination and her prior year bonus (if applicable).

In the event that Ms. Coelho's employment with the Company is terminated by the Company or its successor without Cause, or by Ms. Coelho 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), Ms. Coelho will be entitled to receive a one-time severance payment equal to (i) one and a half (1.5) times her base salary plus (ii) her bonus for the applicable year (calculated at 100% of target). In addition, all unvested time-based options, RSUs and other equity-based awards shall immediately become fully vested and exercisable and shall be exercisable over a period of three (3) years.

Ms. Coelho's employment agreement also includes 2-year non-competition and non-solicitation and confidentiality covenants. Under the terms of this agreement, she 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 included 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. During 2020, the Compensation Committee approved to adjust Mr. Plesha's base salary to $394,060, which was a 3.8% increase from 2019 and an amount consistent with our compensation philosophy.

We may terminate Mr. Plesha's employment agreement without cause and Mr. Plesha is required to give (thirty) 30 days' notice of any resignation. We may immediately terminate Mr. Plesha's employment agreement for 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 Cause or due to his death or disability, 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 plus a prorated target annual bonus.

In the event that Mr. Plesha'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), Mr. Plesha will be entitled to receive a one-time cash severance payment equal to his then current annual base salary plus a prorated target bonus. In addition, all unvested options and 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. 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 23, 2018 included 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. During 2020, the Compensation Committee approved to adjust Dr. Smith's base salary to $376,300, which was a 5.9% increase from 2019 and an amount consistent with our compensation philosophy.

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, including due to his death or disability, 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 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 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 October 25, 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. During 2020, the Compensation Committee approved to adjust Mr. Vollins' base salary to $337,900, which was a 9.0% increase from 2019 and an amount consistent with our compensation philosophy.

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, including due to his death or disability, 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 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 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).

Amended and Restated 2001 Incentive Plan

Our original Amended and Restated 2001 Incentive Plan ("2001 Plan") expired in 2011. Options to purchase 108,535 shares of common stock were outstanding and exercisable as of December 31, 2019 under the 2001 Plan. No additional shares may be issued under the 2001 Plan.

2011 Equity Incentive Plan

In July 2011, our stockholders approved our 2011 Equity Incentive Plan, as amended ("2011 EIP"). Our 2011 EIP was originally comprised of 4,200,000 shares of our common stock. In July 2013, 2014, 2015 and December 2017, our stockholders approved increases to our 2011 EIP in the amounts of 2,600,000, 2,000,000, 2,250,000 and 7,100,000, respectively. In July 2019, our stockholders approved our 2019 Stock Option Incentive Plan ("2019 Plan") discussed below. As a result, no additional shares may be issued under the 2011 EIP. Options to purchase 4,369,045 shares of common stock were outstanding and exercisable as of December 31, 2019 under the 2011 EIP.

2019 Equity Incentive Plan

During the 2019 Annual Meeting of Stockholders, shareholders approved the Company's 2019 Plan, which reserves 14,000,000 shares of stock for issuance under the 2019 Plan.

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 issued during 2019 to directors and employees under the 2011 EIP totaled 1,379,834 shares, at exercise prices ranging from $3.51 to $4.96. Options issued during 2019 to directors and employees under the 2019 Plan totaled 1,008,918 shares, at exercise prices ranging from $3.96 to $6.23.

Options to purchase 5,496,971 shares of our common stock under the 2001 Plan, 2011 EIP and 2019 Plan, at prices ranging from $1.78 to $16.47, are outstanding at December 31, 2019.

Outstanding equity awards

The following table summarizes outstanding unexercised options, unvested stock and equity incentive plan awards held by each of our named executive officers, as of December 31, 2019.

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 ($)
Herm Cukier	228,205	533,334	—	2.18	6/14/2028	—	—	—	—
	—	540,000	—	3.90	1/31/2029	—	—	—	—
	—	—	—	—	—	—	—	133,334 (2)	842,671
	—	—	—	—	—	93,750 (3)	—		592,500
Terry Coelho	—	107,109	—	3.73	1/17/2029	—	—	—	—
	—	—	—	—		55,000 (4)	—	—	347,600
Scott Plesha	—	245,000	—	3.90	1/31/2029	—	—	—	—
	—	—	—	—	—	8,334 (5)	—	8,334 (5)	123,336
	—	—	—	—	—	41,667 (6)	—	41,667 (6)	462,500
	—	—	—	—	—	40,000 (3)	—		252,800
Thomas Smith, M.D.	39,230	78,461	—	2.93	8/1/2028	—	—	—	—
	—	130,000	—	3.90	1/31/2029	—	—	—	—
	—	—	—	—	—	23,000 (3)	—	—	145,360
James Vollins	—	59,651	—	3.46	11/5/2028	—	—	—	—
	—	65,000	—	3.90	1/31/2029	11,500 (3)	—	—	72,680
Ernest DePaolantonio	55,659	—	—	5.39	10/17/2023	—	—	—	—
	—	—	—	—	—	—	—	54,999 (7)	347,594

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

(2) Unvested stock awards consist of Restricted Stock Units ("RSUs") (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 2020 through 2021.

(3) 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 2020.

(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 January 2020.

(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 which began 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 which began 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) Unvested stock awards consist of RSUs (as defined under the 2011 EIP), which are rights to acquire shares of our common stock. These time-based RSUs vest March 2020.

Option Exercises and Stock Vested

The following information sets forth stock options exercised by the executive officers during the year ended December 31, 2019:

	OPTION AWARDS		STOCK AWARDS	
Name	**Number of Shares Acquired on Exercise (#)**	**Value Realized on Exercise ($)**	**Number of Shares Acquired on Vesting (#)**	**Value Realized on Vesting ($)**
Herm Cukier	38,461	178,596	66,666	314,664
Terry Coelho	—	—	—	—
Scott Plesha	—	—	69,998	343,234
Thomas Smith, M.D.	—	—	—	—
James Vollins	29,825	78,441	—	—
Ernest DePaolantonio	—	—	221,816	1,082,317

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, 2019 and (ii) the stock price was $6.32, which was the closing market price of our common stock on December 31, 2019, the last business day of the 2019 fiscal year.

Name	Termination Without Cause ($)	Resignation With Good Reason ($)	Termination Following a Change in Control ($)	Termination Following Death or Disability ($)
Herm Cukier				
Cash severance payment	$ 1,174,200	$ 1,174,200	$ 1,174,200	$ —
Bonus (3)	322,905	322,905	322,905	322,905
Accrued and unused vacation time	22,581	22,581	22,581	22,581
Acceleration of options (1)	4,459,571	4,459,571	4,459,571	—
Acceleration of restricted stock units (2)	—	—	676,771	—
Total Cukier cash and benefits	**$ 5,979,257**	**$ 5,979,257**	**$ 6,656,028**	**$ 345,486**
Terry Coelho				
Cash severance payment	385,000	385,000	577,500	385,000
Bonus	173,250	173,250	173,250	173,250
Accrued and unused vacation time	14,808	14,808	14,808	14,808
Acceleration of options (1)	—	—	277,412	—
Acceleration of restricted stock units (2)	—	—	347,600	—
Total Coelho cash and benefits	**$ 573,058**	**$ 573,058**	**$ 1,390,570**	**$ 573,058**
Scott Plesha				
Cash severance payment	$ 379,600	$ —	$ 379,600	$ 379,600
Bonus	170,820	—	170,820	170,820
Accrued and unused vacation time	14,600	14,600	14,600	14,600
Acceleration of options (1)	—	—	592,900	—
Acceleration of restricted stock units (2)	—	—	884,813	—
Total Plesha cash and benefits	**$ 565,020**	**$ 14,600**	**$ 2,042,733**	**$ 565,020**
Thomas Smith, MD.				
Cash severance payment	$ 355,350	$ 0	$ 355,350	$ 355,350
Pro-rata bonus	142,140	—	142,140	142,140
Accrued and unused vacation time	13,667	13,667	13,667	13,667
Acceleration of options (1)	—	—	713,572	—
Acceleration of restricted stock units (2)	—	—	145,360	—
Total Smith cash and benefits	**$ 511,157**	**$ 13,667**	**$ 1,370,089**	**$ 511,157**
James Vollins				
Cash severance payment	$ 310,000	$ 0	$ 310,000	$ 310,000
Bonus	124,000	0	124,000	124,000
Accrued and unused vacation time	11,923	11,923	11,923	11,923
Acceleration of options (1)	0	0	327,902	0
Acceleration of restricted stock units (2)	—	—	72,680	0
Total Vollins cash and benefits	**$ 445,923**	**$ 11,923**	**$ 846,505**	**$ 445,923**
Ernest DePaolantonio (4)	**—**	**—**	**—**	**—**
Total Mr. DePaolantonio cash and benefits	**$ —**	**$ —**	**$ —**	**$ —**

(1) Determined by taking the excess of the fair market value of our common stock on December 31, 2019, less the exercise price of each accelerated option, multiplied by the number of unvested shares subject to outstanding options.

(2) Determined by taking the fair market value of our common stock on December 31, 2019, multiplied by the number of shares subject to invested RSUs.

(3) Mr. Cukier is entitled to a pro-rated bonus upon death or disability.

(4) Pursuant to Mr. DePaolantonio's retirement on April 30, 2019, he was not a party to an employment agreement or change of control benefits as of December 31, 2019.

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 – 23:1

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), total compensation in fiscal year 2019 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 45 of this Report. Pay elements that were included in the annual total compensation for each employee are:

- annualized salary in fiscal year 2019;
- annual bonus payment received for performance in fiscal year 2019;
- grant date fair value of stock option exercises and RSU grants in fiscal year 2019;
- company-paid 401(k) Plan match made during fiscal year 2019; and
- auto and phone allowance paid in fiscal year 2019.

Our calculation includes all employees as of December 31, 2019.

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 170 employees), and we used ranked employee number 85 on the list as our (“Median Employee”). In 2019, we experienced a modest increase in our headcount. The annualized total compensation for fiscal year 2019 for our CEO was $2,937,522 and for the Median Employee was $127,193. We estimate that the resulting ratio of our CEO’s pay to the pay of our Median Employee for fiscal year 2019 is 23 to 1.

Compensation of Directors Summary Table

DIRECTOR COMPENSATION

2019 Director Compensation Table

The following table presents and summarizes the compensation of our non-employee directors for service during 2019.

Name (a)	Fees Earned or Paid in Cash ($)		Stock Awards ($) (13)		Option Awards ($) (13)		Non-Equity Incentive Plan Compensation ($)	Non-Qualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Peter S. Greenleaf (1)	72,500		—		—		—	—	—	72,500
Mark A. Sirgo, PharmD. (2)	51,250		210,600	(3)	58,275	(4)	—	—	—	320,125
Frank E. O'Donnell, Jr. (5)	53,750		210,600	(3)	58,275	(4)	—	—	—	322,625
W. Mark Watson (6)	70,000		—		—		—	—	—	70,000
Todd C. Davis (7)	75,000		—		—		—	—	—	75,000
Kevin Kotler (8)	62,500		—		—		—	—	—	62,500
Vanila Singh, M.D. MAMC (9)	4,298	(10)	99,360	(11)	347,520	(12)	—	—	—	451,178

(1) Mr. Greenleaf holds 50,000 unexercisable options and 87,500 unvested RSUs.

(2) Dr. Sirgo holds 11,250 unexercisable options and 58,971 unvested RSUs.

(3) The stock awards disclosed in this item consists of 45,000 RSUs issued in 2019 with a FMV of $4.68 for serving on the board which half vested in 2019 and the remaining half vest in 2020.

(4) The stock options disclosed in this item consists of 22,500 options granted in 2019 with a FMV of $2.59 which half vested in 2019 and the remaining half vest in 2020.

(5) Dr. O'Donnell holds 11,250 unexercisable options and 225,784 unvested RSUs.

