

PDL<sup>®</sup>



2018  
Annual Report

**PDL BioPharma** seeks to provide a significant return to its shareholders by entering into strategic transactions involving late clinical or early commercial stage pharmaceutical products and companies with attractive revenue growth potential.



**PDL BioPharma** — Incline Village, Nevada



**LENSAR** — Orlando, Florida



**Noden Pharma** — Dublin, Ireland

**PDL**



NODEN PHARMA™



Dear PDL Shareholders:

On December 31, 2018 I assumed the role of CEO at PDL BioPharma, having joined the company as President in September 2017. John McLaughlin served as our CEO for the past 10 years, and I thank him for his commitment and important legacy to PDL and our shareholders. All of us at PDL wish him a most enjoyable retirement. I feel fortunate that John has agreed to continue to serve on our board of directors.

With three decades in commercial and management roles in the biopharmaceutical industry, I am delighted to lead our strategy to build shareholder value by assembling a portfolio of carefully selected companies and assets that have the potential to generate profitable, growing revenue and deliver attractive returns on our invested capital. We are strongly positioned to consummate the right transactions.

We are targeting late clinical- or early commercial-stage assets that are well differentiated, address important medical needs and offer compelling value propositions. We seek products and companies that hold multiyear sales growth potential. We are currently evaluating potential transactions across a range of therapeutic areas with a preference for those that address the U.S. market.

Our primary focus is to find the right companies and/or products in which we can significantly enhance shareholder value through our capital and commercialization expertise. We are flexible on the structure of these transactions that may span from full acquisitions or substantial equity positions to commercialization partnerships or licensing. We seek to take an active role in the management of these assets. Unlike the past, our strategy no longer includes making passive investments such as royalty or debt financing, unless such financing is part of an M&A transaction.

Our strong balance sheet provides us with the purchasing power to execute this strategy, with a substantial net cash position and royalty rights assets that could be monetized if necessary. We also

generate significant positive cash flow from operations that may further fund our strategic transactions.

Finally, we have the in-house expertise to implement this strategy. Our high-quality team at PDL has an established track record of consummating successful transactions and delivering shareholder value through rigorous strategic planning and operational execution. Each member of our executive team brings 20 to 35 years of relevant experience that includes commercializing products in the U.S. and in international markets. We also bring nimbleness, flexibility and speed, all important advantages that will enable us to be highly competitive in pursuing quality assets and in closing attractive transactions.

### **Stock Repurchase Program**

We have been capitalizing on the discrepancy between our stock price and our book value per share to deliver additional shareholder value by executing a \$100 million share repurchase program that was approved by our Board of Directors last September. As of mid-March 2019, we had spent approximately \$61 million to repurchase more than 19 million shares under this program, with an average per-share purchase price of \$3.15. This is our third and largest stock repurchase program to date, with \$55 million in share repurchase through programs completed over the past several years. Even with the full execution of our \$100 million stock repurchase program, we will have sufficient cash on hand to execute our business development strategy.

### **Portfolio of Operating Companies**

In reviewing our current business, our portfolio features two wholly owned operating companies. LENSAR® is an innovation and technology leader with its Augmented Reality™ Streamline system for the use of femtosecond lasers in the treatment of cataract surgery. LENSAR has ample opportunity for growth as cataract surgery is the highest volume surgical procedure in the world, and femtosecond laser technology has only captured a small share of that market.

We are very pleased with LENSAR's continued progress since we acquired the company in May 2017. Revenues from LENSAR reached more than \$25 million in 2018 with positive EBITDA reported for the

fourth quarter. As part of our investment in LENSAR, we were also able to utilize net operating losses, which resulted in cash tax savings of \$2.8 million in 2018. We are regularly evaluating our strategic options on how best to maximize the value of this asset for our shareholders.

Our second portfolio company, Noden Pharma, is a specialty pharmaceutical company marketing Tekturna® in the U.S. and Rasilez® internationally for the management of hypertension. We acquired Noden Pharma in 2016 and subsequently built an efficient, global structure for commercialization. Given the likelihood of generic competition in the U.S., in early March 2019 we announced a partnership with Prasco Laboratories to commercialize an authorized generic of Tekturna®. Our entry ahead of generic competition was timed to provide Noden with a first-to-market competitive advantage. In parallel, we restructured our U.S. commercial efforts with a focus on profitability. Outside of the U.S., we have a robust distribution network that includes the EU, Switzerland and Japan, with the expectation of a near-term launch by our partner in China.

### Closing Thoughts

It is an exciting time to be leading PDL as we focus on developing a portfolio of biopharma assets with opportunities to generate growing revenues and positive cash flows. We continue to evaluate a steady stream of potential transactions, and we remain highly disciplined in our selection and evaluation of these opportunities. We are committed to our strategy as our primary means of creating value for our shareholders.

On behalf of the PDL BioPharma Board of Directors, I would like to thank our employees for their outstanding efforts and commitment, and our investors for their continued support.

Sincerely,



Dominique Monnet  
President, Chief Executive Officer and Director

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

FORM 10-K

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

For the fiscal year ended December 31, 2018  
OR

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: 000-19756



**PDL BioPharma, Inc.**  
(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

94-3023969

(I.R.S. Employer Identification No.)

932 Southwood Boulevard  
Incline Village, Nevada 89451  
(Address of principal executive offices)

Registrant's telephone number, including area code  
(775) 832-8500

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

<u>Title of Class</u>	<u>Name of Exchange on which Registered</u>
Common Stock, par value \$0.01 per share	The Nasdaq Stock Market LLC
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 and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

If an emerging growth company, indicated 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 Act). Yes  No

The aggregate market value of shares of common stock held by non-affiliates of the registrant, based on the closing sale price of a share of common stock on June 29, 2018 (the last business day of the registrant's most recently completed second fiscal quarter), as reported on the Nasdaq Global Select Market, was \$332,399,179.

As of February 25, 2019, the registrant had outstanding 128,108,466 shares of common stock.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant's proxy statement to be delivered to stockholders with respect to the registrant's 2019 Annual Meeting of Stockholders to be filed by the registrant with the U.S. Securities and Exchange Commission are incorporated by reference into Part III of this Annual Report on Form 10-K. The registrant intends to file its proxy statement within 120 days after its fiscal year end.

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**PDL BIOPHARMA, INC.**

**2018 Form 10-K Annual Report**

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## PART I

### Forward-looking Statements

*This Annual Report contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). All statements other than statements of historical facts are “forward-looking statements” for purposes of these provisions, including any projections of earnings, revenues or other financial items, any statements of the plans and objectives of management for future operations, including any statements concerning new licensing, any statements regarding future economic conditions or performance, and any statement of assumptions underlying any of the foregoing. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. In some cases, forward-looking statements can be identified by the use of terminology such as “may,” “will,” “intends,” “plans,” “believes,” “anticipates,” “expects,” “estimates,” “predicts,” “potential,” “continue” or “opportunity,” or the negative thereof or other comparable terminology. The forward-looking statements in this Annual Report are only predictions. Although we believe that the expectations presented in the forward-looking statements contained herein are reasonable at the time of filing, there can be no assurance that such expectations or any of the forward-looking statements will prove to be correct. These forward-looking statements, including with regards to our future financial condition and results of operations, are subject to inherent risks and uncertainties, including but not limited to the risk factors set forth below, and for the reasons described elsewhere in this Annual Report. All forward-looking statements and reasons why results may differ included in this Annual Report are made as of the date hereof. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.*

We own or have rights to certain trademarks, trade names, copyrights and other intellectual property used in our business, including PDL BioPharma, Inc. and the PDL logo, each of which is considered a registered trademark. All other company names, product names, trade names and trademarks included in this Annual Report are trademarks, registered trademarks or trade names of their respective owners.

## ITEM 1. BUSINESS

### Overview

In this report all references to “PDL,” “we,” “us,” “our” or the “Company” mean collectively PDL BioPharma, Inc. and its subsidiaries, except where it is made clear that the term means only PDL BioPharma, Inc.

We seek to provide a significant return for our stockholders by acquiring commercial stage pharmaceutical assets with multiple year revenue growth potential as well as late clinical stage pharmaceutical products. Our leadership team has extensive experience in acquiring, commercializing and managing the life cycle of therapeutic products domestically and internationally across a number of indications and modalities. We intend to leverage this experience by pursuing the acquisition, growth and potential monetization of pharmaceutical products and companies.

Historically, we generated a substantial portion of our revenues through the license agreements related to patents covering the humanization of antibodies, which we refer to as the Queen et al. patents. In 2012, we began providing alternative sources of capital through royalty monetizations and debt facilities, and, in 2016, we began acquiring commercial-stage products and launching specialized companies dedicated to the commercialization of these products. To date, we have consummated seventeen such transactions, the following ten of which are active and outstanding:

Investment	Investment Type	Segment	Deployed Capital <sup>5</sup> (in millions)
Noden <sup>1</sup> .....	Equity and loan	Pharmaceutical	\$ 191.2
LENSAR, Inc. (“LENSAR”).....	Converted equity and loan	Medical Devices	\$ 47.0
CareView Communications, Inc. (“CareView”).....	Debt	Income Generating Assets	\$ 20.0
Direct Flow Medical, Inc. (“DFM”) <sup>2</sup> .....	Debt	Income Generating Assets	\$ 59.0
Wellstat Diagnostics <sup>3</sup> .....	Royalty/debt hybrid	Income Generating Assets	\$ 44.0
Assertio <sup>4</sup> .....	Royalty	Income Generating Assets	\$ 260.5
The Regents of the University of Michigan (“U-M”) .....	Royalty	Income Generating Assets	\$ 65.6
AcelRx Pharmaceuticals, Inc. (“AcelRx”).....	Royalty	Income Generating Assets	\$ 65.0
Viscogliosi Brothers, LLC (“VB”).....	Royalty	Income Generating Assets	\$ 15.5
KYBELLA <sup>®</sup> .....	Royalty	Income Generating Assets	\$ 9.5

<sup>1</sup> Noden Pharma DAC and Noden Pharma USA, Inc. (together, and including their respective subsidiaries, “Noden”).

<sup>2</sup> DFM ceased operations in December 2016 and we subsequently foreclosed upon and obtained most of the assets of DFM and impaired them by \$51.1 million. Since taking over the DFM assets, we have collected \$8.7 million in cash and, as of December 31, 2018 an intangible asset with a carrying value of \$1.6 million remains on our books. For further detail see Note 9, *Notes and Other Long-term Receivables*, and Note 13, *Intangible Assets*, to the Consolidated Financial Statements included in Item 8.

<sup>3</sup> Wellstat Diagnostics, LLC (also known as Defined Diagnostic, LLC) (“Wellstat Diagnostics”).

<sup>4</sup> Assertio Therapeutics, Inc., formerly Depomed, Inc. Hereafter referred to as “Assertio”.

<sup>5</sup> Excludes transaction costs.

Based on the composition of our existing investment portfolio, we currently operate in three segments designated as Pharmaceutical, Medical Devices and Income Generating Assets.

Our Pharmaceutical segment consists of revenue derived from branded prescription medicine products sold under the name Tekturna<sup>®</sup> and Tekturna HCT<sup>®</sup> in the United States, and Rasilez<sup>®</sup> and Rasilez HCT<sup>®</sup> in the rest of the world (collectively, the “Noden Products”). Our Medical Devices segment consists of revenue derived from the LENSAR<sup>®</sup> Laser System sales. Our Income Generating Assets segment consists of revenue derived from (i) notes and other long-term receivables, (ii) royalty rights and hybrid notes/royalty receivables, (iii) equity investments and (iv) royalties from issued patents in the United States and elsewhere covering the humanization of antibodies, which we refer to as the Queen et al. patents.

Prospectively, we expect to focus on the acquisition and development of additional pharmaceutical products and companies with revenue growth potential. We anticipate that over time, as a result of these new acquisitions, more of our revenues will come from our Pharmaceutical segment and less of our revenues will come from our Income Generating Assets and Medical Devices segments.

Financial information about our operations, including our revenues and net (loss) income for the years ended December 31, 2018, 2017 and 2016, and our total assets as of December 31, 2018 and 2017, is included in our Consolidated Financial Statements and accompanying notes in Item 8.