(6) Mr. Watson holds 37,500 unexercisable options and 75,000 unvested RSUs.

(7) Mr. Davis holds 37,500 unexercisable options and 75,000 unvested RSUs.

(8) Mr. Kotler holds 37,500 unexercisable options and 75,000 unvested RSUs.

(9) Dr. Vanila Singh was appointed member of our Board of Directors effective November 22, 2019, and holds 96,000 unexercisable options and 16,000 unvested RSUs.

(10) Dr. Vanila Singh was appointed member of our Board of Directors effective November 22, 2019. The fees disclosed were earned in 2019 and paid in 2020.

(11) The stock awards disclosed in this item consists of 16,000 RSUs issued in 2019 with a FMV of $6.21 for being appointed to the Board of Directors, which vest ratably in thirds from 2020-2022.

(12) The stock options disclosed in this item consists of 96,000 options issued in 2019 with a FMV of $3.62 for being appointed to the Board of Directors, which vest ratably in thirds from 2020-2022.

(13) 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 2019 follows (all annual cash retainers are paid quarterly in arrears):

- $45,000 annual cash retainer to each board member.
- $25,000 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.
- 8,000 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.
- 48,000 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.

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, 2019 was 141,000, which vests between April 2020 to November 2022.

The total number of RSUs granted to members of our board of directors during the year ended December 31, 2019 was 106,000 which vests between April 2020 to November 2022.

In early 2019, the Compensation Committee revised its existing equity grant philosophy to provide the board of directors with equity compensation in line with the 75th percentile of our peer group. As part of that decision, the Compensation Committee also decided all future equity awards to the board of directors would be comprised of 75% options and 25% RSUs.

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.

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, 2019.

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

Todd C. Davis, Chairman
Peter C. Greenleaf
Kevin Kotler
Dr. Vanila Singh

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 five executive officers, each of whom served as a "Named Executive Officer" (or NEO) for purposes of SEC reporting during 2019: (1) Herm Cukier, our Chief Executive Officer; (2) Terry Coelho, our Chief Financial Officer; (3) Scott Plesha, our President and Chief Commercial Officer; (4) Dr. Thomas Smith, our Chief Medical Officer; and (5) James Vollins, our General Counsel, Chief Compliance Officer and Corporate Secretary. Our former Chief Financial Officer, Ernest De Paolantonio, served as Principal Financial Officer in 2019 during the transition until our new Chief Financial Officer, Terry Coelho started January 15, 2019.

This Compensation Discussion and Analysis sets forth a discussion of the compensation for our NEOs as of December 31, 2019 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 Willis Towers Watson (which we refer to herein as WTW) 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. WTW is a recognized independent consulting company and services clients throughout the U.S.

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, 2019 was approved by the Compensation Committee in September 2017 and includes the following companies:

Company	
AcelRx Pharmaceuticals, Inc.	Cumberland Pharmaceuticals, Inc.
Adamis Pharmaceuticals	DURECT Corporation
Alimera Sciences, Inc.	KemPharm
Antares Pharma, Inc.	Neos Therapeutics, Inc.
BioCryst Pharmaceuticals, Inc.	Recro Pharma
Collegium Pharmaceutical	Sorrento Therapeutics
Corium	Strongbridge BioPharma plc
CTI BioPharma Corp.	Vivus, Inc.

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 relied on WTW 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 four main components: base salary, performance cash bonuses, long-term compensation in the form of stock options or restricted stock units (or RSUs) and benefit programs. We believe these 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. The LTIP concluded with the 2019 performance period. We also provide certain of our executive officers with severance and change in control arrangements because we believe that, in a competitive market for talent, severance arrangements are necessary to attract and retain high quality executives. In addition, the change in control benefit allows and incentivizes executives to maintain their focus on our business during a period when they otherwise might be distracted.

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 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 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.

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.

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 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.

Equity Incentive Compensation

We view long-term compensation 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. Our current equity program consists 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). 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. In July 2019 at the Annual Meeting of Stockholders, stockholders approved the 2019 Stock Option and Incentive Plan, which we refer to herein as the Plan. Equity awards in 2019 were granted under our 2011 Equity Incentive Plan and under our Plan.

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 29, 2020, the Compensation Committee determined that 1/3rd of each of the 2017 and 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.

During 2019, we granted solely time-based equity incentive awards.

Performance Long Term Incentive Plan

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. 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 lasted through our fiscal year ended December 31, 2019. The total number of Performance RSUs covered by the LTIP was 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 were 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 2019, a cumulative total of 194,637 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). A cumulative total of 818,363 unvested LTIP shares were returned back to the 2019 Plan pool.

Post-Termination Payments

In addition to the main components of compensation outlined above, we also provide contractual severance and/or change in control benefits to the NEOs. 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.

Other Benefits

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.

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 external 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 consultant, 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 industry survey data for below-executive level personnel, which data focuses on similarly-sized life science companies in the Southeastern region of the U.S. 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 not 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 2019 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.

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 2020, see "Equity Awards in January 2020" under "Compensation Decisions For Performance in 2019" 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 vested, if earned, on the first open trading window after filing our Annual Report on Form 10-K, and valued using the closing stock price the day proceeding the vest date. 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 board meeting of the year, our board of directors and the Compensation Committee, review 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 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 WTW of $0.009 million in 2019. 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 2019

General Assessment of Management Performance in 2019

The Compensation Committee and our board of directors conducted the performance and compensation review for 2019 in January 2020. The Compensation Committee compared performance as elaborated below.

These non-weighted key corporate objectives for 2019 included the following:

(1) Key financial objectives including targeted revenue of $101 million, (2) commercial objectives including BELBUCA sales of $93 million, (3) organizational objectives including the addition of new commercial product to portfolio, (4) favorable refinance of debt position. and (5) the development of a long-term enterprise strategy.

The Compensation Committee determined that the Company had achieved 100% of all 2019 key objectives as established and exceeded expectations of targeted performance measures.

2019 Cash Bonus Calculations

After reviewing the achievement of the corporate goals and objectives for 2019 as noted above, and after taking into account the individual performance ratings of each NEO, the Compensation Committee determined that all NEOs should be awarded a cash bonus between 110%-120% of their target. 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 2019 performance (but paid in March 2020) was approximately $1.1 million for NEOs and approximately $1.1 million for employees.

Equity Awards in January 2020

On January 29, 2020, the total amount of stock options awarded to our NEOs and senior executives was 1,039,555, 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 $3.5 million.

The total amount of the RSUs awarded to our NEOs and senior executives was 213,769, having an approximate value on the date preceding the grant of $1.2 million based on a share price of $5.52.

All RSUs and stock options awarded in January 2020 were granted pursuant to the Plan.

Individual Compensation of Herm Cukier, our Chief Executive Officer

Mr. Cukier received a base salary of $587,100 in 2019.

Mr. Cukier was awarded a cash bonus for 2019 in the amount of $355,135, which is 110% of his target bonus of 55% of his base salary in 2019, a calculation consistent with our cash bonus policy. Mr. Cukier was also granted in January 2020, 440,490 stock options and 90,580 RSUs, which are subject to time-based vesting.

Individual Compensation of Terry Coelho, our Chief Financial Officer

Ms. Coelho received a base salary of $385,000 in 2019.

Ms. Coelho was awarded a cash bonus for 2019 in the amount of $190,575, which is 110% of her target bonus of 45% of her base salary in 2019, a calculation consistent with our cash bonus policy. Ms. Coelho was also granted in January 2020, 148,665 stock options and 30,571 RSUs, which are subject to time-based vesting.

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

Mr. Plesha received a base salary of $379,600 in 2019.

Mr. Plesha was awarded a cash bonus for 2019 in the amount of $205,200, which is 120% of his target bonus of 45% of his base salary in 2019, a calculation consistent with our cash bonus policy. Mr. Plesha was also granted in January 2020, 158,576 stock options and 32,609 RSUs, which are subject to time-based vesting.

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

Dr. Smith received a base salary of $355,300 in 2019.

Dr. Smith was awarded a cash bonus for 2019 in the amount of $156,200, which is 110% of his target bonus of 40% of his base salary in 2019, a calculation consistent with our cash bonus policy. Dr. Smith was also granted in January 2020, 110,122 stock options and 22,645 RSUs, which are subject to time-based vesting.

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

Mr. Vollins received a base salary of $310,000 in 2019.

Mr. Vollins was awarded a cash bonus for 2019 in the amount of $148,800, which is 120% of his target bonus of 40% of his base salary in 2019, a calculation consistent with our cash bonus policy. Mr. Vollins was also granted in January 2020, 121,135 stock options and 24,909 RSUs, which are subject to time-based vesting.

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.

Clawback Policy

If we are required to prepare an accounting restatement due to the material non-compliance of ours with any financial reporting requirement and/or intentional misconduct by a covered officer, then the Independent Director Committee may require any covered officer to repay to us any excess compensation.

The Independent Director Committee may take into account any factors it deems reasonable in determining whether to seek recoupment of previously paid excess compensation and how much excess compensation to recoup from individual covered officers (which need not be the same amount or proportion for every covered officer), including any conclusion by the Committee that a covered officer engaged in wrongdoing or committed grossly negligent acts or omissions. The amount and form of the compensation to be recouped shall be determined by the Independent Director Committee in its discretion, and recoupment of compensation paid as annual cash bonuses or long term incentives may be made, in the Committee's discretion, through cancellation of vested or unvested stock options, cancellation of unvested restricted stock, cancellation of unvested restricted stock units and/or cash payment.

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

The following table sets forth, as of March 6, 2020, 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 of Beneficial Owner	Amount and Nature of Beneficial Ownership	Percentage of Class as of March 6, 2020,(1)
Blackrock Inc. (2)	7,304,342	7.58 %
Broadfin Capital, LLC (3)	6,722,289	6.98 %
Nantahala Capital Management (4)	4,846,167	5.03 %
Herm Cukier (5)	510,652	*
Mary Theresa Coelho (6)	12,018	*
Scott M. Plesha (7)	345,670	*
Thomas Smith, M.D. (8)	87,302	*
James Vollins (9)	25,500	*
Peter S. Greenleaf (10)	38,952	*
Mark A. Sirgo, Pharm.D. (11)	1,559,595	1.62 %
Frank E. O'Donnell, Jr., M.D.(12)	767,038	*
W. Mark Watson (13)	53,219	*
Todd C. Davis (14)	248,537	*
Kevin Kotler (15)	6,732,912	6.99 %
Vanila Singh, M.D. MAMC (16)	—	*
All Directors and Officers as a group (12 persons)	10,381,395	10.66 %

* Less than 1%

(1) Based on 96,344,995 shares of Common Stock outstanding as of March 6, 2020 and shares beneficially owned by the referenced parties as described below.

(2) Based on 13G filed by Blackrock Inc. with the SEC on February 7, 2020.

(3) Based on 13F/A filed by Broadfin Capital, LLC with the SEC on December 23, 2019. Includes 2,422,223 shares of Common Stock issuable upon conversion of 436 shares of Series B Preferred Stock beneficially owned by Broadfin Capital LLC.

(4) Based on 13G filed by Nantahala Capital Management with the SEC on February 14, 2020.

(5) Mr. Cukier is our Chief Executive Officer and a director.

(6) Ms. Coelho is our Chief Financial Officer.

(7) Mr. Plesha is our President.

(8) Dr. Smith is our Chief Medical Officer

(9) Mr. Vollins is our General Counsel, Chief Compliance Officer and Corporate Secretary.

(10) Mr. Greenleaf is our Chairman of the Board and a director.

(11) Dr. Sirgo is our Vice Chairman and a director.

(12) Dr. O'Donnell is a director.

(13) Mr. Watson is a director.

(14) Mr. Davis is a director.

(15) Mr. Kotler is a director.

(16) Dr. Vanila Singh became our director on November 22, 2019.

The following table sets forth, as of March 6, 2020, each of our directors and executive officers, (i) shares owned, (ii) options exercisable within 60 days, and (iii) RSUs vesting within 60 days, as included in the beneficial ownership table. Additionally, (i) options unexercisable and (ii) RSUs unvested are disclosed.

Name of Director or Officer	Included in beneficial ownership table: Shares owned		Options exercisable within 60 days	RSUs vesting within 60 days	Total	Not included in beneficial ownership table: Options unexercisable	RSUs unvested	
Herm Cukier	35,781		408,205	66,666	510,652	793,824	219,748	(1)
Mary Theresa Coelho	12,018		—	—	12,018	220,071	67,238	
Scott M Plesha	205,669		81,667	58,334	345,670	321,909	100,943	(1)
Thomas Smith , M.D.	4,739		82,563	—	87,302	275,250	37,979	
James Vollins	3,833		21,667	—	25,500	224,119	32,576	
Peter S Greenleaf	24,788		14,164	—	38,952	50,000	87,500	
Mark A Sirgo, Pharm.D.	1,478,124		22,500	58,971	1,559,595	—	—	
Frank E. O'Donnell, Jr. M.D.	548,754		22,500	195,784	767,038	—	30,000	(1)
W. Mark Watson	35,979		17,240	—	53,219	37,500	75,000	
Todd C Davis	237,914		10,623	—	248,537	37,500	75,000	
Kevin Kotler	6,722,289	(2)	10,623	—	6,732,912	37,500	75,000	
Vanila Singh, M.D. MAMC	—		—	—	—	96,000	16,000	

(1) Includes unvested RSUs potentially issuable if certain pre-determined company targets are achieved.

(2) Includes 2,422,223 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 4,300,066 shares owned by Broadfin, Capital LLC.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table indicates shares of common stock authorized for issuance under our 2019 Stock Option Incentive Plan as of December 31, 2019:

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	7,145,530	3.64	13,539,076
Equity compensation plans not approved by security holders	—	—	—
Total	7,145,530	3.64	13,539,076

(1) Includes 108,535 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. Also includes 4,369,045 shares of common stock underlying options previously granted under our 2011 Equity Incentive Plan, as amended, which are still exercisable despite the fact that such plan expired July 2019.

(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, 2019 and 2018 totaled $234,000 and $216,000, 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, 2019 and 2018 were $105,775 and $131,776, 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, 2019 and 2018 were $39,550 and $34,600, 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 2019. 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 information called for by this Item is incorporated herein by reference to the Exhibit Index in this Form 10-K.

Number	Description
3.1	Second Amended and Restated By-laws of the Company, adopted on November 17, 2017, filed with Form 8-K, dated November 17, 2017.
3.2	Articles of Incorporation and Certificates of Amendments, dated July 25, 2019, filed with 10-Q, dated August 8, 2019.
4.1*	Description of the registrant's securities registered pursuant to Section 12 of the Securities Exchange Act of 1934
10.1	Amended and Restated 2001 Incentive Plan, filed with PRE14A, dated June 17, 2003.
10.2	Amendment No. 1 to Amended and Restated 2001 Incentive Plan, filed as Annex A to Schedule 14A, dated June 27, 2006.
10.3	Amendment to Amended and Restated 2001 Incentive Plan of the Company, dated November 19, 2008, filed with Form 10-K, March 20, 2009.
10.4+	Intellectual Property Assignment Agreement, dated August 2, 2006, by and between QLT USA, Inc. and Arius Two, Inc., filed with Form 8-K, dated August 9, 2006.
10.5+	Sublicensing Consent, dated August 2, 2006, between Arius Two, Inc. and Arius Pharmaceuticals, Inc., filed with Form 8-K, dated August 9, 2006.
10.6+	Sublicensing Consent dated September 5, 2007, between Arius Pharmaceuticals, Inc. and Arius Two, Inc., filed with Form 8-K, dated September 10, 2007.
10.7+	License Agreement dated, September 5, 2007, by and between Arius Two, Inc., and Arius Pharmaceuticals, Inc., filed with Form 8-K, dated September 10, 2007.
10.8+	Intellectual Property Assignment Agreement dated, September 5, 2007 by and between QLT USA, Inc. and Arius Two., filed with Form 8-K, dated September 10, 2007.
10.9	Assignment of Patent and Trademarks, dated September 5, 2007, filed with Form 8-K, dated September 10, 2007.
10.10	Amendment Consent (EU), dated January 2, 2009, between Arius Pharmaceuticals, Inc. and Arius Two, Inc., filed with Form 8-K, January 6, 2009.
10.11	2011 Equity Incentive Plan, filed with PRE14A, dated June 1, 2011.
10.12	Amendment No. 1 to 2011 Equity Incentive Plan, filed with PRE14A, dated June 12, 2013.
10.13	Amendment No. 2 to 2011 Equity Incentive Plan, filed with PRE14A, dated June 10, 2014.
10.14	Performance Long Term Incentive Plan, filed with Form 10-K, dated March 16, 2015.
10.15	Amendment No. 3 to 2011 Equity Incentive Plan, filed with DEF14A, dated June 5, 2015.
10.16	Amendment No. 4 to 2011 Equity Incentive Plan, filed with DEF14A, dated November 1, 2017.
10.17	Form of Incentive Stock Option Agreement under the 2011 Equity Incentive Plan, filed with Form 10-Q, dated November 8, 2018.
10.18	Form of Nonqualified Stock Option Agreement for Company Employees under the 2011 Equity Incentive Plan, filed with Form 10-Q, dated November 8, 2018.
10.19	Form of Nonqualified Stock Option Agreement for Non-Employee Directors under the 2011 Equity Incentive Plan, filed with Form 10-Q, dated November 8, 2018.
10.20	Form of Restricted Stock Unit Award Agreement for Company Employees under the 2011 Equity Incentive Plan, filed with Form 10-Q, dated November 8, 2018.
10.21	Form of Restricted Stock Unit Award Agreement for Non-Employee Directors under the 2011 Equity Incentive Plan, filed with Form 10-Q, dated November 8, 2018.

10.22	Form of Performance Restricted Stock Unit Award Agreement for Company Employees under the 2011 Equity Incentive Plan, filed with Form 10-Q, dated November 8, 2018.
10.23	Offer of Promotion, dated December 20, 2017, by and between the Company and Scott M. Plesha, filed with Form 8-K, dated December 22, 2017.
10.24	Form of Director Indemnification Agreement, by and between the Company and each of the Directors of the Company, filed with Form 8-K, dated February 6, 2018.
10.25	Employment Agreement, dated May 2, 2018, between the Company and Herm Cukier, filed with Form 8-K, dated May 8, 2018.
10.26	Director Indemnification Agreement, dated May 2, 2018, by and between the Company and Herm Cukier, filed with Form 8-K, dated May 8, 2018.
10.27	Confidentiality, Intellectual Property and Non-Competition Agreement, dated May 2, 2018, between the Company and Herm Cukier, filed with Form 8-K, dated May 8, 2018.
10.28	Conditional Offer of Employment, dated July 20, 2018, between the Company and Thomas Smith, filed with Form 10-Q, dated November 8, 2018.
10.29	Transition Period and Separation of Employment, dated January 23, 2019 by and between the Company and Ernest De Paolantonio, filed with Form 8-K, dated January 23, 2019.
10.30	Conditional Offer of Employment, dated November 5, 2018, between the Company and James Vollins, filed with Form 10-K, dated March 14, 2019.
10.31	Conditional Offer of Employment, dated January 15, 2019, between the Company and Terry Coelho, filed with Form 10-K, dated March 14, 2019.
10.32+	Exclusive License Agreement dated, April 4, 2019, between the Company and Shionogi, Inc.,filed with Form 8-K, dated April 10, 2019.
10.33	Loan Agreement dated May 23, 2019 between the Company and Biopharma Credit PLC, filed with Form 10-Q, dated August 8, 2019.
10.34	2019 Stock Option and Incentive Plan, filed with DEF14A, dated June 17, 2019.
10.35	Form of Incentive Stock Option Agreement under the 2019 Stock Option and Incentive Plan, filed with Form 10-Q, dated August 8, 2019.
10.36	Form of Nonqualified Stock Option Agreement for Company Employees under the 2019 Stock Option and Incentive Plan, filed with Form 10-Q, dated August 8, 2019.
10.37	Form of Nonqualified Stock Option Agreement for Non-Employee Directors under the 2019 Stock Option and Incentive Plan, filed with Form 10-Q, dated August 8, 2019.
10.38	Form of Restricted Stock Unit Award Agreement for Company Employees under the 2019 Stock Option and Incentive Plan, filed with Form 10-Q, dated August 8, 2019.
10.39	Form of Restricted Stock Unit Award Agreement for Non-Employee Directors under the 2019 Stock Option and Incentive Plan, filed with Form 10-Q, dated August 8, 2019.
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.

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, 2019 and 2018, 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, 2019, the related notes, and Schedule II – Valuation and Qualifying Accounts and Reserves (collectively referred to as the "financial statements"). We have also audited the Company's internal control over financial reporting as of December 31, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2019, 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, 2019, 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 2019 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 independent registered public accounting firm since 2003.

Raleigh, North Carolina
March 12, 2020

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

	December 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash	$ 63,888	$ 43,822
Accounts receivable, net	38,790	13,627
Inventory, net	11,312	5,406
Prepaid expenses and other current assets	3,769	3,188
Total current assets	117,759	66,043
Property and equipment, net	2,075	3,072
Goodwill	2,715	2,715
License and distribution rights, net	60,309	36,000
Other intangible assets, net	47	703
Total assets	$ 182,905	$ 108,533
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 53,993	$ 21,539
Total current liabilities	53,993	21,539
Notes payable, net	58,568	51,652
Other long-term liabilities	580	5,600
Total liabilities	113,141	78,791
Commitments and contingencies (Notes 7 and 17)		
Stockholders' equity:		
Preferred Stock, 5,000,000 shares authorized; 2,714,300 shares issued; Series A Non-Voting Convertible Preferred Stock. $0.001 par value, 2,093,155 shares outstanding at both December 31, 2019 and December 31, 2018, respectively; Series B Non-Voting Convertible Preferred Stock, $0.001 par value, 618 and 3,100 shares outstanding at December 31, 2019 and December 31, 2018 respectively.	2	2
Common Stock, $.001 par value; 175,000,000 and 125,000,000 shares authorized at December 31, 2019 and December 31, 2018 respectively; 96,189,074 and 70,793,725 shares issued;96,173,583 and 70,778,234 shares outstanding at December 31, 2019 and December 31, 2018, respectively.	96	71
Additional paid-in capital	436,306	381,004
Treasury stock, at cost, 15,491 shares	(47)	(47)
Accumulated deficit	(366,593)	(351,288)
Total stockholders' equity	69,764	29,742
Total liabilities and stockholders' equity	$ 182,905	$ 108,533

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,		
	2019	2018	2017
Revenues:			
Product sales	$ 107,888	$ 51,410	$ 34,922
Product royalty revenues	3,341	3,389	5,070
Research and development reimbursements	—	—	799
Contract revenue	160	841	21,194
Total revenues	111,389	55,640	61,985
Cost of sales	21,590	15,783	19,496
Expenses:			
Research and development	—	4,903	13,040
Selling, general and administrative	86,063	58,602	58,869
Total expenses	86,063	63,505	71,909
Income (loss) from operations	3,736	(23,648)	(29,420)
Interest expense	(19,040)	(10,192)	(8,577)
Bargain purchase gain	—	—	27,336
Other income (expense), net	4	(14)	(26)
Loss before income taxes	(15,300)	(33,854)	(10,687)
Income tax (expense) benefit	(5)	(13)	15,972
Net (loss) income	(15,305)	(33,867)	5,285
Beneficial conversion feature of convertible preferred stock	—	(12,500)	—
Net (loss) income attributable to common stockholders	$ (15,305)	$ (46,367)	$ 5,285
Basic:			
Weighted average common stock shares outstanding	83,213,704	63,165,063	55,355,802
Basic (loss) earnings per share	$ (0.18)	$ (0.73)	$ 0.10
Diluted:			
Diluted weighted average common stock shares outstanding	83,213,704	63,165,063	56,402,479
Diluted (loss) earnings per share	$ (0.18)	$ (0.73)	$ 0.09