### **Pharmaceutical**

Our goal is to deliver market-leading shareholder value through the acquisition, growth and potential monetization of a portfolio of actively managed pharmaceutical assets. We are focused on acquiring (1) commercial-stage assets with multiple year revenue growth potential and (2) late clinical stage pharmaceutical products. In both instances, our acquisition strategy focuses on our ability to add value to these assets by giving them access to our capital and commercialization expertise. We have a leadership team with a proven track record of consummating deals and putting businesses on the path to growth and profitability, and we have a strong, liquid balance sheet that can be deployed to finance the right transactions. Our goal is to build growing, profitable revenues from a balanced portfolio of operating companies' cash flows and, when appropriate, to capture further market value through optimally timed exit strategies.

#### *Noden*

On July 1, 2016, our subsidiary, Noden Pharma DAC, entered into an asset purchase agreement (“Noden Purchase Agreement”) whereby it purchased from Novartis Pharma AG (“Novartis”) the exclusive worldwide rights to manufacture, market, and sell the Noden Products and certain related assets and assumed certain related liabilities (the “Noden Transaction”). Upon the consummation of the Noden Transaction, a noncontrolling interest holder acquired a 6% equity interest in Noden. We purchased the equity interest of the noncontrolling interest holder in May 2017. For details regarding the Noden Transaction see Note 23, *Business Combinations*, to the Consolidated Financial Statements included in Item 8.

Tekturna (or Rasilez outside of the United States) contains aliskiren, a direct renin inhibitor, for the treatment of hypertension. While indicated as a first line treatment, it is more commonly used as a third line treatment in those patients who are intolerant of angiotensin-receptor blockers (“ARBs”) or angiotensin converting enzyme inhibitors (“ACEIs”). Studies indicate that approximately 12% of hypertension patients are ARB/ACEI inhibitor-intolerant. It is not indicated for use with ARBs and ACEIs in patients with diabetes or renal impairment and is contraindicated for use by pregnant women. On March 4, 2019, we announced the U.S commercial launch of an authorized generic of Tekturna, aliskiren hemifumarate 150 mg and 300 mg tablets with the same drug formulation as Tekturna. The launch is being carried out by Prasco, LLC d/b/a Prasco Laboratories.

Tekturna HCT is a combination of aliskiren and hydrochlorothiazide, a diuretic, for the treatment of hypertension in patients not adequately controlled by monotherapy and as an initial therapy in patients likely to need multiple drugs to achieve their blood pressure goals. It is not indicated for use with ACEIs and ARBs in patient with diabetes or renal impairment, or for use in patients with known anuria or hypersensitivity to sulfonamide derived drugs and is contraindicated for use by pregnant women.

The agreement between Novartis and Noden provides for various transition periods for development and commercialization activities relating to the Noden Products. Initially, Novartis distributed the Noden Products on behalf of Noden worldwide and Noden received a profit transfer on such sales. Generally, the profit transfer to Noden was defined as gross revenues less product cost and a low single digit percentage fee to Novartis. The profit transfer terminated upon the transfer of the marketing authorization from Novartis to Noden in each country. In the United States, the duration of the profit transfer ran from July 1, 2016 through October 4, 2016. Outside the United States, the profit transfer ended in the first quarter of 2018. Prior to the transfer of the marketing authorization, revenue was presented on a “net” basis; after the transfer of the marketing authorization, revenue is presented on a “gross” basis, meaning product costs are reported separately and there is no fee to Novartis.

### **Intellectual Property**

The Noden Products are protected by multiple patents worldwide, which specifically cover the composition of matter, the pharmaceutical formulations and methods of production. In the United States, the Food and Drug Administration (“FDA”) Orange Book lists one patent, U.S. patent No. 5,559,111 (the “’111 Patent”), which covers compositions of matter comprising aliskiren. The ‘111 Patent expired on January 21, 2019, and was previously extended for six months through a pediatric extension. In

addition, the FDA Orange Book for Tekturna lists U.S. Patent No. 8,617,595 (the “595 Patent”), which covers certain compositions comprising aliskiren, together with other formulation components, and will expire on February 19, 2026.

On June 12, 2017, our subsidiary Noden Pharma DAC (“Noden DAC”) filed a complaint against Anchen Pharmaceuticals, Inc. (“Anchen”) and Par Pharmaceutical (“Par”) for infringement of the ‘595 Patent based on their submission of an Abbreviated New Drug Applications (“ANDA”) seeking authorization from the FDA to market a generic version of aliskiren hemifumarate tablets, 150 mg and 300 mg, in the United States. Noden DAC’s suit triggered a 30-month stay of FDA approval of that application under the Hatch Waxman Act. Par filed a counterclaim seeking a declaratory judgment that their proposed generic version of aliskiren hemifumarate hydrochlorothiazide tablets (150 mg eq. base/12.5 mg HCT, 150 mg eq. base/25 mg HCT, 300 mg eq. base/12.5 mg HCT, and 300 mg eq. base/25 mg HCT), described in a separate ANDA submitted by Par to FDA, alleging noninfringement of U.S. Patent No. 8,618,172 (the “172 Patent”), also owned by Noden DAC. This case was filed in the United States District Court for the District of Delaware. In March 2018, each of the parties to the proceeding filed a joint stipulation of dismissal of the defendants’ counterclaim seeking a declaratory judgment of non-infringement of the ‘172 Patent. In the stipulation, Anchen and Par agreed that they will not seek, or otherwise join or assist in, any post-grant review, including *inter partes* review, of the ‘172 Patent or U.S. Patent No. 9,023,893 (the “893 Patent”). The defendants further stipulated that they will not seek marketing approval of Par’s ANDA or submit any other ANDA seeking approval to market aliskiren hemifumarate hydrochlorothiazide prior to the expiration of the ‘172 Patent in July of 2028. Both the ‘172 Patent and the ‘893 Patent are listed in the Orange Book for Tekturna HCT.

On June 8, 2018, Noden and Anchen entered into a settlement agreement (the “Settlement Agreement”). Under the Settlement Agreement, the parties agreed to file a stipulation of dismissal with the court to facilitate dismissal of the litigation in its entirety, with prejudice. In the Settlement Agreement, Noden granted Anchen a non-exclusive, royalty free, fully paid up and non-transferable license to manufacture and commercialize in the United States a generic version of aliskiren which is described in Anchen’s ANDA, and Anchen agreed not to commercialize its generic version of aliskiren prior to March 1, 2019. The license grant excludes certain formulations covered by the ‘595 Patent which closely relate to the commercial formulation of Tekturna marketed by Noden. The Settlement Agreement includes a release by each party for liabilities associated with the litigation and an acknowledgment from Anchen that the ‘595 Patent claims are valid and enforceable.

As a result of the Settlement Agreement and the increased probability of a generic version of aliskiren being launched in the United States, management evaluated the ongoing value of the Noden DAC asset group and concluded that the Noden DAC acquired product rights and customer relationship long-lived assets, with a carrying amount of \$192.5 million, were no longer recoverable and wrote them down to their estimated fair value of \$40.1 million, resulting in an impairment charge of \$152.3 million in the second quarter of 2018.

The FDA Orange Book for Tekturna HCT lists U.S. patent No. 8,618,172, which covers certain compositions comprising aliskiren, together with other formulation components, and will expire on July 13, 2028. In Europe, European patent No. 678 503B (the “503B Patent”) expired in 2015. However, numerous Supplementary Protection Certificates (“SPCs”) have been granted which are based on the ‘503B Patent and which will provide for extended protection. These SPCs generally expire in April of 2020. European Patent Publication Number 2 305 232 (the “232 Patent”), currently pending before the European Patent Office, has received a positive indication of allowability. The ‘232 Patent covers certain pharmaceutical compositions comprising aliskiren and HCT and, if granted, will expire in 2021. The Company intends to file applications with selected national patent offices for the grant of SPCs which, if granted, would extend the date of expiration for up to five years.

## **Manufacturing**

Noden and Novartis entered into a supply agreement pursuant to which Novartis will manufacture and supply to Noden a bulk tableted form of the Noden Products, and for the additional supply of active pharmaceutical ingredient (“API”) form, for specified periods of time prior to the transfer of manufacturing responsibilities for the Noden Products to another manufacturer. This arrangement is covered by a long-term supply agreement in effect through November 2020. For additional details regarding the supply agreement, see Note 15, *Commitments and Contingencies*, to the Consolidated Financial Statements included in Item 8. To date, Novartis has met our manufacturing requirements and we expect that it is capable of providing sufficient quantities of the Noden Products to meet anticipated demands. We have contracted with an additional third-party located outside of the United States for the manufacture of Noden products once the agreement with Novartis expires.

## **Sales and Distribution**

In anticipation of the commercialization of Anchen’s generic version of aliskiren and in order to optimize profitability, in the third quarter of 2018, Noden discontinued its direct sales force and transitioned to a non-personal promotion strategy.

We entered into an arrangement with a third-party logistics provider to distribute the Noden Products within the United States on our behalf. The Noden Products are sold directly to wholesalers from a distribution center owned by the third-party logistics provider.

As of December 31, 2018, the Noden Products were distributed in 13 countries outside of the United States. During 2018, we ceased distribution of the Noden Products in several European countries where they were not profitable or had extremely low gross margins.

The pharmaceutical industry's largest wholesale distributors, Amerisource Bergen Corporation, McKesson Corporation and Cardinal Health, Inc., accounted for 15.4%, 17.0% and 13.2%, respectively, of our total net pharmaceutical sales for the year ended December 31, 2018, and 19.8%, 22.2% and 15.0%, respectively, of our total net pharmaceutical sales for the year ended December 31, 2017.

## **Competition**

The pharmaceutical industry is characterized by rapid innovation and intense competition which is applicable to the therapeutic area our Noden Products are approved. The Noden Products are direct renin inhibitors approved for the treatment of hypertension. They compete against a number of classes of treatments including changes in diet, exercise, thiazide diuretics, ACEIs, ARBs, calcium channel blockers, cardioselective beta blockers, alpha blockers, direct vasodilators and centrally acting agents. With the exception of diet and exercise, there are numerous drugs within each of the classes enumerated above, most of which have generic versions that are less expensive than Tekturna and Tekturna HCT. Physicians may also treat hypertension patients by combining one or more of the enumerated classes of treatments. Diet, thiazide diuretics, ACEIs, ARBs and calcium channel blockers are most commonly used as first line treatments for hypertension and dominate the market, in part, because of the availability of low cost generics in each category. Renin inhibitors, such as Tekturna and Tekturna HCT which are the only approved direct renin inhibitors, and beta blockers are used thereafter followed by direct vasodilators, central acting agents and alpha blockers. Tekturna and Tekturna HCT are generally perceived as alternatives for patients who do not respond to, or are intolerant of, the first line therapies. As noted above, on March 4, 2019, we announced the U.S. commercial launch of an authorized generic of Tekturna, aliskiren hemifumarate 150 mg and 300 mg tablets with the same drug formulation as Tekturna.

## **Employees**

As of December 31, 2018, we had 20 full-time employees at Noden, who manage its business and operations.

## **Medical Devices**

### *LENSAR*

In December 2016, LENSAR filed a voluntary petition under Chapter 11 of the U.S. Bankruptcy Code (the "Chapter 11 case"). With our support, LENSAR filed a Chapter 11 plan of reorganization under which LENSAR would issue 100% of its equity interests to us in exchange for the cancellation of our claims as a secured creditor in the Chapter 11 case. On May 11, 2017, pursuant to the Chapter 11 plan of reorganization, most of LENSAR's outstanding debt owed to us was converted to equity and LENSAR became our wholly-owned operating subsidiary ("the LENSAR Transaction"). For additional details regarding the LENSAR, the LENSAR Transaction and the Chapter 11 case, see Note 23, *Business Combinations*, to the Consolidated Financial Statements included in Item 8.