See notes to consolidated financial statements

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

	Preferred Stock Series A		Preferred Stock Series B		Common Stock		Additional Paid-In Capital	Treasury Stock	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
Balances, January 1, 2017	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
Stock-based compensation	—	—	—	—	—	—	5,418	—	—	5,418
Stock option exercises	—	—	—	—	799,800	—	2,319	—	—	2,319
Restricted stock awards	—	—	—	—	806,661	1	(1)	—	—	—
Series B conversion to Common Stock	—	—	(2,482)	—	13,788,888	14	(14)	—	—	—
Equity offering, net of finance costs	—	—	—	—	10,000,000	10	47,580	—	—	47,590
Net loss	—	—	—	—	—	—	—	—	(15,305)	(15,305)
Balances, December 31, 2019	2,093,155	$ 2	618	$ —	96,189,074	$ 96	$ 436,306	$ (47)	$ (366,593)	$ 69,764

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,		
	2019	**2018**	**2017**
Operating activities:			
Net (loss) income	$ (15,305)	$ (33,867)	$ 5,285
Adjustments to reconcile net (loss) income to net cash flows provided by (used in) operating activities			
Depreciation	1,846	740	693
Accretion of debt discount and loan costs	11,508	4,138	2,392
Amortization of intangible assets	6,981	5,157	5,425
Provision for (recovery from) inventory obsolescence	197	(56)	243
Impairment loss on equipment	—	78	—
Stock-based compensation expense	5,416	5,941	14,801
Deferred income taxes	—	40	(15,972)
Bargain purchase gain	—	—	(27,336)
Changes in assets and liabilities, net of effect of acquisition:			
Accounts receivable	(25,163)	(4,640)	(5,884)
Inventories	(6,102)	741	2,448
Prepaid expenses and other assets	(581)	422	526
Accounts payable and accrued expenses	32,275	(2,807)	6,644
Deferred revenue	—	—	(21,716)
Net cash flows provided by (used in) operating activities	11,072	(24,113)	(32,451)
Investing activities:			
Product acquisitions	(30,685)	(1,951)	(5,853)
Acquisitions of equipment	(79)	(112)	(11)
Net cash flows used in investing activities	(30,764)	(2,063)	(5,864)
Financing activities:			
Proceeds from exercise of stock options	2,321	670	439
Proceeds from issuance of common stock, less underwriters discount	48,000	—	—
Proceeds from issuance of Series B preferred stock	—	50,000	—
Payment on note payable	(67,346)	—	(30,000)
Proceeds from notes payable	59,987	—	60,000
Equity finance costs	(410)	(1,417)	—
Payment of deferred financing fees	—	(450)	(2,948)
Loss on refinancing of former debt	(2,794)	—	—
Net cash flows provided by financing activities	39,758	48,803	27,491
Net change in cash and cash equivalents	20,066	22,627	(10,824)
Cash and cash equivalents at beginning of year	43,822	21,195	32,019
Cash and cash equivalents at end of year	**$ 63,888**	**$ 43,822**	**$ 21,195**
Cash paid for interest	$ 6,809	$ 6,053	$ 5,285

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 a right of use asset and a corresponding liability in the amount of $0.9 million in exchange for an operating lease liability as a result of the adoption of Accounting Standards Codification, ASC, Topic 842, Leases, ("ASC842") on January 1, 2019.

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 9, 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 former 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

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.

The Company is a rapidly growing specialty pharmaceutical company dedicated to patients living with chronic pain and associated conditions. The Company has built a portfolio of products that includes utilizing its novel and proprietary BioErodible MucoAdhesive, or BEMA, drug-delivery technology to develop and commercialize new applications of proven therapies aimed at addressing important unmet medical needs. The Company commercializes in the U.S. using its own sales force while working in partnership with third parties to commercialize its products outside the U.S.

As used herein, the Company's common stock, par value $0.001 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 and Arius Two. 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 made by the Company include: revenue recognition associated with 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 four active pharmaceutical ingredient ("API") suppliers for BELBUCA, Symproic 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 Symproic business, which would affect the Company's financial position and results of operations.

In 2019, the Company utilized only one contract manufacturer to create the BELBUCA and BUNAVAIL laminates and a second contract manufacturer to package the laminates into final product. The Company utilizes only one contract manufacturer to create the Symproic tablets and only one contract manufacturer to package the tablets 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 Symproic supply delays. Amounts due to these vendors represented approximately 30.3% and 6.3% of total accounts payable as of December 31, 2019 and 2018, respectively.

(U.S. DOLLARS IN THOUSANDS)

In 2019, the Company sold its BELBUCA, Symproic 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	**2019**	**2018**
Customer A	42 %	47 %
Customer B	35 %	22 %
Customer C	18 %	25 %
Total	**95 %**	**94 %**

These three customers accounted for 94%, 92% and 92% of total annual sales during the years ended December 31, 2019, 2018 and 2017 respectively.

In March 2020 the Company announced that it will discontinue marketing of BUNAVAIL in 2020.

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, 2019, the Company had approximately $65.1 million, which exceeded these insured limits. As of December 31, 2018, the Company had approximately $43.6 million, which exceeded these insured limits.

Accounts receivable

The Company offers wholesale distributors a prompt payment discount if they make payments within a prescribed number of days. 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 $0.9 million and $0.3 million as of December 31, 2019 and 2018, 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, 2019 or 2018. 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 $0.4 million and $0.2 million in reserves for inventory obsolescence as of December 31, 2019 and 2018, respectively. The 2019 reserve includes an additional $0.2 million associated with the announced discontinuation of marketing of BUNAVAIL.

Inventory is composed of the following at December 31:

(U.S. DOLLARS IN THOUSANDS)

	2019	2018
Raw Materials & Supplies	$ 624	$ 645
Work-in-process	6,198	2,093
Finished Goods	4,874	2,855
Finished Goods Reserve	(384)	(187)
Total Inventories	$ 11,312	$ 5,406

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. In connection with the discontinuation of the marketing of BUNAVAIL, the company recorded an additional $1.5 million of depreciation related to certain equipment used in the production of BUNAVAIL. 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, 2019 or 2018.

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 2019, 2018 or 2017.

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
Symproic license and distribution rights	12 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 2019, 2018 or 2017.

Revenue recognition

The Company recognizes revenue in accordance with ASC, Topic 606, Revenue from Contracts with Customers ("ASC606"), which was adopted on January 1, 2018, using the modified retrospective transition method.

Product sales

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 obligation on product sold.

Performance obligations

A performance obligation is a promise in a contract to transfer a distinct good or service to the customer. 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, vouchers 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 and Medicare 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. In connection with the March 2020 announcement of the discontinuation of marketing of BUNAVAIL, the 2019 results include a one-time reserve of $2.2 million for additional BUNAVAIL product returns.

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. During 2019, the Company had voucher programs for BELBUCA Symproic 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 current utilization and historical 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 a prescribed number of 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 license agreements that are described in note 7, of which these revenues are classified as contract revenue.

Cost of sales

In 2019, cost of sales included the direct costs attributable to the production of BELBUCA, Symproic and BUNAVAIL. It included raw materials, production costs at the Company's three contract manufacturing sites, quality testing directly related to the products, inventory adjustment charges, and depreciation on equipment that the Company had 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.

(U.S. DOLLARS IN THOUSANDS)

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 consisted 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.

As of January 1, 2019, the Company has focused entirely on commercialized products rather than research and development. As such, there were no expenses incurred in research and development during the year ended December 31, 2019. Research and development expense for the years ended December 31, 2018 and 2017 totaled $4.9 million and $13.0 million, respectively.

Advertising

Advertising costs, which include promotional expenses and the cost of placebo samples, are expensed as incurred. Advertising expenses were $10.8 million, $4.5 million and $3.8 million for the years ended December 31, 2019, 2018 and 2017, respectively, and are included in selling, general and administrative expenses in the accompanying consolidated statements of operations.

Shipping and handling costs

Shipping and handling costs, which include expenses from our wholesalers, are expensed as incurred. Shipping and handling costs were $0.03 million, $0.02 million and $0.01 million for the years ended December 31, 2019, 2018 and 2017, 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:

	2019	2018	2017
Expected price volatility	61.66%-64.10%	60.34%-68.77%	68.76%-78.79%
Risk-free interest rate	1.36%-2.66%	2.05%-3.00%	1.77%-2.05%
Weighted average expected life in years	6 years	6 years	6 years
Dividend yield	—	—	—

(U.S. DOLLARS IN THOUSANDS)

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. The Company considers the carrying amount of its cash and cash equivalents to approximate fair value due to short-term nature of this instrument. 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)

The following table summarizes the cash and cash equivalents measured at fair value on a recurring basis as of December 31, 2019:

	Level 1	Level 2	Level 3	Balance
Cash and cash equivalents	$ 63,888	—	—	$63,888

Accounting Pronouncements adopted in 2019

In February 2016, the FASB issued ASU No. 2016-02, *Leases* (Topic 842). The authoritative guidance significantly amends the current accounting for leases. Under the new provisions, all lessees will report a right-of-use asset and a liability for the obligation to make payments for all leases with the exception of those leases with a term of 12 months or less. All other leases will fall into one of two categories: (i) a financing lease or (ii) an operating lease. In July 2018, the FASB issued ASU No. 2018-10, *Codification Improvements to Topic 842 (Leases)*, which amends narrow aspects of the guidance issued in the amendments in ASU 2016-02, and ASU No. 2018-11, Leases (Topic 842): Targeted Improvements, which allows entities to recognize a cumulative-effect adjustment from the application of ASU 2016-02 to the opening balance of retained earnings in the period of adoption. Effective January 1, 2019, the Company adopted Topic 842 using the modified retrospective method as of January 1, 2019 and will not restate comparative periods. The Company elected the optional package of practical expedients, which allowed the Company to not reassess: (i) whether any expired or existing contracts are considered or contain leases; (ii) lease classification for any expired or existing leases; and (iii) initial direct costs for any existing leases. The new standard also allows entities to make certain policy elections, including a policy to not separate lease and non-lease components, which the Company did not elect for its facility and office equipment lease. Refer to footnote three “Leases” for further information.

Accounting Pronouncements not yet adopted

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses of Financial Instruments;* in November 2018 the FASB issued a subsequent amendment ASU No. 2018-19, *Codi*fication *Improvements to Topic 326, Financial Instruments—Credit Losses;* in April 2019 the FASB issued ASU No. 2019-04, *Codification Improvements to Topic 326, Financial Instruments—Credit Losses.* In May 2019 the FASB issued ASU No. 2019-05, *Financial Instruments—Credit Losses (Topic 326): Targeted Transition Relief;* and in November 2019 the FASB issued ASU No. 2019-11, *Codification Improvements to Topic 326, Financial Instruments—Credit Losses.* The new guidance changes the methodology for measuring credit losses on financial instruments and the timing of when such losses are recorded. In November 2019 the FASB issued ASU No. 2019-10, *Financial Instruments—Credit Losses* (Topic 326). This guidance is effective for fiscal years beginning after December 15, 2022 and early adoption is permitted. The Company is currently evaluating the timing and effect the new guidance will have on its consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement* (Topic 820): *Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement*, which modifies the disclosure requirements on fair value

measurements. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019 and early adoption is permitted. The Company is currently evaluating but does not expect the new guidance to have a material impact on its consolidated financial statements.