LENSAR is a medical device company focused on the next generation femtosecond cataract laser technology for refractive cataract surgery. Femtosecond cataract surgery uses advanced laser technology as compared to conventional phacoemulsification cataract surgery which uses an ultrasonic device. Cataract surgery is the highest volume surgical procedure performed worldwide with over 27 million surgeries estimated to have been performed in 2018, the majority of which use the conventional phacoemulsification technique. The LENSAR<sup>®</sup> Laser System offers cataract surgeons automation and customization for their astigmatism treatment planning and other essential steps of the refractive cataract surgery procedure with the highest levels of precision, accuracy, and efficiency. These features assist surgeons in managing their astigmatism treatment plans for optimal overall visual outcomes.

The LENSAR<sup>®</sup> Laser System has been approved by the FDA for anterior capsulotomy, lens fragmentation, corneal and arcuate incisions. The LENSAR Laser with Augmented Reality<sup>™</sup> provides an accurate 3-D model of the relevant anatomical features of each patient's anterior segment, allowing precise laser delivery and to enhance the surgical confidence in performing accurate

corneal incisions, precise size, shape and location of free-floating capsulotomies, and efficient lens fragmentation for all grades. The LENSAR<sup>®</sup> Laser System - fs 3D (LLS-fs 3D) with Streamline<sup>™</sup> includes the integration with various pre-op diagnostic devices, automated Iris Registration with automatic cyclorotation adjustment, IntelliAxis-C<sup>™</sup> (corneal) and IntelliAxis-L<sup>™</sup> (lens) markers for simple alignment without errors associated with manually marking the eye, of Toric IOLs as well as treatment planning tools for precision guided laser treatments. The corneal incision-only mode, expanded remote diagnostics capabilities, additional pre-programmable preferences, thoughtful ergonomics, and up to 20 seconds faster laser treatment times with Streamline allow for seamless integration and maximum surgical efficiency.

## **Intellectual Property**

LENSAR has developed the LENSAR<sup>®</sup> Laser System, which is the only femtosecond cataract laser built specifically for refractive cataract surgery. The LENSAR<sup>®</sup> Laser System is protected by over 60 granted patents in the United States and rest of the world and over 45 pending patent applications in the United States and rest of the world.

## **Manufacturing**

Through our LENSAR subsidiary, we currently manufacture our LENSAR<sup>®</sup> Laser System at a facility in Orlando, Florida.

LENSAR purchases both custom and off-the-shelf components from a small number of suppliers and subjects them to stringent quality specifications and processes. Some of the components necessary for the assembly of the LENSAR<sup>®</sup> Laser System are currently provided by sole-sourced suppliers (the only recognized supply source available to us) or single-sourced suppliers (the only approved supply source for us among other sources). LENSAR purchases the majority of its components and major assemblies through purchase orders with limited long-term supply agreements and generally do not maintain large volumes of finished goods.

LENSAR has entered into various supply agreements for the manufacture and supply of certain components. The supply agreements commit LENSAR to a minimum purchase obligation of approximately \$3.8 million over the next twenty-four months of which \$3.5 million is due in the next 12 months. LENSAR expects to meet these requirements.

## **Sales and Distribution**

LENSAR markets and sells the LENSAR<sup>®</sup> Laser System to ophthalmic ambulatory surgical centers, specialty ophthalmic hospitals and multi-specialty hospitals in the United States through a direct sales force. Outside of the United States, LENSAR typically sells the LENSAR<sup>®</sup> Laser System through distributors. Two distributors in Asia each represent 12% of the net sales in our Medical Devices segment for the year ended December 31, 2018.

## **Competition**

The LENSAR<sup>®</sup> Laser System is a femtosecond cataract laser for refractive cataract surgery. Cataract surgery is the highest volume surgical procedure globally, with 27 million cataract surgeries estimated to have been performed in 2018. We estimate that the market penetration of femtosecond cataract laser surgery is approximately 10.6% of total procedures in the United States, while approximately 2.8% of the total cataract surgeries performed globally. We believe femtosecond cataract laser procedures are expected to grow approximately 7.5% annually through 2023.

## **Employees**

As of December 31, 2018, we had 67 full-time employees at LENSAR, who manage its business and operations.

## **Income Generating Assets**

We have pursued income generating assets when such assets can be acquired on terms that we believe allow us to increase return to our stockholders. The income generating assets typically consist of (i) notes and other long-term receivables, (ii) royalty rights and hybrid notes/royalty receivables, (iii) equity investments and (iv) royalties from the Queen et al. AI patents. We focus our income generating asset acquisition strategy on commercial-stage therapies and medical devices having strong economic fundamentals. However, our acquired income generating assets will not, in the near term, replace completely the revenues we generated from our license agreements related to our Queen et al. patents. In the second quarter of 2016, our revenues materially decreased after we stopped receiving payments from certain Queen et al. patent licenses and legal settlements, which accounted for 2%, 11% and 68% of our 2018, 2017 and 2016 total revenues.

## *Notes and Other Long-Term Receivables*

We have entered into credit agreements with borrowers across the healthcare industry, under which we make available cash loans to be used by the borrower. Obligations under these credit agreements are typically secured by a pledge of substantially all the assets of the borrower and any of its subsidiaries. While we currently maintain this portfolio of notes receivable, our intention is to pursue fewer of these transactions. As of December 31, 2018, we had two notes receivable transactions outstanding, CareView and Wellstat Diagnostics, which are summarized below:

### CareView

#### *Technology*

CareView is a provider of products and on-demand application services for the healthcare industry by specializing in bedside video monitoring, archiving and patient care documentation systems and patient entertainment services.

#### *Deal Summary*

In June 2015, we entered into a credit agreement with CareView, whereby we made available to CareView up to \$40.0 million in loans comprised of two tranches of \$20.0 million each, subject to CareView's attainment of specified milestones and under which we have a security interest in substantially all of CareView's assets. In October 2015, we and CareView entered into an amendment of the credit agreement to modify certain definitions related to the first and second tranche milestones and we funded the first tranche of \$20.0 million, net of fees, based on CareView's attainment of the first milestone, as amended. The second \$20.0 million tranche was not funded due to CareView's failure to meet the funding milestone and we have no further funding obligation at this time. The outstanding borrowing under the credit agreement bears interest at the rate of 13.5% per annum payable quarterly in arrears. Principal repayment was to commence on the ninth quarterly interest payment date in equal installments until final maturity of the loan in October 2020.

In February 2018, we entered into a modification agreement with CareView (the "February 2018 Modification Agreement") whereby we agreed, effective as of December 28, 2017, to modify the credit agreement before remedies could otherwise have become available to us under the credit agreement in relation to certain obligations of CareView that would potentially not be met, including the requirement to make principal payments. Under the February 2018 Modification Agreement, we agreed that (i) a lower liquidity covenant would be applicable and (ii) principal repayment would be delayed for a period of up to December 31, 2018. In exchange for agreeing to these modifications, among other things, the exercise price of our warrants to purchase 4.4 million shares of common stock of CareView was reduced and, subject to the occurrence of certain events, CareView agreed to grant us additional equity interests. In September 2018, we entered into an amendment to the February 2018 Modification Agreement with CareView whereby we agreed, effective as of September 28, 2018, that a lower liquidity covenant would be applicable.

In December 2018, the Company further modified the loan by agreeing that (i) a lower liquidity covenant would be applicable, (ii) the principal repayment would be deferred until January 31, 2019, and (iii) the scheduled interest payment due on December 31, 2018 would be deferred until January 31, 2019. The principal repayment and interest payment were subsequently deferred until March 31, 2019 under additional amendments.

### Wellstat Diagnostics

#### *Technology*

Wellstat Diagnostics is a private company formerly dedicated to the development, manufacture, sale and distribution of small point of care diagnostic systems.

#### *Deal Summary*

In March 2012, we executed a \$7.5 million two-year senior secured note receivable with the holders of the equity interests in Wellstat Diagnostics. In August 2012, we and Wellstat Diagnostics amended the note receivable, providing a senior secured note receivable of \$10.0 million, bearing interest at 12% per annum, to replace the original \$7.5 million

note receivable. This \$10.0 million note receivable was repaid on November 2, 2012, using the proceeds of the \$40.0 million credit facility we entered into on the same date.

In November 2012, we entered into a \$40.0 million credit agreement with Wellstat Diagnostics pursuant to which we were to accrue quarterly interest payments at the rate of 5% per annum. In January 2013, Wellstat Diagnostics defaulted on the credit agreement, and as a result both parties agreed to enter into a forbearance agreement whereby we agreed to provide additional funding. In August 2013, we entered into an amended and restated credit agreement with terms substantially the same as those of the original credit agreement. However, pursuant to the amended and restated credit agreement the principal amount was reset to approximately \$44.1 million.

During 2015, 2016 and 2017, we, Wellstat Diagnostics, and Samuel J. Wohlstadter, Nadine H. Wohlstadter, Duck Farm, Inc., Hebron Valley Farms, Inc., HVF, Inc., Hyperion Catalysis EU Limited, Hyperion, NHW, LLC, Wellstat AVT Investment, LLC, Wellstat Biocatalysis, LLC, Wellstat Biologics Corporation, Wellstat Diagnostics, Wellstat Immunotherapeutics, LLC, Wellstat Management Company, LLC, Wellstat Ophthalmics Corporation, Wellstat Therapeutics Corporation, Wellstat Therapeutics EU Limited, Wellstat Vaccines, LLC and SJW Properties, Inc., the guarantors of Wellstat Diagnostics' obligations to us (collectively, the "Wellstat Diagnostics Guarantors") were involved in a series of legal actions. A further discussion of the Wellstat litigation is included in Note 25, *Legal Proceedings*, to the Consolidated Financial Statements included in Item 8.

#### *Royalty Rights - At Fair Value*

We have entered into various royalty purchase agreements with counterparties, whereby the counterparty conveys to us the right to receive royalties that are typically payable on sales revenue generated by the sale, distribution or other use of the counterparties' products. Certain of our royalty agreements provide the counterparty with the right to repurchase the royalty rights at any time for a specified amount.

We record the royalty rights at fair value using discounted cash flows related to the expected future cash flows to be received. We use significant judgment in determining our valuation inputs, including estimates as to the probability and timing of future sales of the licensed product. A third-party expert is generally engaged to assist us with the development of our estimate of the expected future cash flows. The estimated fair value of the asset is subject to variation should those cash flows vary significantly from our estimates. At each reporting period, an evaluation is performed to assess those estimates, discount rates utilized and general market conditions affecting fair market value.

While we currently maintain this portfolio of royalty rights, our intention is to no longer pursue these transactions while we focus on acquiring additional pharmaceutical products or companies.

At December 31, 2018, we had a total of five royalty rights transactions outstanding, which are summarized below in chronological order:

#### Assertio (formerly Depomed)

##### *Deal Summary*

In October 2013, we entered into a Royalty Purchase and Sale Agreement (the "Assertio Royalty Agreement") with Assertio, whereby we acquired the rights to receive royalties and milestones payable on sales of five Type 2 diabetes products licensed by Assertio in exchange for a \$240.5 million cash payment.

In August 2018, we entered into an amendment to the Assertio Royalty Agreement pursuant to which we purchased Assertio's remaining interests in royalty and milestone payments payable on sales of Type 2 diabetes products licensed by Assertio for \$20.0 million.

The Assertio Royalty Agreement terminates on the third anniversary following the date upon which the later of the following occurs: (a) October 25, 2021, or (b) at such time as no royalty payments remain payable under any license agreement and each of the license agreements has expired by its terms.



## *Technology*

The rights acquired include Assertio's royalty and milestone payments accruing from and after October 1, 2013: (a) from Santarus, Inc. ("Santarus"), which was subsequently acquired by Salix Pharmaceuticals, Inc. ("Salix"), which itself was acquired by Valeant Pharmaceuticals International, Inc. ("Valeant"), which, in July 2018 changed its name to Bausch Health Companies Inc. (hereafter referred to as "Bausch Health") with respect to sales of Glumetza® (metformin HCL extended-release tablets) in the United States; (b) from Merck & Co., Inc. ("Merck") with respect to sales of Janumet XR® (sitagliptin and metformin HCL extended-release); (c) from Janssen Pharmaceuticals N.V. ("Janssen Pharmaceuticals") with respect to potential future development milestones and sales of its fixed-dose combination of Invokana® (canagliflozin, a sodium glucose cotransporter 2 (SGLT2) inhibitor) and extended-release metformin tablets, marketed as Invokamet XR®; (d) from Boehringer Ingelheim GmbH ("Boehringer Ingelheim") and Eli Lilly & Company ("Eli Lilly") with respect to potential development milestones and sales of the fixed-dose combinations of drugs and extended-release metformin subject to Assertio's license agreement with Boehringer Ingelheim including its approved products, Jentadueto XR® and Synjardy XR®, and (e) from LG Life Sciences and Bausch Health for sales of extended-release metformin in Korea and Canada, respectively.

On May 31, 2016, Boehringer Ingelheim and Eli Lilly announced that the FDA approved Jentadueto XR (a fixed dose combination of Linagliptin, a dipeptidyl peptidase-4 inhibitor and extended-release metformin tablets) for the treatment of type 2 diabetes in adults, which will be marketed by both companies. This approval triggered the payment of a milestone to us of \$6.0 million. On September 21, 2016, Janssen Pharmaceuticals announced that the FDA approved Invokamet XR for the treatment of type 2 diabetes in adults. This approval triggered the payment of a milestone to us of \$5.0 million. On December 13, 2016, Boehringer Ingelheim and Eli Lilly announced that the FDA approved Synjardy® XR (a fixed dose combination of Empagliflozin, a sodium-glucose co-transporter 2 inhibitor, and extended-release metformin tablets) for the treatment of type 2 diabetes in adults, which will be marketed by both companies. This approval triggered the payment of a milestone to us of \$6.0 million. In 2017, we started to receive royalties on the net sales of these three newly approved products.

In February 2013, a generic equivalent to Glumetza was approved by the FDA and in August of 2016, two additional generic equivalents to Glumetza were approved to enter the U.S. market. In February 2016, Lupin Pharmaceuticals, Inc., in August 2017, Teva Pharmaceutical Industries Ltd., and in July 2018, Sun Pharmaceuticals, Inc. each launched a generic equivalent approved product.

In May 2017, we received notification that a subsidiary of Valeant had launched an authorized generic equivalent product in February 2017, and we received royalties on such authorized generic equivalent product under the same terms as the branded Glumetza product, retroactive to February 2017.

## Viscogliosi Brothers

### *Deal Summary*

In June 2014, we entered into a Royalty Purchase and Sale Agreement (the "VB Royalty Agreement") with VB, whereby we acquired the right to receive royalties on net sales of a spinal implant that had received pre-market approval from the FDA held by VB and commercialized by Paradigm Spine, LLC ("Paradigm Spine") in exchange for a \$15.5 million cash payment. The royalty rights acquired includes royalties accruing from and after April 1, 2014. We receive all royalty payments due to VB pursuant to certain technology transfer agreements between VB and Paradigm Spine until we have received payments equal to 2.3 times the cash payment it made to VB, after which all rights to receive royalties will be returned to VB. VB's ability to repurchase the royalty rights for a specified amount expired on June 26, 2018.

### *Technology*

The coflex® Interlaminar technology is an Interlaminar Stabilization® device indicated for use in one or two level lumbar stenosis from L1-L5 in skeletally mature patients with at least moderate impairment in function.

## University of Michigan

### *Deal Summary*

In November 2014, we acquired a portion of U-M's worldwide royalty interest in Cerdelga<sup>®</sup> (eliglustat) for \$65.6 million pursuant to the Royalty Purchase and Sale Agreement with U-M (the "U-M Royalty Agreement"). Under the terms of the U-M Royalty Agreement, we will receive 75% of all royalty payments due under U-M's license agreement with Genzyme Corporation, a Sanofi company ("Genzyme") until expiration of the licensed patents, excluding any patent term extension. The royalty rate used to calculate the royalties to be paid by Genzyme to U-M was not disclosed by the parties.

### *Technology*

Cerdelga, an oral therapy for adult patients with Gaucher disease type 1, was developed by Genzyme. Cerdelga was approved in the United States in August 2014, in the European Union in January 2015 and in Japan in March 2015.

## AcelRx

### *Deal Summary*

In September 2015, we entered into a royalty interest assignment agreement (the "AcelRx Royalty Agreement") with ARPI LLC, a wholly-owned subsidiary of AcelRx, whereby we acquired a portion of the royalties and certain milestones on expected sales of Zalviso<sup>®</sup> (sufentanil sublingual tablet system) in the European Union, Switzerland and Australia by AcelRx's commercial partner, Grünenthal, in exchange for \$65.0 million. Under the terms of the agreement, we receive 75% of the royalties AcelRx receives from Grünenthal as well as 80% of the first four commercial milestone payments, until the earlier of occur of (i) receipt by us of payments equal to three times the cash payments made to AcelRx and (ii) the expiration of the licensed patents. We believe that the applicable patents run until January 2032. Zalviso received marketing approval by the European Commission in September 2015. Grünenthal launched Zalviso in the second quarter of 2016 and we started to receive royalties in the third quarter of 2016.

### *Technology*

Zalviso is a combination drug and device product which, using a patient controlled dispenser, delivers a sub-lingual formulation of sufentanil, an opioid with a high therapeutic index.

## KYBELLA

### *Deal Summary*

In July 2016, we entered into a royalty purchase and sales agreement with an individual, whereby we acquired the individual's rights to receive certain royalties on sales of KYBELLA<sup>®</sup> by Allergan, Plc ("Allergan") in exchange for a \$9.5 million cash payment and up to \$1.0 million in future milestone payments based upon achieving specified product sales targets. We started to receive royalty payments during the third quarter of 2016.

### *Technology*

KYBELLA is an FDA approved injectable treatment for adults with moderate-to-severe fat below the chin, known as submental fat. KYBELLA contains deoxycholic acid which destroys fat cells and allows for a safer and less invasive alternative to surgical procedures.

## *Equity Investments*

In connection with credit and royalty agreements, from time to time we may make equity investments in healthcare companies. Our investment objective with respect to potential equity investments is to maximize our portfolio total return by generating current income from capital appreciation, and our primary business objectives are to increase our net income, net operating income and asset value by investing in companies with the potential for equity appreciation and realized gains.

### *Royalties from Queen et al. patents*

Historically, we generated a substantial portion of our revenues through the license agreements related to patents covering the humanization of antibodies, which we refer to as the Queen et al. patents. While the Queen et al. royalty revenue has dropped substantially since the first quarter of 2016, we continued to receive royalty revenue in 2018 from one product under the Queen et al. patent licenses, Tysabri<sup>®</sup>, as a result of sales of the product that was manufactured prior to patent expiry. In November 2017, we were notified by Biogen Inc. (“Biogen”) that product supply for Tysabri<sup>®</sup> that was manufactured prior to patent expiry, and for which we would receive royalties on, had been extinguished in the United States and was rapidly being reduced in other countries. As a result, royalties from product sales of Tysabri were substantially lower in 2018 and no additional royalties are expected in 2019. Our total revenues from licensees under our Queen et al. patents were \$4.5 million, \$36.4 million and \$166.2 million, net of rebates and foreign exchange hedge adjustments, for the years ended December 31, 2018, 2017 and 2016, respectively.

### *Licensing Agreements for Marketed Products*

For the years ended December 31, 2018, 2017 and 2016, we received royalties on sales of Tysabri from Biogen, and in the year ended December 31, 2016, we also received royalties on sales of the six humanized antibody products listed below from Genentech, Inc. (“Genentech”).

#### *Biogen*

We entered into a patent license agreement, effective April 24, 1998, under which we granted to Elan Corporation, plc (“Elan”) a license under our Queen et al. patents to make, use and sell antibodies that bind to the cellular adhesion molecule 44 in patients with multiple sclerosis. Under the agreement, we are entitled to receive a flat royalty rate in the low, single digits based on Elan’s net sales of the Tysabri product. This license agreement entitles us to royalties following the expiration of our patents with respect to sales of licensed product manufactured prior to patent expiry in jurisdictions providing patent protection. In April 2013, Biogen completed its purchase of Elan’s interest in Tysabri, and in connection with such purchase all obligations under our patent license agreement with Elan were assumed by Biogen.

In November 2017, we were notified by Biogen that product supply that was manufactured prior to patent expiry, and for which we would receive royalties on, had been extinguished in the United States and was rapidly being reduced in other countries. This resulted in a reduction in royalties from product sales of Tysabri, and royalties were substantially lower in 2018 and no additional royalties are expected.

#### *Genentech*

We entered into a master patent license agreement, effective September 25, 1998, under which we granted Genentech a license under our Queen et al. patents to make, use and sell certain antibody products.

On January 31, 2014, we entered into the Settlement Agreement (the “Settlement Agreement”) with Genentech and F. Hoffman LaRoche, Ltd. (“Roche”) that resolved all existing legal disputes between the parties.

The Settlement Agreement precluded Genentech and Roche from challenging the validity of our patents, including our SPCs in Europe, from contesting their obligation to pay royalties to us, from contesting patent coverage for Avastin, Herceptin, Lucentis, Xolair, Perjeta, Kadcyla and Gazyva<sup>®</sup> (collectively, the “Genentech Products”) and from assisting or encouraging any third-party in challenging our patents and SPCs. Under the terms of the Settlement Agreement, we ceased receiving any revenue from Genentech after the first quarter of 2016.

### **Major Customers**

In 2016, Genentech accounted for 43% of our total revenues. It did not account for any of our revenues in 2018 or 2017. In 2018, 2017 and 2016, Biogen accounted for 2%, 11%, and 24% of our total revenues, respectively.

### **Competition**

The underlying products associated with our income generating assets compete with existing products and are vulnerable to new branded or generic entrants in the marketplace.

## **Governmental Regulation**

The research and development, manufacturing and marketing of pharmaceutical and medical device products are subject to regulation by numerous governmental authorities in the United States and other countries. We and our borrowers and royalty-agreement counterparties, depending on specific activities performed, are subject to these regulations. In the United States, pharmaceuticals and medical devices are subject to regulation by both federal and various state authorities, including the FDA. The Federal Food, Drug and Cosmetic Act (“FDCA”) governs the testing, manufacture, safety, efficacy, labeling, storage, record keeping, approval, advertising and promotion of pharmaceutical and medical device products, and with respect to biologics, compliance with the Public Health Service Act is also required. There are also comparable laws and regulations that apply at the state level and in other countries as well. For both currently marketed and products in development, failure to comply with applicable regulatory requirements can, among other things, result in delays, the suspension of regulatory approvals, as well as possible civil and criminal sanctions.

### ***Regulation of Pharmaceuticals in the United States***

The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA’s good laboratory practice, or GLP, regulations;
- submission to the FDA of an investigational new drug application, or IND, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practice, or GCP, requirements to establish the safety and efficacy of the proposed drug product for each indication;
- submission to the FDA of a new drug application, or NDA;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with current good manufacturing practice, or cGMP, requirements and to assure that the facilities, methods and controls are adequate to preserve the drug’s identity, strength, quality and purity; and
- FDA review and approval of the NDA.

### ***Preclinical Studies***

Preclinical studies include laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies to assess potential safety and efficacy. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, among other things, to the FDA as part of an IND. Some preclinical testing may continue even after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

### ***Clinical Trials***

Clinical trials involve the administration of the investigational new drug to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, an IRB at each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution. Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on their [www.clinicaltrials.gov](http://www.clinicaltrials.gov) website.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined:

- Phase 1: The drug is initially introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness.

- Phase 2: The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- Phase 3: The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients.

### *Marketing Approval*

Assuming successful completion of the required clinical testing, the results of the preclinical and clinical studies, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. In most cases, the submission of an NDA is subject to a substantial application user fee. Under the Prescription Drug User Fee Act, or PDUFA, guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes twelve months from the date the NDA is submitted to FDA because the FDA has 60 days to make a "filing" decision.

In addition, under the Pediatric Research Equity Act of 2003, or PREA, as amended and reauthorized, certain NDAs or supplements to an NDA must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. The FDA also may require submission of a risk evaluation and mitigation strategy, or REMS, plan to ensure that the benefits of the drug outweigh its risks. The REMS plan could include medication guides, physician communication plans, assessment plans, and/or elements to assure safe use, such as restricted distribution methods, patient registries, or other risk minimization tools.