In November 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements* (Topic 808): *Clarifying the Interaction between Topic 808 and Topic 606*, which amends ASC 808 to clarify ASC 606 should apply in entirety to certain transactions between collaborative arrangement participants. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. The Company is currently evaluating but does not expect the new guidance to have a material impact on its consolidated financial statements.

In December 2019, the FASB issued ASU 2019-12, Income Taxes (Topic 740)—*Simplifying the Accounting for Income Taxes*, which is intended to simplify accounting for income taxes. It removes certain exceptions to the general principles in Topic 740 and amends existing guidance to improve consistent application. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020 and early adoption is permitted. The Company is currently evaluating but does not expect the new guidance to have a material impact on its consolidated financial statements.

2. Revenue from contracts with customers:

The main types of revenue contracts are:

- *Product sales*-Product sales amounts relate to sales of BELBUCA, Symproic 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. In March 2020 the Company announced it will discontinue marketing of BUNAVAIL in 2020.

- *Product royalty revenues*-Product royalty revenue amounts are based on sales revenue of 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 Company implemented ASC 606 January 1, 2018. As such, the accounting treatment for 606 is already reflected in the consolidated financials for the year ended December 31, 2019.

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

3. Leases:

On January 1, 2019, the Company adopted ASC Topic 842, which is intended to improve financial reporting about leasing transactions. Under the standard, organizations that lease assets, referred to as "Lessees" shall recognize on the balance sheet the assets and liabilities for the rights and obligations created by those leases. In addition, the standard requires disclosures including financial statements to assess the amount, timing and uncertainty of cash flows arising from leases.

The Company elected to use the practical expedients permitted under the transition guidance within the new standard, which among other things, allows the Company to carryforward the historical lease classification. The Company made 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 recognized those lease payments in the Consolidated Statements of Operations on a straight-line basis over the lease term. Under the new standard, the Company's lease liability is based on the present value of such payments and the related right-of-use asset will generally be based on the lease liability.

The impact of the adoption of Topic 842 on the accompanying consolidated balance sheet as of January 1, 2019 is as follows (in thousands):

	December 31, 2018	Adjustments Due to the Adoption of Topic 842		January 1, 2019
		Right-of-use asset	Lease liability	
Property and equipment, net	$ 3,072	$ 939	$ —	$ 4,011
Current liabilities	$ 21,539	$ —	$ 212	$ 21,751
Other long-term liabilities	$ 5,600	$ —	$ 822	$ 6,422

The components of lease expense were as follows:

	Twelve months ended December 31,	
	2019	2018
Lease Cost		
Operating lease cost		
Operating lease	$ 328	$ 325
Variable lease costs	$ 13	$ 2
Total lease cost	$ 341	$ 327

Supplemental cash flow information related to leases were as follows:

	Twelve months ended December 31,	
	2019	2018
Other information		
Cash paid for amounts included in the measurement of lease liabilities		
Operating cash flows from operating leases	$ 351	$ 327

	Twelve months ended December 31,	
	2019	2018
Lease term and discount rate		
Weighted-average remaining lease term operating leases	3.0 years	4.0 years
Weighted-average discount rate operating leases	11.8 %	11.8 %

(U.S. DOLLARS IN THOUSANDS)

Maturity of Lease Liabilities

Future minimum lease payments under non-cancellable leases as of December 31, 2019 were as follows:

Maturity of lease liabilities	
2020	$360
2021	$370
2022	$219
Total lease payments	$949
Less: Interest	$(128)
Present value of lease liabilities	$821

Components of Lease Assets and Liabilities

		December 31, 2019
Assets		
Property and equipment, net operating lease-right of use asset	$	720
Liabilities		
Current liabilities operating lease-current liability	$	281
Other long-term liabilities operating lease-noncurrent liability	$	540
Total lease liabilities	$	821

4. Liquidity:

At December 31, 2019, the Company had cash of approximately $63.9 million. The Company generated $11.1 million of cash in operations during the year ended December 31, 2019 and had stockholders' equity of $69.8 million, versus stockholders' equity of $29.7 million at December 31, 2018. The Company believes that it has sufficient current cash 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. 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.

(U.S. DOLLARS IN THOUSANDS)

5. Accounts payable and accrued liabilities:

The following table represents the components of accounts payable and accrued liabilities as of December 31:

	2019	2018
Accounts payable	$ 11,704	$ 3,166
Accrued rebates	28,528	12,261
Accrued compensation and benefits	5,545	3,814
Accrued acquisition costs	—	318
Accrued returns	4,438	715
Accrued royalties	535	159
Accrued clinical trial costs	—	464
Accrued regulatory fees	331	—
Accrued legal	1,484	70
Accrued other	1,428	572
Total accounts payable and accrued expenses	$ 53,993	$ 21,539

As of December 31, 2019, three vendors comprised 61% of the accounts payable balance. As of December 31, 2018, three vendors comprised 37% of the accounts payable balance.

6. Property and equipment:

Property and equipment, summarized by major category, consist of the following as of December 31:

	2019	2018
Machinery & equipment	$ 5,635	$ 5,635
Right of use, building and lease	720	—
Computer equipment & software	437	406
Office furniture & equipment	174	155
Leasehold improvements	43	43
Idle equipment	679	679
Total	7,688	6,918
Less accumulated depreciation	(5,613)	(3,846)
Total property, plant & equipment, net	$ 2,075	$ 3,072

Depreciation expense for years ended December 31, 2019, 2018 and 2017 was approximately $0.3 million, $1.0 million and $0.7 million, respectively. The Company evaluated and adjusted the estimated useful life of certain equipment related to the production of BUNAVAIL that resulted in the additional depreciation expense. As such, the 2019 depreciation expense includes an additional $1.5 million associated with accelerated depreciation for BUNAVAIL specific equipment.

7. Other intangible assets:

Other intangible assets, net, consisting of product rights and licenses are summarized as follows:

December 31, 2019	Gross Carrying Value	Accumulated Amortization	Intangible Assets, net	Weighted average Useful Life
Product rights	$ 6,050	$ (6,003)	$ 47	0.61
BELBUCA license and distribution rights	45,000	(13,500)	31,500	3.77
Symproic license and distribution rights	30,636	(1,827)	28,809	4.40
Licenses	1,900	(1,900)	—	0.30
Total intangible assets	$ 83,586	$ (23,230)	$ 60,356	

(U.S. DOLLARS IN THOUSANDS)

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	

The Company incurred amortization expense on other intangible assets of approximately $7.0 million, $5.2 million and $5.4 million for the years ended December 31, 2019, 2018 and 2017, 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,	
2020	$ 6,981
2021	6,935
2022	6,935
2023	6,935
2024	6,935
Thereafter	25,635
	$ 60,356

8. License agreements and acquired product rights:

On April 4, 2019 (the “Effective Date”), the Company and Shionogi Inc. (“Shionogi”) entered into an exclusive license agreement (the “License Agreement”) for the commercialization of Symproic in the United States including Puerto Rico (the “Territory”) for opioid-induced constipation in adult patients with chronic non-cancer pain (the “Field”).

Pursuant to the terms of the License Agreement, the Company paid Shionogi a $20 million up-front payment on the Effective Date and paid Shionogi a $10 million payment on the six-month anniversary of the Effective Date (October 4, 2019), and quarterly, tiered royalty payments on potential sales of Symproic in the Territory that range from 8.5% to 17.5% (plus an additional 1% of net sales on a pass-through basis to a third party licensor of Shionogi) of net sales based on volume of net sales and whether Symproic is being sold as an authorized generic. Assets acquired as part of the License Agreement include: intellectual property, inventory, trademarks and tradenames.

The Company and Shionogi have made customary representations and warranties and have agreed to certain other customary covenants, including confidentiality, limitation of liability and indemnity provisions. Either party may terminate the License Agreement for cause if the other party materially breaches or defaults in the performance of its obligations. Unless earlier terminated, the License Agreement will continue in effect until the expiration of the Company’s royalty obligations, as defined. Upon expiration of the License Agreement, all licenses granted to Company for Symproic in the Field and in the Territory survive and become fully-paid, royalty-free, perpetual and irrevocable.

The Company and Shionogi have also entered into a customary supply agreement under which Shionogi will supply Symproic to the Company at cost plus an agreed upon markup for an initial term of up to two years. In the event the Company elects to source Symproic from a third party supplier, Shionogi would continue to supply the Company with naldemedine tosylate for use in Symproic at cost plus such agreed upon markup for the duration of the License Agreement. The Company and Shionogi also entered into a customary transition services and distribution agreement under which Shionogi will continue to perform certain sales, distribution and related activities and commercialization and administrative services on the Company’s behalf until June 30, 2019 pursuant to the transition services and distribution agreement (the “Transition Date”) (during which time, in lieu of paying royalties and cost-plus supply, distribution and transitional services during this period, Shionogi will retain 35% of the net sales of Symproic in the Territory and remit the remaining 65% of net sales to the Company) and certain other customary transitional services (if so requested by the Company), initially at no cost and thereafter, at a specified hourly rate for a term not to exceed three months from the

(U.S. DOLLARS IN THOUSANDS)

Transition Date or the term of the Agreement. The Company and Shionogi have also entered into a Pharmacovigilance agreement that required ongoing cooperation on adverse event reporting for the duration of License Agreement.

The Company accounted for the Symproic purchase as an asset acquisition under ASC 805-10-55-5b, which provides guidance for asset acquisitions. Under the guidance, if substantially all the acquisition is made up of one asset or several similar assets, then the acquisition is an asset acquisition. The Company believes that the licensing agreement and other assets acquired from Shionogi are similar and consider them all to be intangible assets.

The total purchase price was allocated to the acquired asset based on their relative estimated fair values, as follows:

Symproic license	$	30,000
Transaction expenses	$	636
Total value	$	30,636

Additionally, the Company also purchased from Shionogi $0.4 million of Symproic samples, which have been recorded in selling, general and administrative expenses in the accompanying consolidated statement of operations for year ended December 31, 2019.

The Company is amortizing the Symproic license over the life of the underlying patent, which the earliest date of generic entry for Symproic is November 2031 based on the expiration date of U.S. patent # 9,108,975.

9. Business combination and BELBUCA acquisition:

On December 7, 2016, the Company and Endo Pharmaceuticals, ("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.

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.

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)

10. License agreements:

Mylan license and supply agreement

In 2006, the Company announced collaboration with Meda AB, (which was acquired by Mylan N.V. "Mylan") to develop and commercialize BEMA Fentanyl (marketed as BREAKYL™ in Europe). Under terms of the agreement, the Company granted Mylan rights to the European development and commercialization of BREAKYL. Mylan managed the regulatory submission in Europe that led to approval in October 2010.

In 2009, the Company amended the European agreement to provide Mylan the worldwide rights to ONSOLIS, except for South Korea and Taiwan. The sales royalties to be received by the Company are the same for all territories as agreed to for Europe.

The Company received cumulative payments totaling $2.2 million, $1.8 million and $2.2 million, all which related to royalties based on product purchased by Mylan of BREAKYL. Such amounts are recorded as contract revenue in the accompanying consolidated statement of operations for the years ended December 31, 2019, 2018 and 2017, respectively.

TTY license and supply agreement

In 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. In 2013, the Company announced the regulatory approval of BEMA Fentanyl in Taiwan, where the product is now marketed under the brand name PAINKYL. The Company receives an ongoing royalty based on net sales.

The term of the agreement with TTY is for the period from October 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.

The Company received cumulative payments totaling $1.2 million, $1.5 million and $1.2 million, 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, 2019, 2018 and 2017, respectively.