The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA may inspect one or more clinical trial sites to assure compliance with GCP requirements. After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a complete response letter. A complete response letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA and may require additional clinical or preclinical testing in order for FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically

issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

Even if the FDA approves a product, it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval. Moreover, after approval of an NDA, a company may decide to launch an "authorized generic" version of the drug, which is an approved brand name drug that is marketed without the brand name on its label. Other than the fact that it does not have the brand name on its label, it is the exact same drug product as the branded product. While a separate NDA is not required for marketing an authorized generic, the FDA requires that the NDA holder notify the FDA if it markets an authorized generic. The NDA holder may market both the authorized generic and the brand-name product at the same time.

### *Special FDA Expedited Review and Approval Programs*

The FDA has various programs, including, but not limited to, fast track designation, accelerated approval, priority review, and breakthrough therapy designation, which are intended to expedite or simplify the process for the development and FDA review of drugs that are intended for the treatment of serious or life-threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures.

To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need. The FDA will determine that a product will fill an unmet medical need if it will provide a therapy where none exists or provide a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. The FDA may review sections of the NDA for a fast track product on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA. The FDA may give a priority review designation to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. A priority review means that the goal for the FDA to review an application is six months, rather than the standard review of ten months under current PDUFA guidelines. Under the new PDUFA agreement, these six and ten-month review periods are measured from the "filing" date rather than the receipt date for NDAs for new molecular entities, which typically adds 60 days to the timeline for review and decision from the date of submission. Most products that are eligible for fast track designation are also likely to be considered appropriate to receive a priority review.

In addition, products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may be eligible for accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require a sponsor of a drug receiving accelerated approval to perform post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint, and the drug may be subject to accelerated withdrawal procedures.

Moreover, under the provisions of the Food and Drug Administration Safety and Innovation Act, or FDASIA, passed in July 2012, a sponsor can request designation of a product candidate as a "breakthrough therapy." A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs designated as breakthrough therapies are also eligible for accelerated approval. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

### *Post-Approval Requirements*

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual user fee requirements.

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA. For example, the FDA may require post-marketing testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP requirements and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

### *Medical Devices Regulation in the United States*

Under the FDCA, medical devices are classified into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent of control needed to ensure safety and effectiveness. Class I devices are those for which safety and effectiveness can be assured by adherence to FDA's general controls for medical devices, which include compliance with the applicable portions of the FDA's Quality System Regulation, or QSR, facility registration and product listing, reporting of adverse medical events, and appropriate, truthful and non-misleading labeling, advertising, and promotional materials. Some Class I devices also require premarket clearance by the FDA through the 510(k) premarket notification process described below. Class II devices are subject to FDA's general controls, and any other special controls as deemed necessary by FDA to ensure the safety and effectiveness of the device. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) premarket notification procedure, unless exempt. A Class III product is a product which has a new intended use or uses advanced technology that is not substantially equivalent to that of a legally marketed device. The safety and effectiveness of Class III devices cannot be assured solely by the General Controls and the other requirements described above. These devices almost always require formal clinical studies to demonstrate safety and effectiveness. Our current medical device products are classified Class II medical devices.

When a 510(k) is required, the manufacturer must submit to the FDA a premarket notification submission demonstrating that the device is “substantially equivalent” to either: a device that was legally marketed prior to May 28, 1976, the date upon which the Medical Device Amendments of 1976 were enacted, and for which the FDA has not yet called for the submission of pre-market approval applications, or PMAs, or is a device that has been reclassified from Class III to either Class II or I.

If the FDA agrees that the device is substantially equivalent to a predicate device, it will grant clearance to commercially market the device in the U.S. The FDA’s 510(k) clearance process usually takes from three to twelve months from the date the application is submitted and filed with the FDA, but may take significantly longer and clearance is never assured. Although many 510(k) pre-market notifications are cleared without clinical data, in some cases, the U.S. Food and Drug Administration requires significant clinical data to support substantial equivalence. In reviewing a pre-market notification, the FDA may request additional information, including clinical data, which may significantly prolong the review process. If the FDA determines that the device, or its intended use, is not “substantially equivalent,” the FDA may deny the request for clearance. After a device receives 510(k) clearance, any subsequent modification of the device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, will require a new 510(k) clearance or could require pre-market approval. The FDA requires each manufacturer to make this determination initially, but the FDA may review any such decision and may disagree with a manufacturer’s determination. If the FDA disagrees with a manufacturer’s determination, the FDA may require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or pre-market approval is obtained. We have modified aspects of some of our devices since receiving regulatory clearance and we have made the determination that new 510(k) clearances or pre-market approvals were not required.

Although unlikely for the types of medical devices marketed by us, the FDA may classify the device, or the particular use of the device, into Class III, and the device sponsor must then fulfill more rigorous pre-market approval (“PMA”) requirements. A PMA application, which is intended to demonstrate that a device is safe and effective, must be supported by extensive data, including extensive technical and manufacturing data and data from preclinical studies and human clinical trials. After a PMA application is submitted and filed, the FDA begins an in-depth review of the submitted information, which typically takes between one and three years, but may take significantly longer. During this review period, the FDA may request additional information or clarification of information already provided. Also, during the review period, an advisory panel of experts from outside the FDA will usually be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA will conduct a pre-approval inspection of the manufacturing facility to ensure compliance with the QSR, which impose elaborate design development, testing, control, documentation and other quality assurance procedures in the design and manufacturing process. The FDA may approve a PMA application with post-approval conditions intended to ensure the safety and effectiveness of the device including, among other things, restrictions on labeling, promotion, sale and distribution and collection of long-term follow-up data from patients in the clinical study that supported approval. Failure to comply with the conditions of approval can result in materially adverse enforcement action, including the loss or withdrawal of the approval. New PMA applications or PMA supplements are required for significant modifications to the manufacturing process, labeling of the product and design of a device that is approved through the PMA process. PMA supplements often require submission of the same type of information as an original PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA, and may not require as extensive clinical data or the convening of an advisory panel.

A clinical trial is typically required to support a PMA application and is sometimes required for a 510(k) pre-market notification. Clinical trials generally require submission of an application for an Investigational Device Exemption, or IDE, to the FDA. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the investigational protocol is scientifically sound. The IDE application must be approved in advance by the FDA for a specified number of patients, unless the product is deemed a non-significant risk device and eligible for more abbreviated IDE requirements. Clinical trials for a significant risk device may begin once the IDE application is approved by the FDA as well as the appropriate institutional review boards at the clinical trial sites, and the informed consent of the patients participating in the clinical trial is obtained. After a trial begins, the FDA may place it on hold or terminate it if, among other reasons, it concludes that the clinical subjects are exposed to an unacceptable health risk. Any trials we conduct must be conducted in accordance with FDA regulations as well as other federal regulations and state laws concerning human subject protection and privacy.

In addition, after a device is placed on the market, numerous FDA and other regulatory requirements continue to apply. These include establishment registration and device listing with the FDA; compliance with medical device reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur; and compliance with corrections and removal reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may



present a risk to health. The FDA and the Federal Trade Commission (“FTC”) also regulate the advertising and promotion of our products to ensure that the claims we make are consistent with our regulatory clearances, that there is scientific data to substantiate the claims and that our advertising is neither false nor misleading. In general, we may not promote or advertise our products for uses not within the scope of our intended use statement in our clearances or make unsupported safety and effectiveness claims. Many regulatory jurisdictions outside of the U.S. have similar regulations to which we are subject.

### ***Foreign Regulation of Drugs and Medical Devices***

In order for us to market our products in countries outside the United States, we must obtain regulatory approvals and comply with extensive product and quality system regulations in other countries. These regulations, including the requirements for approvals or clearance and the time required for regulatory review, vary from country to country. Some countries have regulatory review processes which are substantially longer than U.S. processes. Failure to obtain regulatory authorizations or approvals in a timely manner and to meet all local requirements including language and specific safety standards in any foreign country in which we plan to market our products could prevent us from marketing products in such countries or subject us to sanctions and fines.

### ***Foreign Regulation of Drugs***

In order to market drug products in the European Economic Area, or EEA (which is comprised of the 28 Member States of the EU plus Norway, Iceland and Liechtenstein), and many other foreign jurisdictions, we must obtain separate regulatory approvals. More concretely, in the EEA, medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA. There are two types of marketing authorizations:

- The Community MA, which is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use of the European Medicines Agency, or EMA, and which is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, and medicinal products indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.
- National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member State through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure.

Under the above described procedures, before granting the MA, the EMA or the competent authorities of the Member States of the EEA assess the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

In the EEA, marketing authorization applications for new medicinal products not authorized have to include the results of studies conducted in the pediatric population, in compliance with a pediatric investigation plan, or PIP, agreed with the EMA’s Pediatric Committee, or PDCO. The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the drug for which marketing authorization is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data is not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the marketing authorization is obtained in all Member States of the European Union and study results are included in the product information, even when negative, the product is eligible for six months’ supplementary protection certificate extension.

### ***Foreign Regulation of Medical Devices***

Commercialization of medical devices in Europe is regulated by the European Union (“EU”). The EU presently requires that all medical products bear the Conformité Européenne (“CE”) mark, for compliance with the Medical Device Directive (93/42/EEC) as amended. The CE mark is an international symbol of adherence to certain essential principles of safety and performance mandated in applicable European medical device directives, which once affixed, enables a product to be sold in member countries of the EU and those affiliated countries which accept the CE mark. The CE mark is also recognized in many countries outside of

the EU, such as Australia, and can assist in the clearance process. In order to affix the CE mark on products, a recognized European Notified Body must certify a manufacturer's quality system and design dossier for compliance with international and European requirements. To maintain authorization to apply the CE mark, we are subject to annual surveillance audits and periodic re-certification audits. In September 2013, the European Commission adopted a recommendation indicating that all Notified Bodies, including Presafe, an accredited certification body, should carry out unannounced audits, at least once every third year, of the manufacturers whose medical devices they have certified. These unannounced audits can also extend to the manufacturer's critical suppliers or sub-contractors (those that supply a critical input or perform a critical function for the manufacturer).

#### *Federal, State and Foreign Fraud and Abuse and Physician Payment Transparency Laws*

We are also subject to federal and state healthcare laws and regulations pertaining to fraud and abuse, physician payment transparency, privacy, and security laws and regulations. These laws include, without limitation: foreign, federal, and state anti-kickback and false claims laws, as well as transparency laws regarding payments or other items of value provided to healthcare providers. The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any good, facility, item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value, including stock, stock options, and the compensation derived through ownership interests.

Recognizing that the federal Anti-Kickback Statute is broad and may prohibit many innocuous or beneficial arrangements within the healthcare industry, the DHHS issued regulations in July 1991, which the Department has referred to as "safe harbors." These safe harbor regulations set forth certain provisions which, if met in form and substance, will assure medical device manufacturers, healthcare providers and other parties that they will not be prosecuted under the federal Anti-Kickback Statute. Additional safe harbor provisions providing similar protections have been published intermittently since 1991. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the federal Anti-Kickback Statute has been violated. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Moreover, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act (described below).

Violations of the federal Anti-Kickback Statute may result in civil monetary penalties up to \$74,792 for each violation, plus up to three times the remuneration involved. Civil penalties for such conduct can further be assessed under the federal False Claims Act. Violations can also result in criminal penalties, including criminal fines of up to \$100,000 and imprisonment of up to ten years. Similarly, violations can result in exclusion from participation in government healthcare programs, including Medicare and Medicaid. Liability under the federal Anti-Kickback Statute may also arise because of the intentions or actions of the parties with whom we do business. Conduct and business arrangements that do not fully satisfy one of these safe harbor provisions may result in increased scrutiny by government enforcement authorities. The majority of states also have anti-kickback laws which establish similar prohibitions and, in some cases may apply more broadly to items or services covered by any third-party payor, including commercial insurers and self-pay patients.

The federal civil False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval to the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. The federal civil False Claims Act also applies to false submissions that cause the government to be paid less than the amount to which it is entitled, such as a rebate. Intent to deceive is not required to establish liability under the civil federal civil False Claims Act.

In addition, private parties may initiate "qui tam" whistleblower lawsuits against any person or entity under the federal civil False Claims Act in the name of the government and share in the proceeds of the lawsuit. Penalties for federal civil False Claim Act violations include fines for each false claim, plus up to three times the amount of damages sustained by the federal government and, most critically, may provide the basis for exclusion from the federally funded healthcare program. On May 20, 2009, the

Fraud Enforcement Recovery Act of 2009, or FERA, was enacted, which modifies and clarifies certain provisions of the federal civil False Claims Act. In part, the FERA amends the federal civil False Claims Act such that penalties may now apply to any person, including an organization that does not contract directly with the government, who knowingly makes, uses or causes to be made or used, a false record or statement material to a false or fraudulent claim paid in part by the federal government. The government may further prosecute conduct constituting a false claim under the federal criminal False Claims Act. The criminal False Claims Act prohibits the making or presenting of a claim to the government knowing such claim to be false, fictitious or fraudulent and, unlike the federal civil False Claims Act, requires proof of intent to submit a false claim. When an entity is determined to have violated the federal civil False Claims Act, the government may impose civil fines and penalties ranging from \$11,181 to \$22,363 for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs.

The federal Civil Monetary Penalty Act of 1981 imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal healthcare program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent, or offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier.

The Health Insurance Portability and Accountability Act of 1996, or HIPAA, also created additional federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors; knowingly and willfully embezzling or stealing from a healthcare benefit program; willfully obstructing a criminal investigation of a healthcare offense; and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Many foreign countries have similar laws relating to healthcare fraud and abuse. Foreign laws and regulations may vary greatly from country to country. For example, the advertising and promotion of our products is subject to EU Directives concerning misleading and comparative advertising and unfair commercial practices, as well as other EEA Member State legislation governing the advertising and promotion of medical devices. These laws may limit or restrict the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with healthcare professionals. Also, many US states have similar fraud and abuse statutes or regulations that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs.

Additionally, there has been a recent trend of increased foreign, federal, and state regulation of payments and transfers of value provided to healthcare professionals or entities. The federal Physician Payments Sunshine Act imposes annual reporting requirements on certain drug, biologics, medical supplies and device manufacturers for which payment is available under Medicare, Medicaid or CHIP for payments and other transfers of value provided by them, directly or indirectly, to physicians (including physician family members) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. A manufacturer's failure to submit timely, accurately and completely the required information for all payments, transfers of value or ownership or investment interest may result in civil monetary penalties of \$11,052 per failure up to an aggregate of \$165,786 per year (or up to an aggregate of \$1.105 million per year for "knowing failures"). Manufacturers must submit reports by the 90th day of each calendar year. Certain foreign countries and US states also mandate implementation of commercial compliance programs, impose restrictions on device manufacturer marketing practices and require tracking and reporting of gifts, compensation and other remuneration to healthcare professionals and entities.

## **Coverage and reimbursement**

In the United States and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products or the products for which we receive royalty revenue unless coverage is provided, and reimbursement is adequate to cover a significant portion of the cost. Sales of any products therefore depend, in part, on the availability of coverage and adequate reimbursement from third-party payors. Third-party payors include government authorities, managed care plans, private health insurers and other organizations.

The process for determining whether a third-party payor will provide coverage for a pharmaceutical or device product typically is separate from the process for setting the price of such product or for establishing the reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the FDA-approved products for a particular indication. A decision by a

third-party payor not to cover our products could reduce physician utilization of our products and have a material adverse effect on our sales, results of operations and financial condition. Moreover, a third-party payor's decision to provide coverage for a pharmaceutical or device product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. Additionally, coverage and reimbursement for products can differ significantly from payor to payor. One third-party payor's decision to cover a particular medical product or service does not ensure that other payors will also provide coverage for the medical product or service, or will provide coverage at an adequate reimbursement rate.

The reimbursement to the facility from third-party payors is intended to cover the overall cost of treatment, including the cost of our devices used during the procedure as well as the overhead cost associated with the facility where the procedure is performed. We do not directly bill any third-party payors; instead, we receive payment from the hospital or other facility that uses our devices. Failure by physicians, hospitals, and other users of our devices to obtain sufficient coverage and reimbursement from healthcare payors for procedures in which our devices are used, or adverse changes in government and private third-party payors' policies could have a material adverse effect on our business, financial condition, results of operations and future growth prospects.

In addition, there are periodic changes to reimbursement. Third-party payors regularly update reimbursement amounts and also from time to time revise the methodologies used to determine reimbursement amounts. This includes annual updates to payments to physicians, hospitals and other facilities for procedures during which our devices are used. Because the cost of our devices generally is recovered by the healthcare provider as part of the payment for performing a procedure and not separately reimbursed, these updates could directly impact the demand for our devices. An example of such payment updates is the Medicare program's updates to hospital and physician payments, which are done on an annual basis using a prescribed statutory formula. In the past, with respect to reimbursement for physician services under the Medicare Physician Fee Schedule, when the application of the formula resulted in lower payment, Congress has passed interim legislation to prevent the reductions.

The containment of healthcare costs is a priority of federal, state and foreign governments, and the prices of pharmaceutical or device products have been a focus in this effort. Third-party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity and reviewing the cost-effectiveness of pharmaceutical products, medical devices and medical services, in addition to questioning safety and efficacy. If these third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products or, if they do, the level of payment may not be sufficient to allow us to sell our products at a profit.

## **Healthcare Reform**

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. Current and future legislative proposals to further reform healthcare or reduce healthcare costs may limit coverage of or lower reimbursement for the procedures associated with the use of our products. The cost containment measures that payors and providers are instituting, and the effect of any healthcare reform initiative implemented in the future could impact our revenue from the sale of our products.

The implementation of the Affordable Care Act, (the "ACA"), in the United States, for example, has changed healthcare financing and delivery by both governmental and private insurers substantially, and affected medical device manufacturers significantly. The ACA imposed, among other things, a 2.3% federal excise tax, with limited exceptions, on any entity that manufactures or imports Class I, II and III medical devices offered for sale in the United States that began on January 1, 2013. Through a series of legislative amendments, the tax was suspended for 2016 through 2019. Absent further legislative action, the device excise tax will be reinstated on medical device sales starting January 1, 2020. The ACA also provided incentives to programs that increase the federal government's comparative effectiveness research, and implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models. Additionally, the ACA has expanded eligibility criteria for Medicaid programs and created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research. We do not yet know the full impact that the ACA will have on our business.

There have been judicial and Congressional challenges to certain aspects of the ACA, and we expect additional challenges and amendments in the future. Moreover, the Trump Administration and the U.S. Congress may take further action regarding the ACA, including, but not limited to, repeal or replacement.

Moreover, other legislative changes have been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011, among other things, included reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2025 unless additional Congressional action is taken. Additionally, the American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

We expect additional state and federal healthcare reform measures to be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure.

In addition, changes in existing regulations could have a material adverse effect on us or our licensees, borrowers or royalty-agreement counterparties. For a discussion of the risks associated with government regulations, see Item 1A, “Risk Factors.”

## **Manufacturing**

Our manufacturing processes are required to comply with the FDA’s cGMP requirements, which for medical devices, are contained in its QSR and associated regulations and guidance. The QSR covers, among other things, the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all medical devices intended for human use. The QSR also requires maintenance of extensive records which demonstrate compliance with FDA regulation, the manufacturer’s own procedures, specifications, and testing as well as distribution and post-market experience. Compliance with the QSR is necessary to receive FDA clearance or approval to market new products and is necessary for a manufacturer to be able to continue to market cleared or approved product offerings in the United States. A company’s facilities, records, and manufacturing processes are subject to periodic scheduled or unscheduled inspections by the FDA, which may issue reports known as Forms FDA 483 or Notices of Inspectional Observations which list instances where the FDA inspector believes the manufacturer has failed to comply with applicable regulations and/or procedures. If the observations are sufficiently serious or the manufacturer fails to respond appropriately, the FDA may issue Warning Letters, or Untitled Letters, which are notices of potential enforcement actions against the manufacturer. If a Warning Letter or Untitled Letter is not addressed to the satisfaction of the FDA, or if the FDA becomes aware of any other serious issue with a manufacturer’s products or facilities, it could result in fines, injunctions, civil penalties, delays, suspension or withdrawal of clearances, seizures or recalls of products, operating restrictions, total shutdown of production facilities, prohibition on export or import and criminal prosecution. Such actions may have further indirect consequences for the manufacturer outside of the United States, and may adversely affect the reputation of the manufacturer and the product. In the United States, routine FDA inspections usually occur every two years, and may occur more often for cause.

To a greater or lesser extent, most other countries require some form of quality system and regulatory compliance, which may include periodic inspections, inspections by third-party auditors, and specialized documentation. Failure to meet all the requirements of these countries could jeopardize our ability to import, market, support, and receive reimbursement for the use of our products in these countries. In addition to the above, we may seek to conduct clinical studies or trials in the U.S. or other countries on products that have not yet been cleared or approved for a particular indication. Products manufactured outside the United States by or for us are subject to U.S. Customs and FDA inspection upon entry into the United States. We must demonstrate compliance of such products to U.S. regulations and carefully document the eventual distribution or re-exportation of such products. Failure to comply with all applicable regulations could prevent us from having access to products or components critical to the manufacture of finished products and lead to shortages and delays.

## **Employees**

As of December 31, 2018, we had 18 full-time employees managing our intellectual property, acquisitions, operations and other corporate activities, including providing management oversight, accounting, legal and tax support and administrative assistance to our subsidiaries, as well as performing certain essential functions of a public company. In addition, we had 87 full-time employees at our operating subsidiaries, Noden and LENSAR, who manage the subsidiaries’ businesses and operations. Geographically, 86 employees were based in the United States and 19 employees were located internationally. None of our employees are covered by a collective bargaining agreement, and we consider our relationship with our employees to be good.

## About PDL

We were incorporated under the laws of the state of Delaware in 1986 under the name Protein Design Labs, Inc. In 2006, we changed our name to PDL BioPharma, Inc. Our business previously included a biotechnology operation that was focused on the discovery and development of novel antibodies. We spun-off the operation to our stockholders as Facet Biotech Corporation in December 2008. Our principal executive offices are located at 932 Southwood Boulevard, Incline Village, Nevada, 89451, (775) 832-8500, and our website address is [www.pdl.com](http://www.pdl.com). The information in or accessible through our website is not incorporated into, and is not considered part of, this filing.

## Available Information

We file electronically with the U.S. Securities and Exchange Commission (the "SEC") our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The address of that website is [www.sec.gov](http://www.sec.gov).

We make available free of charge on or through our website at [www.pdl.com](http://www.pdl.com) our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and proxy statements, as well as amendments to these reports and statements, as soon as practicable after we have electronically filed such material with, or furnished them to, the SEC. You may also obtain copies of these filings free of charge by calling us at (775) 832-8500. Also, our Audit Committee Charter, Compensation Committee Charter, Nominating and Governance Committee Charter, Litigation Committee Charter, Corporate Governance Guidelines and Code of Business Conduct, as well as amendments thereto, are also available free of charge on our website or by calling the number listed above. The information in or accessible through the SEC and our website is not incorporated into, and is not considered part of, this filing.

We operate our business as three segments as defined by U.S. generally accepted accounting principles ("GAAP"). Our financial results for the years ended December 31, 2018, 2017 and 2016 are discussed in "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Item 8. Financial Statements and Supplementary Data" of this Annual Report.

## ITEM 1A. RISK FACTORS

You should carefully consider and evaluate all of the information included and incorporated by reference in this Annual Report, including the risk factors listed below. Any of these risks, as well as other risks and uncertainties, could materially and adversely affect our business, results of operations and financial condition, which in turn could materially and adversely affect the trading price of shares of our common stock. Additional risks not currently known or currently material to us may also harm our business.