11. Notes payable:

On February 21, 2017, the Company entered into a term loan agreement (the “Term Loan Agreement”) with CRG Servicing LLC, ("CRG"), as administrative agent and collateral agent, and the lenders named in the Term Loan Agreement (the “Lenders”). Pursuant to the Term Loan Agreement, the Company borrowed $45.0 million from the Lenders as of the Closing Date. On December 26, 2017, the Company elected to receive the second draw for gross proceeds of $15.0 million.

On May 23, 2019, the Company entered into a Loan Agreement (the “Loan Agreement”) with Biopharma Credit plc (“Pharmakon”), for a senior secured credit facility consisting of a term loan of $60 million (the “Term Loan”), with the ability to draw an additional $20 million within twelve months of the closing date. The Loan Agreement replaced the Company’s existing Term Loan Agreement (the “Original Loan Agreement”) with CRG.

The Company utilized $60 million of the initial loan proceeds under the Loan Agreement, plus an additional $1.8 million to repay all of the outstanding loan balance owed by the Company under the Original Loan Agreement. The Company also used existing cash on hand to pay a $5.6 million backend facility fee to CRG. Upon the repayment of all amounts owed by the Company under the CRG Original Loan Agreement, all commitments to CRG were terminated and all security interests granted by the Company and its subsidiary guarantors under the CRG Original Loan Agreement were released.

During the year ended December 31, 2019, the Company expensed one-time costs of $5.2 million in unamortized deferred loan fees, $3.9 million in unamortized warrant discount costs and $2.8 million in loan prepayment fees and realized losses

arising out of the CRG Term Loan and recorded as interest expense in the accompanying consolidated statement of operations.

The new facility carries a 72-month term with interest only payments on the term loan for the first 36 months. The Term Loan will mature in May 2025 and bears an interest rate of 7.5% plus the LIBOR rate (LIBOR effective rate as of October 1, 2019 was 2.09%). The Term Loan is subject to mandatory prepayment provisions that require prepayment upon change of control.

The obligations under the Loan Agreement are guaranteed by the Company's subsidiaries and are secured by a first priority security interest in and a lien on substantially all of the assets of the Company and the subsidiary guarantors, subject to certain exceptions.

The following table represents future maturities of the notes payable obligation as of December 31, 2019:

2020	$	—
2021		—
2022		13,846
2023		18,462
2024		18,462
2025		9,230
Total maturities	$	60,000
Unamortized discount and loan costs		(1,432)
Total notes payable obligation	$	58,568

12. Net sales by product:

The Company operates in a single industry engaging in the commercialization of pharmaceutical products for chronic conditions. 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,		
	2019	2018	2017
BELBUCA	$ 97,538	$ 45,988	$ 26,980
% of net product sales	90.4 %	89.5 %	77.3 %
Symproic	8,061	$ —	$ —
% of net product sales	7.5 %	— %	— %
BUNAVAIL	2,289	5,422	7,942
% of net product sales	2.1 %	10.5 %	22.7 %
Net product sales	$ 107,888	$ 51,410	$ 34,922

In March 2020 the company announced it will discontinue marketing of BUNAVAIL in 2020.

13. 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

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Company has calculated the impact of the 2017 Tax Act in its income tax provision during the years ended December 31, 2019, 2018 and 2017 based on the provisions of the Act.

Reconciliation of the Federal statutory income tax rate of 21% to the effective rate is as follows:

	2019	2018	2017
Federal statutory income (benefit) tax rate	21.00 %	21.00 %	(34.00)%
2017 Tax Act, net deferred tax remeasurement	—	—	(626.73)
State taxes, net of federal benefit	(0.18)	(0.11)	(2.01)
Stock compensation	(5.39)	(4.74)	(5.18)
Permanent differences-other	(7.67)	(1.33)	(13.39)
North Carolina tax rate change	—	—	(32.75)
Research and development (“R&D”) credit	—	—	5.54
Valuation release for bargain purchase gain	—	—	(302.23)
Other	1.71	(2.07)	(1.36)
Decrease (increase) in valuation allowance	(9.44)	(12.65)	709.88
	0.03 %	0.10 %	(302.23)%

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)	**2019**	**2018**
Basis difference in equipment	$(438)	$(459)
Basis difference in intangibles	(5,356)	(6,045)
Accrued liabilities and other	3,942	2,246
R&D credit	10,980	10,980
Stock options	4,416	4,360
Net operating loss carry-forward	62,535	64,376
	76,079	75,458
Less: valuation allowance	(76,079)	(75,458)
	$ —	$ —

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. As a result, the Company recorded a valuation allowance with respect to all of the Company’s deferred tax assets for the years ended December 31, 2019 and 2018.

The Company has a federal net operating loss carry forward (“NOLs”) of approximately $271 million as of December 31, 2019. 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 Company has determined that 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 has state NOLs of approximately $261 million as of December 31, 2019. These state NOLs expire in various years through 2037 and certain state NOLs generated in 2018 have an indefinite carryforward period. The federal NOLs incurred through December 31, 2017 expire between 2024 and 2037. The federal NOL generated in 2018 has 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, 2019.

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, 2015.

14. Stockholders' equity:

Common Stock

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 $125 million of the Company's securities for potential future issuance and such registration statement was effective on February 7, 2019.

On July 25, 2019, in connection with the Company's 2019 Annual Meeting of Stockholders, the Company's stockholders approved, among other matters, an amendment to the Company's Certificate of Incorporation to increase the number of authorized shares of Common Stock from 125,000,000 to 175,000,000.

Preferred Stock and Series A Preferred

The Company had authorized five "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 $0.001 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, 2019, 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, 2019, 2018 or 2017.

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, 2019, a cumulative total of 2,482 shares of Series B Preferred Stock from various holders were converted into 13,788,888 shares of Common Stock. As of December 31, 2019, 618 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 an increase to additional paid-in capital, increasing net loss attributable to the Company Common stockholders.

Public Offering

On April 15, 2019 the Company completed an underwritten public offering by the Company and a selling stockholder of 12,000,000 shares of common stock at a public offering price of $5.00 per share. The gross proceeds from the Company’s portion of the offering (10,000,000 shares), before deducting the underwriter discounts and commission and other offering expenses, was $50.0 million. The net proceeds were $47.6 million. The gross proceeds to the selling stockholder were approximately $19.0 million, which includes shares sold pursuant to the underwriters’ exercise of their option to purchase an additional 1,800,000 shares of common stock at the public offering price.

Stock options

During the 2017 Annual Meeting of Stockholders, shareholders approved an amendment to the Company’s 2011 Equity Incentive Plan (the "2011 EIP"), 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.

Additionally, during the 2019 Annual Meeting of Stockholders, shareholders approved the Company’s 2019 Stock Option and Incentive Plan (the “2019 Plan”), which reserves 14,000,000 shares of stock for issuance under the 2019 Plan.

An additional 108,535 shares of Common Stock underlying options previously granted under the Company’s Amended and Restated 2001 Incentive Plan (the "2001 Plan), remain outstanding and exercisable as of December 31, 2019. The 2001 Plan expired in July 2011 and no new securities may be issued thereunder.

An additional 4,369,045 shares of Common Stock underlying options previously granted under the 2011 EIP, remain outstanding and exercisable as of December 31, 2019. The 2011 Plan expired in July 2019 and no new securities may be issued thereunder.

Options may be awarded during the ten-year term of the 2019 Plan to Company employees, directors, consultants and other affiliates.

During the years ended December 31, 2019, 2018 and 2017, Company employees, directors and affiliates exercised approximately 800,000, 400,000 and 200,000 stock options, respectively, with net proceeds to the Company of approximately $2.3 million, $0.7 million and $0.4 million, respectively.

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Stock option activity for the years ended December 31, 2019, 2018 and 2017 is as follows:

	Number of Shares	Weighted Average Exercise Price Per Share	Aggregate Intrinsic Value
Outstanding at January 1, 2017	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	(505,686)	3.48	
Outstanding at December 31, 2018	4,406,004	$ 3.19	$ 4,172
Granted in 2019:			
Officers and Directors	1,228,109	$ 4.08	
Others	1,160,643	4.51	
Exercised	(799,800)	2.90	
Forfeitures	(497,985)	2.03	
Outstanding at December 31, 2019	5,496,971	$ 3.64	$ 15,455

Options outstanding at December 31, 2019 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	5,011,678	8.38	$ 3.28	
$5.01 – 10.00	415,537	6.81	$ 6.16	
$10.01 – 15.00	38,756	5.15	$ 13.09	
$15.01 – 20.00	31,000	4.74	$ 16.20	
	5,496,971			$ 15,455

Options exercisable at December 31, 2019 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	1,284,107	7.46	$ 2.63	
$5.01 – 10.00	269,861	5.14	$ 6.36	
$10.01 – 15.00	38,756	5.15	$ 13.09	
$15.01 – 20.00	31,000	4.74	$ 16.20	
	1,623,724			$ 4,712

The weighted average grant date fair value of options granted during the years ended December 31, 2019, 2018 and 2017 was $4.29, $1.57 and $1.46, respectively. There were no options granted during the years ended December 31, 2019, 2018 or 2017 whose exercise price was lower than the estimated market price of the stock at the grant date.

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Nonvested stock options as of December 31, 2019, 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, 2019	2,763,833		
Granted	2,388,752		
Vested	(995,589)		
Forfeited	(283,749)		
Nonvested at December 31, 2019	3,873,247	$ 3.55	$ 10,743

As of December 31, 2019, there was approximately $3.4 million of unrecognized compensation cost related to unvested share-based compensation awards granted. These costs will be expensed over the next three years.

Stock-based compensation

During the year ended December 31, 2019, a total of 2,388,752 options to purchase Common Stock, with an aggregate fair market value of approximately $10.2 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.

Restricted stock units

During the year ended December 31, 2019, 376,250 RSUs, were granted to members of the Company's executive officers, board of directors, certain employees and a former officer, with a fair market value of approximately $1.7 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.

Of the aforementioned RSU grants, 360,250 RSUs were issued under the 2011 Plan, and vest as following: (i) For executive officers, directors and employees, in equal installments over three years and (ii) for a former officer, the grant vested immediately in full April 2019. The remaining 16,000 RSUs were issued to a director under the 2019 Plan and vest in equal installments over three years.

Restricted stock activity during the year ended December 31, 2019 was as follows:

	Number of Restricted Shares	Weighted Average Fair Market Value Per RSU
Outstanding at January 1, 2018	2,166,102	$ 2.59
Granted:		
Executive officers	223,250	$ 4.44
Directors	106,000	$ 5.06
Employees	47,000	$ 4.77
Vested	(806,661)	$ 4.80
Forfeitures	(87,132)	$ 2.30
Outstanding at December 31, 2019	1,648,559	$ 3.86

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

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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 ended during the fiscal year ending December 31, 2019. The total number of Performance RSUs covered by the LTIP was 1,078,000, of which 1,013,000 were awarded between in 2012 and 2015. No additional Performance RSUs were awarded between 2016 to 2019. The Performance RSUs under the LTIP vested each year over the 8-year term of the LTIP depending on the achievement of pre-defined annual revenue amounts by the Company, as reported in its Annual Report on Form 10-K. During the years ended 2019, 2018 and 2017, a total of 54,755, 31,036 and 9,958 RSUs vested, respectively. A cumulative total of 818,363 unvested LTIP shares were returned back to the 2019 Plan pool.

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, 2017, 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, 2019, a cumulative of 84,986 warrants to Midcap and affiliates remain outstanding.

In February 2017, the Company granted warrants to purchase 1,701,582 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, 2019, a cumulative of 2,051,034 warrants to CRG and affiliates remain outstanding.

15. 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, 2019, 2018 and 2017.

	December 31,		
	2019	**2018**	**2017**
Basic:			
Net (loss) income	$ (15,305)	$ (33,867)	$ 5,285
Less deemed dividend related to beneficial conversion feature on Series B Preferred Stock	—	(12,500)	—
Net (loss) income attributable to common stockholders, basic	$ (15,305)	$ (46,367)	$ 5,285
Weighted average common shares outstanding	83,213,704	63,165,063	55,355,802
Basic (loss) income per common share	**$ (0.18)**	**$ (0.73)**	**$ 0.10**

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	December 31,		
	2019	2018	2017
Diluted:			
Effect of dilutive securities:			
Net (loss) income attributable to common stockholders, diluted	$ (15,305)	$ (46,367)	$ 5,285
Weighted average common shares outstanding	83,213,704	63,165,063	55,355,802
Effect of dilutive options and warrants	—	—	1,046,677
Diluted weighted average common shares outstanding	83,213,704	63,165,063	56,402,479
Diluted (loss) income per common share	**$ (0.18)**	**$ (0.73)**	**$ 0.09**

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, 2019, 2018 and 2017, outstanding stock options, RSUs, warrants and convertible preferred stock of 11,116,195, 28,424,998 and 6,531,346, 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, 2019 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, 2019, 2018 and 2017, respectively.

	2019	2018	2017
Options, RSUs, warrants and convertible preferred stock to purchase Common Stock	11,375,323	10,739,378	9,555,869

16. 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 $1.0 million, $0.8 million and $0.5 million in years, 2019, 2018 and 2017.

17. Commitments and contingencies:

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 2018. Ongoing expenses are shared equally by the member companies and were paid monthly during 2019. Future ongoing expenses are anticipated to be paid monthly 2020 through 2023.

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

The following disclosure regarding the Company's ongoing litigations with Aquestive Therapeutics, Inc. (formerly MonoSol Rx, "Aquestive") and Indivior PLC (formerly RB Pharmaceuticals Limited, "Indivior") 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 the Company's previously filed periodic filings with the SEC.

Litigation related to BUNAVAIL

On October 29, 2013, Reckitt Benckiser, Inc., Indivior, and Aquestive (collectively, the "RB Plaintiffs") filed an action against the Company relating to its 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 the Company's 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 the Company's '019 Patent in 2015 and this decision was not appealed by Aquestive.

On September 20, 2014, the Company proactively filed a declaratory judgment action in the United States District Court for the EDNC requesting the Court to make a determination that the Company's 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"). The Company invalidated the "'080 Patent" in its entirety in an inter partes reexamination proceeding. The Company 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. The Company's 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 the Company (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"). The Company believes this is an anticompetitive attempt by the RB Plaintiffs to distract the Company's efforts from commercializing BUNAVAIL. On December 12, 2014, the Company filed a motion to transfer the case from New Jersey to North Carolina and a motion to dismiss the case against its commercial partner.

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. On February 7, 2019, the PTAB issued three decisions on remand purporting to deny institution of the three previously instituted IPRs of the '167 patent. On March 11, 2019, the Company timely appealed the PTAB decisions on remand to U.S. Court of Appeal for the Federal Circuit. On March 20, 2019, Aquestive and Indivior moved to dismiss the appeal, and the Company opposed that motion. On August 29, 2019, a three-judge panel of the Court of Appeals for the Federal Circuit granted the motion and dismissed the Company's appeal. On September 30, 2019, the Company filed a petition for an en banc rehearing of the order dismissing the Company's appeal by the full Federal Circuit Court of Appeals.

On January 13, 2020, by the Court of Appeals for the Federal Circuit denied BDSI's petition for *en banc* rehearing of the dismissal of BDSI's appeal relating to *inter partes* review proceedings on the '167 patent. BDSI intends to appeal the decision dismissing BDSI's appeal to the U.S. Supreme Court.

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. On November 20, 2018, the Company moved the EDNC to dismiss the complaint for patent infringement for failure to state a claim for relief. On August 6, 2019, the EDNC granted the Company's motion to dismiss, and dismissed the complaint without prejudice.

On or about November 11, 2019, Aquestive refiled a complaint in the EDNC against the Company alleging that BELBUCA infringes the '167 Patent. 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, or (formerly Actavis, "Teva") 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, the Company 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 the Company asserted in its 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, the Company 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, the Company 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, 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 has 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 it 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 the Company 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, 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 has 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 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, the Company filed a complaint for patent infringement in the Federal District Court of Delaware in Wilmington 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 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 its 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 the Company. The Company was served with the complaint on April 27, 2018. The complaint specifically alleged that it 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 us from the Arkansas case, without prejudice.

Chemo Research, S.L

On March 1, 2019, the Company filed a complaint for patent infringement in the Federal District Court of Delaware in Wilmington 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 BELBUCA 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. On March 15, 2019, the Company filed a complaint against the Defendants in New Jersey asserting the same claims for patent infringement made in the Delaware lawsuit. On April 19, 2019, Defendants filed an answer to the Delaware complaint wherein they denied infringement of the ‘866, ‘843 and ‘539 patents and asserted counterclaims seeking declaratory relief concerning the alleged invalidity and non-infringement of such patents. On April 25, 2019, the Company voluntarily dismissed the New Jersey lawsuit given Defendants’ consent to jurisdiction in Delaware.

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.

Derivative Litigation

On July 2, 2018, the Company filed a Schedule 14A Proxy Statement (the “Proxy”) with the U.S. Securities and Exchange Commission (the “SEC”) in connection with its 2018 Annual Meeting. Proposals 1 and 2 of the Proxy sought stockholder approval to amend the Company’s Certificate of Incorporation by deleting Article TWELFTH of the Company’s Certificate of Incorporation in its entirety and replacing it with a new Article TWELFTH that, among other things (i) provided for the declassification of the Company’s Board in phases, with the full declassification to be achieved in 2020 (the “Declassification Amendment”) and (ii) changed the voting standard for the uncontested election of directors to the Board from a plurality standard to the majority of votes cast standard as set forth in the bylaws of the Company (the “Election Amendment” and together with the “Declassification Amendment”, the “Amendments”).

On August 2, 2018, the Company held the 2018 Annual Meeting, at which time the stockholders voted on the Amendments. Following the 2018 Annual Meeting, based on consultation with the Company’s advisors, the Company determined that the Amendments had been adopted by the requisite vote of stockholders and effected the Amendments by

filing a Certificate of Amendment to the Certificate of Incorporation with the Secretary of State of the State of Delaware on August 6, 2018.

On September 11, 2019, two purported stockholders of the Company filed a putative class action against the Company and our directors in the Court of Chancery of the State of Delaware, captioned Drachman v. BioDelivery Sciences International, Inc., et al., C.A. No. 2019-0728-AGB (Del. Ch.) (the "Complaint"). The Complaint alleges that the Amendments did not receive the requisite vote of stockholders at the 2018 Annual Meeting and asserts claims for violation of the Delaware General Corporation Law, breach of fiduciary duties, and declaratory judgment. The Complaint seeks, inter alia, a declaration that the Amendments were not validly approved and invalidation of the Amendments, including altering the one-year terms of all directors duly elected at the 2018 and 2019 Annual Meetings to three-year terms. The Complaint also seeks costs and disbursements, including attorneys' fees. The Company will respond to the complaint by the December 6, 2019 deadline set by the Court and defend against it vigorously.

On November 5, 2019, the Board determined that ratifying the declassification of the Board and the change in the voting standard as set forth in the Amendments, as well as ratifying the filing and effectiveness of the Amendments, is in the best interests of the Company and its stockholders. The Board thus approved resolutions ratifying such acts and the filing and effectiveness of the Amendments under Section 204 of the Delaware General Corporation Law. The Company will submit the ratification to its stockholders for their adoption in accordance with Section 204 at its 2020 Annual Meeting.

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, 2019	June 30, 2019	September 30, 2019	December 31, 2019
Revenue	$ 19,769	$ 29,677	$ 30,306	$ 31,637
Gross profit	15,717	24,754	24,956	24,372
Income (loss) from operations	(1,272)	2,799	1,596	613
Net income (loss)	(3,833)	(11,130)	354	(696)
Basic loss per share	(0.05)	(0.13)	—	—
Diluted loss per share	(0.05)	(0.13)	—	—

	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)	(0.16)	(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)

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, 2019:	$ 75,458	$ 1,235	$ —	$ —	$ 76,693
Year ended December 31, 2018:	$ 71,515	$ 3,943	$ —	$ —	$ 75,458
Year ended December 31, 2017:	$ 109,030	$ (37,515)	$ —	$ —	$ 71,515
Allowance for rebates					
Year ended December 31, 2019:	$ 12,261	$ 81,217	$ 1,664	$ (65,801)	$ 29,341
Year ended December 31, 2018:	$ 5,648	$ 37,070	$ 813	$ (31,270)	$ 12,261
Year ended December 31, 2017:	$ 3,842	$ 17,236	$ (132)	$ (15,298)	$ 5,648
Allowance for price adjustments and chargebacks					
Year ended December 31, 2019:	$ 4,018	$ 29,552	$ 1	$ (26,647)	$ 6,924
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
Allowance for inventory obsolescence					
Year ended December 31, 2019:	$ 187	$ 149	$ —	$ (92)	$ 244
Year ended December 31, 2018:	$ 243	$ (56)	$ —	$ —	$ 187
Year ended December 31, 2017:	$ —	$ 243	$ —	$ —	$ 243

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 12, 2020

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 12, 2020
/S/ MARK A. SIRGO **Mark A. Sirgo**	Vice Chairman	March 12, 2020
/S/ HERM CUKIER **Herm Cukier**	Chief Executive Officer and Director	March 12, 2020
/S/ FRANK E. O'DONNELL, JR. **Francis E. O'Donnell, Jr.**	Director	March 12, 2020
/S/ WILLIAM M. WATSON **William M. Watson**	Director	March 12, 2020
/S/ TODD C. DAVIS **Todd C. Davis**	Director	March 12, 2020
/S/ KEVIN KOTLER **Kevin Kotler**	Director	March 12, 2020
/S/ VANILA SINGH **Vanila Singh**	Director	March 12, 2020

Exhibit 4.1

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

Description of Capital Stock

The following description of the capital stock of BioDelivery Sciences International, Inc. (the "Company", "we", "us" and "our") is a summary and does not purport to be complete. It is subject to and qualified in its entirety by reference to our Certificate of Incorporation ("Certificate of Incorporation"), as amended, and our Amended and Restated Bylaws ("Bylaws"), each of which are incorporated by reference as an exhibit to the Annual Report on Form 10-K of which this Exhibit 4.1 is a part, and by applicable law. We encourage you to read our Certificate of Incorporation, our Bylaws and the applicable provisions of the Delaware General Corporation Law for additional information.

Authorized Capital Stock

Our authorized capital stock consists of 175,000,000 shares of common stock, par value $0.001 per share (the "common stock"), and 5,000,000 shares of preferred stock, par value $0.001 per share (the "preferred stock"), of which 2,709,300 shares are designated as Series A Non-Voting Convertible Preferred Stock, par value $0.001 per share, and 5,000 shares are designated as Series B Preferred Stock.

Common Stock

We may issue shares of our common stock from time to time. The holders of shares of our common stock are entitled to one vote for each share held of record on all matters to be voted on by stockholders and do not have cumulative voting rights. Subject to the rights of holders of any future series of undesignated preferred stock which may be designated, each share of the outstanding common stock is entitled to participate ratably in any distribution of net assets made to the stockholders in the event of our liquidation, dissolution or winding up and is entitled to participate equally in dividends if and when declared by our board of directors. There are no redemption, sinking fund, conversion or preemptive rights with respect to shares of common stock. All shares of common stock have equal rights and preferences.

Our common stock is listed on the Nasdaq Global Select Market under the trading symbol "BDSI."

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC.

Preferred Stock

Our board of directors will have the authority, without further action by our stockholders, to issue up to 5,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of common stock. The issuance of our preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon our liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control of our company or other corporate action.

Series A Non-Voting Convertible Preferred Stock

In connection with our registered financing which closed on December 3, 2012, our board of directors designated 2,709,300 of the 5,000,000 authorized shares of preferred stock as our Series A Non-Voting Convertible Preferred Stock, par value $.001 per share.