**We have historically derived a significant portion of our royalty revenues from Genentech and other Queen et al. patent licensees which, in the case of our largest licensee, Genentech, expired in early 2016. Failure to acquire additional sources of revenue, after expiration of our Queen et al. patents and the related licenses may cause us to have insufficient revenues and cash flows to continue operations.**

Our revenues through the first quarter of 2016 consisted almost entirely of royalties from licensees of our Queen et al. patents. Of this revenue from licensees of the Queen et al. patents accounted for 2%, 11% and 68% of our revenues for the years ended December 31, 2018, 2017 and 2016, respectively. Our license agreement with Genentech expired in the first quarter of 2016, and our other licensees, and efforts to identify and replace those sources of revenues in the future might not be successful. Failure to replace the Queen et al. patent license revenues in an amount sufficient to continue our operations would have a material adverse effect on our business.

Prospectively, we expect to focus on the acquisition of additional pharmaceutical products and companies. We anticipate that over time more of our revenues will come from our Pharmaceutical and Medical Devices segments and less of our revenues will come from our Income Generating Assets segment. We do not expect that our acquisitions under these segments will, in the near term, fully replace the revenues we have generated from our license agreements related to the Queen et al. patents. Specifically, after the first quarter of 2016, our revenues materially decreased after we stopped receiving significant payments from these Queen et al. patents license agreements and related legal settlements. Our continued success will become more dependent on the timing and our ability to acquire assets and companies in our Pharmaceuticals segment to generate revenues going forward to support our business model. We may be unable to acquire or develop sufficient pharmaceutical products for a number of reasons, including the fact that the acquisition of new products or companies is a highly competitive area in which other companies, financial

institutions and private funds compete for assets of interest to us. Those entities may have access to lower costs of capital, strategic opportunities or competitive advantages that may not be available to us. We may acquire products earlier in development that may not generate income right away, may require additional capital be invested any may involve additional risks related to development and regulatory requirements.

Other factors that may prevent us from acquiring additional pharmaceutical products or companies include the following:

- we may be unable to acquire additional pharmaceutical products or companies on terms that would allow us to make an appropriate level of return;
- our products and asset investments may be less successful in the marketplace than may be necessary to generate an appropriate level of return from the asset; or
- we may be forced to undertake more risk in obtaining the assets we pursue.

If we are unable to acquire additional pharmaceutical products or companies, our business may suffer and we may determine that a wind-down, sale, or liquidation is in the best interests of our stockholders.

**Any difficulties from strategic acquisitions of pharmaceutical products and companies could materially and adversely affect our stock price and results of operations.**

We may acquire pharmaceutical products and companies that complement or augment our existing business. We may not be able to integrate any acquired products and companies successfully or operate any acquired companies profitably. Integrating any newly acquired products and companies could be expensive and time-consuming. Integration efforts often take a significant amount of time, place a significant strain on managerial, operational and financial resources and could prove to be more difficult or expensive than we predict. The diversion of our management's attention and any delay or difficulties encountered in connection with any future acquisitions we may consummate could result in the disruption of our ongoing business or inconsistencies in standards and controls that could negatively affect our ability to maintain third-party relationships. Moreover, we may need to raise additional funds through public or private debt or equity financing, or issue additional shares, to acquire any products or companies, which may result in dilution for stockholders or the incurrence of indebtedness.

Our investment in Noden is our first investment in commercial products in support of our Pharmaceutical segment, rather than an investment in financial assets or royalties for income generation. Our returns from the investment in Noden are dependent upon the success of the acquired prescription pharmaceutical products sold under the brand names Tekturna, Tekturna HCT, Rasilez and Rasilez HCT and there can be no assurance that we will be able to successfully attain and maintain significant market acceptance of our products among physicians, patients, third-party payors and others in the health care community. We also expect generic product competition for our products to increase in the future, which may reduce our market share, pricing and revenues from the Noden Products. In March 2019, under an agreement with Prasco Laboratories, we launched in the United States an authorized generic form of Tekturna. There can be no assurance that we will be able to generate meaningful revenues from sales of this authorized generic product, and there can be no assurance that we will be able to successfully gain market acceptance of this authorized generic product. In addition, our acquisition of 100% of the equity interests in LENSAR resulted in establishing our Medical Devices segment. Our revenues from our Pharmaceutical segment consist entirely of sales of the Noden Products, and our revenues from our Medical Devices segment consist entirely of sales and leasing of the LENSAR laser system. There can be no assurance that we will be able successfully develop these segments on a commercial scale.

We are dependent upon Noden and its management team for sales in our Pharmaceutical segment, and LENSAR and its management team for sales in Medical Devices segment, in each case in gaining and maintaining acceptance among physicians, third-party payors, patients and others in the healthcare community for our products or devices.

Continued market acceptance of any approved product depends on a number of other factors, including:

- the receipt of regulatory clearance of marketing claims for the uses that we may in the future develop;
- the establishment and demonstration of the advantages and safety of our products;
- pricing and reimbursement policies of government and third-party payers such as insurance companies, health maintenance organizations and other health plan administrators;
- the effectiveness of sales and marketing efforts.

Noden is currently undertaking the commercialization of the Noden Products without a sales force in the United States and no current commercial infrastructure outside the United States. Our revenues from the investment in Noden depend on Noden's ability to successfully transition the Noden Products from a contract sales force to a non-personal promotion strategy, the failure

of which could have an adverse impact on our revenues, could lead to an additional impairment charge of our long-lived assets and could have an adverse impact on the value of our investment in Noden.

In addition, the supply agreement with Novartis commits Noden to minimum purchase obligations of the Noden Products, which may result in excess inventory if Noden's commercial team is not able to sell the Noden Products at sufficient levels to cover the minimum purchase obligations. If we experience excess inventory, it may be necessary to write down or even write off such excess inventory, which could materially and adversely affect our business and operating results.

**Through our investment in Noden, we have a significant investment in the commercialization of products worldwide, and our returns on investment on the Noden Products are subject to a number of risks associated with international operations that could materially and adversely affect our business, results of operations and cash flows.**

As a result of our acquisition of the Noden Products through our investment in Noden, we are subject to a number of risks related to the sale of products worldwide, including:

- international regulatory requirements for drug marketing and pricing in foreign countries;
- varied standards of care in various countries that could complicate the commercial success of products;
- varied drug import and export rules;
- varying standards for the protection of intellectual property rights which may result in reduced or compromised exclusivity in certain countries;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- varied reimbursement systems and different competitive drugs indicated to treat the indications for which Noden Products are being commercialized;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws applicable to foreign operations;
- compliance with the U.S. Foreign Corrupt Practices Act ("FCPA"), the UK Bribery Act, and other anti-corruption and anti-bribery laws;
- foreign taxes and duties;
- foreign currency fluctuations and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- reliance on management, contract services organizations and other third parties that may be less experienced with manufacturing and commercialization than the party from whom the Noden Products were acquired;
- potential liability resulting from product liability laws or the activities of foreign distributors; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters.

In addition, our international operations could be affected by capital and exchange controls, expropriation and other restrictive government actions as well as by political unrest, unstable governments and legal systems and inter-governmental disputes. Any of these circumstances could materially and adversely affect our business, results of operations and cash flows.

**We rely on third-party manufacturers to manufacture our products, and these third parties may not perform adequately.**

We do not have any operating manufacturing facilities for Noden Products at this time, and do not expect to independently manufacture our products or any future products under the Pharmaceutical segment. We currently rely on Novartis for a specified period of time to manufacture and package the Noden Products, and are required thereafter to identify and transition to third parties to scale-up, manufacture and supply the Noden Products. The facilities used by our contract manufacturers to manufacture our drug products must be approved by the FDA pursuant to the approved NDA and are subject to FDA inspection for our drug and medical devices. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements, known as current good manufacturing practice, or cGMP, requirements for manufacture of our drug and device products. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not authorize these facilities for the manufacture of our product candidates or if it withdraws any such authorization in the future, we may need to find alternative manufacturing facilities, which would take time and resources and significantly impact our business, results of operations and cash flows.



Other risks arising from reliance on third-party manufacturers include:

- inability to identify and enter into a manufacturing and supply agreement with a third-party manufacturer having the appropriate capabilities to cost-effectively and timely manufacture products at the sales levels that we anticipate;
- reduced control and additional burdens of oversight as a result of using third-party manufacturers for all aspects of manufacturing activities, including regulatory compliance and quality control and assurance;
- termination or non-renewal of manufacturing and supply agreements with third parties in a manner or at a time that may negatively impact commercialization activities; and
- disruption in the operations of third-party manufacturers or suppliers unrelated to our products, including the bankruptcy of the manufacturer or supplier or a catastrophic event affecting the third manufacturers or suppliers.

Any of these events could adversely affect our ability to successfully commercialize our products. In addition, if any third-party manufacturer terminates its engagement with us or fails to perform as agreed, we may be required to find replacement manufacturers, which would result in significant cost and delay.

In addition, difficulties or delays in product manufacturing and reliance on third-party manufacturing could affect our future results reflected in the performance of Noden and the Noden Products by virtue of regulatory actions, shut-downs, approval delays, withdrawals, recalls, penalties, supply disruptions or shortages or force majeure events, reputational harm, product liability, unanticipated costs or otherwise. Examples of such difficulties or delays include, but are not limited to, the inability to increase production capacity commensurate with demand; the possibility that the supply of incoming materials may be delayed or become unavailable or be subject to increased costs and that the quality of incoming materials may be substandard and not detected; the possibility that third-party manufacturers may fail to maintain appropriate quality standards throughout the internal and external supply network and/or comply with cGMPs and other applicable regulations such as tracking and tracing of products in the supply chain to enhance patient safety; risks to supply chain continuity as a result of natural or man-made disasters at a supplier or vendor; or failure to maintain the integrity of the supply chains against intentional and criminal acts such as economic adulteration, product diversion, product theft, and counterfeit goods.

**Product sales are expected to generate a significant share of our revenues in the future and are subject to the risks and uncertainties of branded pharmaceutical products.**

If our products become subject to problems such as changes in prescription growth rates, product liability litigation, unexpected side effects, regulatory proceedings, manufacturing issues, publicity affecting doctor or patient confidence, pressure from existing competitive products, changes in labeling, loss of patent protection (when applicable), or, if a new, more effective treatment should be introduced, the adverse impact on our revenues could be significant.

**We depend upon a limited number of wholesalers for a significant portion of our revenues from the Noden Products, and the loss of, or significant reduction in sales to, any one of these wholesalers could materially and adversely affect our business, results of operations and financial condition.**

We sell the Noden Products primarily to wholesalers. Wholesalers sell the Noden Products to hospitals and pharmacies. We do not promote the Noden Products to wholesalers, and they do not set or determine demand for Noden Products. Our ability to successfully commercialize Noden Products will depend, in part, on the extent to which we are able to provide adequate distribution of the Noden Products to patients. Although we have contracted with a number of wholesalers, they are expected generally to carry a very limited inventory and may be reluctant to be part of our distribution network in the future if demand for the product does not increase.

The use of pharmaceutical wholesalers involves certain risks, including, but not limited to, risks that these pharmaceutical wholesalers will not provide us accurate or timely information regarding their inventories, demand from wholesaler customers buying the Noden Products or complaints about the Noden Products, that these wholesalers will reduce their efforts or discontinue to sell or support or otherwise not effectively sell or support the Noden Products, or not devote the resources necessary to sell the Noden Products in the volumes and within the time frames that we expect.

Further, it is possible that these wholesalers could decide to change their policies or fees, or both, at some time in the future. This could result in their refusal to carry smaller volume products such as Noden Products, or lower margins or the need to find alternative methods of distributing the Noden Products. Although we believe we can find alternative channels to distribute the Noden Products on relatively short notice, our revenue during that period of time may suffer and we may incur additional costs to replace any such wholesaler. The loss of any large wholesaler as part of our distribution network, a significant reduction in sales

we make to wholesalers, or any failure to pay for the Noden Products we have shipped to them could materially and adversely affect our business, results of operations and financial condition.