Rank

The Series A Preferred Stock rank:

- senior to our common stock;
- senior to any class or series of our capital stock hereafter created specifically ranking by its terms junior to the Series A Preferred Stock; and
- junior to any class or series of our capital stock hereafter created specifically ranking by its terms senior to the Series A Preferred Stock,

in each case, as to dividends or distributions of assets upon our liquidation, dissolution or winding up whether voluntarily or involuntarily.

Conversion

Each share of Series A Preferred Stock is convertible into one share of our common stock (subject to adjustment as provided in the certificate of designation for the Series A Preferred Stock) at any time at the option of the holder, except that a holder will be prohibited from converting shares of Series A Preferred Stock into shares of common stock if, as a result of such conversion, such holder, together with its affiliates, would beneficially own more than 9.98% of the total number of shares of our common stock then issued and outstanding, which percentage may be increased or decreased by on sixty-five days' notice from the holder of Series A Preferred Stock to us.

Liquidation Preference

In the event of our liquidation, dissolution or winding up, holders of Series A Preferred Stock will receive a payment equal to $.001 per share of Series A Preferred Stock before any proceeds are distributed to the holders of our common stock and in parity with our Series B Preferred Stock. After the payment of this preferential amount, and subject to the rights of holders of any class or series of our capital stock hereafter created specifically ranking by its terms senior to the Series A Preferred Stock, holders of Series A Preferred Stock (and holders of the Series B Preferred Stock) 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.

Voting Rights

Shares of Series A Preferred Stock generally have no voting rights, except as required by law and except that the consent of holders of a majority of the outstanding Series A Preferred Stock will be required to amend the terms of the Series A Preferred Stock or the certificate of designation for the Series A Preferred Stock.

Dividends

Holders of Series A Preferred Stock are entitled to receive, and we are required to pay, dividends on shares of the Series A Preferred Stock equal (on an as-if-converted-to-common-stock basis) to and in the same form as dividends (other than dividends in the form of common stock) actually paid on shares of the common stock when, as and if such dividends (other than dividends in the form of common stock) are paid on shares of the common stock.

Redemption

We are not obligated to redeem or repurchase any shares of Series A Preferred Stock. Shares of Series A Preferred Stock are not otherwise entitled to any redemption rights, or mandatory sinking fund or analogous fund provisions.

Listing

There is no established public trading market for the Series A Preferred Stock, and we do not expect a market to develop. In addition, we do not intend to apply for listing of the Series A Preferred Stock on any national securities exchange or trading system.

Fundamental Transactions

If, at any time that shares of Series A Preferred Stock are outstanding, we effect a merger or other change of control transaction, as described in the certificate of designation and referred to as a fundamental transaction, then a holder will have the right to receive, upon any subsequent conversion of a share of Series A Preferred Stock (in lieu of conversion shares) for each issuable conversion share, the same kind and amount of securities, cash or property as such holder would have been entitled to receive upon the occurrence of such fundamental transaction if such holder had been, immediately prior to such fundamental transaction, the holder of one share of common stock.

Series B Preferred Stock

Our board of directors has designated 5,000 of the 5,000,000 authorized shares of preferred stock as our Series B Preferred Stock.

Rank

The Series B preferred stock rank:

- par with our outstanding Series A Preferred Stock;
- senior to our common stock;
- senior to any class or series of our capital stock hereafter created specifically ranking by its terms junior to the Series B Preferred Stock;
- on parity with any class or securities of our capital stock hereafter created specifically ranking by its terms on parity with the Series B Preferred Stock; and
- junior to any class or series of capital stock hereafter created specifically ranking by its terms senior the Series B Preferred Stock,

in each case, as to dividends or distributions of assets upon our liquidation, dissolution or winding up whether voluntarily or involuntarily.

Conversion

Each share of Series B Preferred Stock is convertible, from time to time at the option of the holder thereof, into a number of shares of our common stock determined by dividing $10,000 by a conversion price of $1.80 per share (subject to certain adjustments for stock splits and stock dividends), except that a holder will be prohibited from converting shares of Series B Preferred Stock into shares of common stock if, as a result of such conversion, such holder, together with its affiliates, would beneficially own more than 9.98% of the total number of shares of common stock then issued and outstanding, which percentage may be increased or decreased on sixty-one (61) days' notice from the holder of Series B Preferred Stock to the Company.

Pursuant to written notice, we may also cause each holder of Series B Preferred Stock to convert all or part of such holder's Series B Preferred Stock into common stock, except that a holder will not be forced to convert shares of Series B Preferred Stock into shares of common stock if, as a result of such conversion, such holder would beneficially own more than 9% of the total number of shares of common stock then issued and outstanding immediately after giving effect to the issuance of shares of common stock, pursuant to such written notice. We shall not deliver a forced conversion notice to holders of Series B Preferred Stock more than one time in a ninety (90) day period.

Liquidation Preference

In the event of our liquidation, dissolution or winding up, holders of Series B Preferred Stock will receive a payment equal to $0.001 per share of Series B Preferred Stock before any proceeds are distributed to the holders of our common stock and in parity with our outstanding Series A Preferred Stock. After the payment of this preferential amount, and subject to the rights of holders of any class or series of our capital stock hereafter created specifically ranking by its terms senior to the Series B Preferred Stock (and the holders of the Series A Preferred Stock), holders of Series B Preferred Stock (and the holders of the Series A Preferred Stock) 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.

Voting Rights

Shares of Series A Preferred Stock generally have no voting rights, except as required by law and except that the consent of holders of 80% of the outstanding Series B Preferred Stock will be required to amend the terms of the Series B Preferred Stock or the certificate of designation for the Series B Preferred Stock, to authorize any class of securities that is senior to the Series B Preferred Stock with respect to distribution of assets upon liquidation, the payment of dividends or rights of redemption.

Dividends

Holders of Series A Preferred Stock are entitled to receive, and we are required to pay, dividends on shares of the Series A Preferred Stock equal (on an as-if-converted-to-common-stock basis) to and in the same form as dividends (other than dividends in the form of common stock) actually paid on shares of the common stock when, as and if such dividends (other than dividends in the form of common stock) are paid on shares of the common stock.

Redemption

We are not obligated to redeem or repurchase any shares of Series B Preferred Stock. Shares of Series B Preferred Stock are not otherwise entitled to any redemption rights, or mandatory sinking fund or analogous fund provisions.

Listing

There is no established public trading market for the Series B Preferred Stock, and we do not expect a market to develop. In addition, we do not intend to apply for listing of the Series A Preferred Stock on any national securities exchange or trading system.

Fundamental Transactions

If, at any time that shares of Series B Preferred Stock are outstanding, we effect a merger or other change of control transaction, as described in the certificate of designation and referred to as a fundamental transaction, then a holder will have the right to receive, upon any subsequent conversion of a share of Series A Preferred Stock (in lieu of conversion shares) for each issuable conversion share, the same kind and amount of securities, cash or property as such holder would have been entitled to receive upon the occurrence of such fundamental transaction if such holder had been, immediately prior to such fundamental transaction, the holder of one share of common stock.

Anti-Takeover Effects of Our Certificate of Incorporation and Our Bylaws

Our Certificate of Incorporation and our Bylaws include a number of provisions that may have the effect of delaying, deferring or preventing another party from acquiring control of us and encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with our board of directors rather than pursue non-negotiated takeover attempts. These provisions include the items described below.

Board Composition and Filling Vacancies.

Until the election of directors at the annual meeting scheduled to be held in 2020, our Certificate of Incorporation provides for the division of our board of directors into three classes serving staggered three-year terms, with one class being elected each year. Starting with the annual meeting held in 2018, directors elected by stockholders will be elected to one-year terms. Beginning at the 2020 annual meeting of our stockholders, the board of directors will be completely declassified and all directors will be subject to annual election for one-year terms. Until the election of directors at the annual meeting scheduled to be held in 2021, our Certificate of Incorporation provides that directors may be removed only for cause and then only by the affirmative vote of the holders of two-thirds of the shares of the capital stock then entitled to vote at an election of directors. Furthermore, any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of our board, may only be filled by the affirmative vote of a majority of our directors then in office even if less than a quorum or by a sole remaining director. The classification of directors, together with the limitations on removal of directors and treatment of vacancies, has the effect of making it more difficult for stockholders to change the composition of our board of directors.

Meetings of Stockholders.

Our Bylaws provide that a special meeting of stockholders may be called exclusively by: (i) the Chairman of the Board of Directors or the Chief Executive Officer, President or other executive officer of the Company, (ii) an action of the Board of Directors or (iii) request in writing of the stockholders of record owning not less than sixty-six and two-thirds percent (66 2/3%) of the entire capital stock of the Company issued and outstanding and entitled to vote. Our Bylaws limit the business that may be conducted at an annual meeting of stockholders to those matters properly brought before the meeting.

Advance Notice Requirements.

Our Bylaws establish advance notice procedures with regard to stockholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of our stockholders. These procedures provide that notice of stockholder proposals must be timely given in writing to our corporate secretary prior to the meeting at which the action is to be taken. Generally, to be timely, notice must be received at our principal executive offices not less than 90 days or more than 120 days prior to the first anniversary date of the annual meeting for the preceding year. Our Bylaws specify the requirements as to form and content of all stockholders' notices. These requirements may preclude stockholders from bringing matters before the stockholders at an annual or special meeting.

Amendment to Certificate of Incorporation and Bylaws.

Any amendment of our Certificate of Incorporation must first be approved by a majority of our board of directors, and if required by law or our Certificate of Incorporation, must thereafter be approved by a majority of the outstanding shares entitled to vote on the amendment and a majority of the outstanding shares of each class entitled to vote thereon as a class. Our Bylaws may be amended by the affirmative vote of a majority of the directors then in office, subject to any limitations set forth in the Bylaws; and may also be amended by the affirmative vote of at least sixty-six and two-thirds percent (66 2/3%) of the outstanding shares entitled to vote on the amendment.

Undesignated Preferred Stock

Our Certificate of Incorporation provides for 5,000,000 authorized shares of preferred stock. The existence of authorized but unissued shares of preferred stock may enable our board of directors to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise. For example, if in the due exercise of its fiduciary obligations, our board of directors were to determine that a takeover proposal is not in the best interests of our stockholders, our board of directors could cause shares of preferred stock to be issued without stockholder approval in one or more private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer or insurgent stockholder or stockholder group. In this regard, our Certificate of

Incorporation grants our board of directors broad power to establish the rights and preferences of authorized and unissued shares of preferred stock. The issuance of shares of preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of common stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in control of us.

Section 203 of the Delaware General Corporation Law

We are subject to the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

- before the stockholder became interested, our board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances, but not the outstanding voting stock owned by the interested stockholder; or

- at or after the time the stockholder became interested, the business combination was approved by our board of directors and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;

- any sale, transfer, lease, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;

- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; and

- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person

Exhibit 21.1

Subsidiaries of the Registrant

1. Arius Pharmaceuticals, Inc., a Delaware corporation
2. Arius Two, Inc., a Delaware corporation

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, 333-157173, 333-156839, 333-173261, 333-192618, 333-179257, 333-205483, and 333-160121) and on Form S-8 (Nos. 333-143590, 333-176476, 333-190796, 333-206326, and 333-222734) of our report dated March 12, 2020 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, 2019 and 2018, 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, 2019, and Schedule II – Valuation and Qualifying Accounts and Reserves for each of the years in the three-year period ended December 31, 2019, and the effectiveness of internal control over financial reporting for the Company as of December 31, 2019.

/s/ Cherry Bekaert LLP

Raleigh, North Carolina
March 12, 2020

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 12, 2020

/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 12, 2020

/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 12, 2020

/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 12, 2020

/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.