**We have significantly restructured our business and revised our business plan, including entering into a new segment reporting structure. Our three industry segments designated as Pharmaceutical, Medical Devices and Income Generating Assets, and our restructured business plan, have been in effect for a limited period of time and there are no assurances that we will be able to successfully implement our business plan or successfully operate in our Pharmaceutical or Medical Devices segments.**

From 2012 to 2016 we focused on acquiring income generating assets when such assets can be acquired on terms that we believe allow us to increase return to our stockholders. Currently and prospectively, we expect to focus on the acquisition of additional pharmaceutical products and companies and do not expect to transact royalty transactions and debt transactions under our Income Generating Assets segment or additional acquisitions in our Medical Devices segment. We anticipate that over time, as a result of these new acquisitions, more of our revenues will come from our Pharmaceutical segment and less of our revenues will come from our Income Generating Assets and Medical Devices segments. Our strategy is based on a number of factors and assumptions, some of which are not within our control, such as the actions of third parties. There can be no assurance that we will be able to successfully execute all or any elements of our strategy, or that our ability to successfully execute our strategy will be unaffected by external factors. If we are unsuccessful in growing our business as planned, our financial performance could be adversely affected.

**Our current pharmaceutical products, medical devices and/or income generating assets and future acquisitions of other pharmaceutical products and companies may not produce anticipated revenues, and if such acquisitions are reliant on a single, or limited number of, products we may not be able to recuperate our capital expenditures in the acquisition.**

We are engaged in a continual review of opportunities to acquire pharmaceutical products or to acquire companies who own or are acquiring pharmaceutical products. We currently, and generally at any time, have acquisition opportunities in various stages of active review, including, for example, our engagement of consultants and advisors to analyze particular opportunities, technical, financial and other confidential information, submission of indications of interest and involvement as a bidder in competitive auctions or other processes for the acquisition of pharmaceutical products. Many potential acquisition targets do not meet our criteria, and for those that do, we may face significant competition for these acquisitions from other financial investors and enterprises whose cost of capital may be lower than ours. Competition for future pharmaceutical product or company acquisitions in our markets is competitive and we may be forced to increase the price we pay for such assets or face reduced potential acquisition opportunities.

In addition, ten out of seventeen of our acquisitions to date have been or are dependent on, or secured by, single product revenue streams, which increases the risk of payments based on the competitive factors in the market as well as the pricing of the product. The success of our income generating asset acquisitions is based on our ability to make accurate assumptions regarding the valuation, timing and amount of revenue, which is highly complex and uncertain, and the success of our equity investments and product and device acquisitions are based on our ability to accurately measure the anticipated commercial success, including regulatory approval and pricing, of our products or devices and our counterparties products or devices, which is difficult and subject to various competitive and market factors that may be outside of our control. For example, recently there has been heightened governmental scrutiny over the manner in which drug manufacturers set prices for their commercial products, which has resulted in several Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. We are unable to control the pricing strategies used by our counterparties, and if our counterparties fail to use appropriate pricing strategies, or receive negative reactions to their pricing strategies, it could negatively impact products from which our revenues would be derived. The failure of any of our acquisitions to produce anticipated revenues may impact our ability to recuperate our capital expenditures in an acquisition, which in turn could materially and adversely affect our business, results of operations and financial condition.

**Certain of our income generating assets are secured by collateral, and we may be, or may become, under secured by the collateral, or such collateral may not have a value equal to our investment in the event of a default by our counterparties, or may lose value, each of which could negatively affect our ability recuperate our capital expenditures in such income generating assets.**

Some of our past debt transactions expose us to credit risk in the event of default by the counterparty. To mitigate this risk, we have obtained security interests as collateral in the assets of such counterparty. Our credit risk in respect of such counterparty may be exacerbated when the collateral held by us cannot be realized upon or is liquidated at prices not sufficient to recover the full

amount we are due pursuant to the terms of the particular income generating assets or products. This could occur in circumstances where the original collateral was not sufficient to cover a complete loss (e.g., our interests were only partially secured) or may result from the deterioration in value of the collateral, so that, in either such case, we are unable to recover our full capital outlay and any anticipated return. Further, we rely in part on receiving the principal and interest under certain of our notes and other long-term receivables. For example, we have entered into credit agreements with borrowers across the healthcare industry, under which we make available cash loans to be used by the borrower. Obligations under these credit agreements are typically secured by a pledge of substantially all the assets of the borrower and any of its subsidiaries. Although these income generating acquisitions are secured, we cannot guarantee that we will be able to collect all or part of the amounts owed to us under any notes receivable or other long-term receivables. If we are unable to collect any amount, or amounts collected are not equal to our investment in the event of default by our counterparties, the value of our assets may decrease, which could materially and adversely affect our business, results of operations, financial condition. Additionally, we may face difficulty in collection efforts with respect to a credit agreement counterparty that is in default under a credit agreement with us. Such difficulties could lead to litigation or other legal procedures which may or may not be successful, and which will require significant financial and management resources to address. For example, we have been engaged in multiple legal proceedings with Wellstat Diagnostics and its affiliates related to their credit agreement default, which is described in more detail in Note 25, *Legal Proceedings*, of this Annual Report. Any such losses resulting therefrom could materially and adversely affect our business, results of operations and financial condition.

**We are exposed to the credit risk of some of our customers, which could result in material losses.**

In our Medical Devices segment, customers may finance through leasing the acquisition of certain devices, and we believe there has been an increase in demand for customer financing through leasing in recent years. We may experience loss from a customer's failure to make payments according to the contractual lease terms. Our exposure to the credit risks relating to our lease financing arrangements may increase if our customers are adversely affected by changes in healthcare laws, coverage and reimbursement, economic pressures or uncertainty, or other customer-specific factors. The factors affecting our customers' ability to make timely payments according to the contractual lease terms are out of control, and as a result, exposes us to additional risks that may materially and adversely affect our business and results of operations. The occurrence of any such factors affecting our customers may cause delays in payments or, in some cases, defaults on payment obligations, which could result in material losses.

Although we have programs in place that are designed to monitor and mitigate the associated risk, there can be no assurance that such programs will be effective in reducing credit risks relating to these lease financing arrangements. If the level of credit losses we experience in the future exceed our expectations, such losses could have a material adverse effect on our financial condition or results of operations.

**We and our licensees, borrowers and royalty-agreement counterparties may be unable to maintain regulatory approvals for currently licensed products, or to obtain regulatory approvals or favorable pricing for new products, and we or they may voluntarily remove currently licensed products from marketing and commercial distribution. Any of such events, whether due to safety issues or other factors, could reduce our revenues.**

We and our licensees, borrowers and royalty-agreement counterparties are subject to stringent regulation with respect to product safety and efficacy by various international, federal, state and local authorities. Of particular significance are the FDA requirements covering research and development, testing, manufacturing, quality control, labeling and promotion of drugs for human use in the United States. As a result of these requirements, the length of time, the level of expenditures and the laboratory and clinical information required for approval of a biologic license application or new drug application are substantial and can require a number of years. In addition, even if our products, or our licensees', borrowers' and royalty-agreement counterparties' products receive regulatory approval, we and they will remain subject to ongoing FDA and other international regulations including, but not limited to, obligations to conduct additional clinical trials or other testing, changes to the product label, new or revised regulatory requirements for manufacturing practices, written advisements to physicians and/or a product recall or withdrawal. We and our licensees, borrowers and royalty-agreement counterparties may not maintain necessary regulatory approvals for our or their existing licensed products or we or our licensees may not obtain necessary regulatory approvals on a timely basis, if at all, for any of our products, or the licensed products our licensees are developing or manufacturing. Moreover, the current political environment in the United States is focused on potential reductions in pricing for pharmaceutical and other healthcare products, which may negatively impact any existing or new products from which our revenues would be derived. We are unable to control the pricing strategies used by our licensees, borrowers and royalty-agreement counterparties, and if they fail to use appropriate pricing strategies, or receive negative reactions to their pricing strategies, it could negatively impact our revenues. We may also select pricing strategies for our own products and medical devices that are less competitive than those of our competitors, or we may fail to obtain acceptable prices or an adequate level of reimbursement for products or medical devices from third-party payors or governmental agencies, which could negatively impact our revenues.

In addition, communications from government officials regarding pricing for pharmaceutical and other health care products could have a negative impact on our stock price, even if such communications do not ultimately impact our products or our licensees', borrowers' and royalty-agreement counterparties' products. The occurrence of adverse events reported by any licensee, borrower or royalty-agreement counterparty may result in the revocation of regulatory approvals or decreased sales of the applicable product due to a change in physicians' willingness to prescribe, or patients' willingness to use the applicable product. We and our licensees, borrowers and royalty-agreement counterparties could also choose to voluntarily remove licensed products from marketing and commercial distribution. For example, in November 2011, the FDA removed the indication for breast cancer from Avastin's label. In 2005, Tysabri, was temporarily suspended and then returned to the market. In such cases, our revenues could be materially and adversely affected. In any of these cases, our revenues could be materially and adversely affected.

In addition, the current regulatory framework could change, or additional regulations could arise at any stage during our licensees' product development or marketing which may affect our licensees' ability to obtain or maintain approval of their licensed products. Delays in our licensees receiving regulatory approval for licensed products or their failure to maintain existing regulatory approvals could have a material adverse effect on our business.

**Many of our pharmaceutical products, medical devices and income generating assets are in companies or assets that have limited commercialized revenue-generating products or are dependent on the actions of unrelated third parties, which may negatively impact our investment returns.**

In July 2016 we began acquiring pharmaceutical products and medical devices. Our investment objective with respect to these transactions is to maximize our portfolio's total return by generating current income from product sales or sales of medical devices. We consummated our first investment in our Pharmaceutical segment with Noden in July 2016 and in our Medical Devices segment with LENSAR in May 2017. In addition, we have made and will likely continue to make investments in pharmaceutical products and companies, which investments may be in companies that, at the time of investment, have limited or no commercialized revenue-generating products. If the assets are not successfully commercialized, the value of our investments would be negatively affected, and our investment returns would be negatively impacted. The ultimate success of any future investments in potential pharmaceutical products or companies will depend on our ability, and the ability of our counterparties or their licensees to innovate, develop and commercialize such assets, in competitive and highly regulated markets. Our or their inability to do so would negatively affect our investment returns.

In addition, in connection with our income generating assets, we are dependent, to a large extent, on third parties to enforce certain rights for our benefit. For example, when we acquired certain royalty rights from Assertio (formerly Depomed), which, as the licensor of certain patents, retains various rights, including the contractual right to audit its licensees and to ensure those licensees are complying with the terms of the underlying license agreements. Assertio also retained full responsibility to protect and maintain the intellectual property rights underlying the licenses. While we have contractual rights to require Assertio to take action regarding many of these rights, because Assertio's economic interest in the license agreements is limited, it may not enforce or protect those rights as it otherwise would have had it retained the full economic interest in the payments under the license agreements. Moreover, in respect of the royalty stream relating to the Glumetza diabetes medication that we acquired from Assertio, which is the royalty right producing the highest revenues from our Assertio acquired royalties, a single generic manufacturer was approved by the FDA in February 2013 and in August 2016, two additional generic manufacturers were approved by the FDA to enter the US as provided for in settlement agreements between Assertio and these generic manufacturers. In February 2016, Lupin Pharmaceuticals, Inc., and in August 2017, Teva Pharmaceutical Industries Ltd., and in July 2018, Sun Pharmaceutical, Inc., each launched a generic equivalent approved product. We were aware of these settlement agreements, considered them in the cost of the acquiring this asset and expect the entry of these generic products to reduce our Glumetza revenues.

**We and our companies' licensees, borrowers and royalty-agreement counterparties face significant market pressures with respect to our and their products, and the amount of revenues from our or their pharmaceutical products or medical devices, or from our income generating assets that we receive are subject to various competitive and market factors that may be outside of our control.**

We and our companies, licensees, borrowers and royalty-agreement counterparties face competition from other pharmaceutical, biotechnology, device and diagnostic companies. The introduction of new competitive products may result in lost market share for us or our licensees, borrowers and royalty-agreement counterparties, reduced use of our or their products or devices, lower prices and/or reduced sales, any of which could reduce our royalty revenues, or the revenues on which we rely to produce the returns on our acquisitions, and have a material adverse effect on our results of operations.

The amount of any royalties or revenues, and the subsequent returns on our investments that we receive from our pharmaceutical products, medical devices and/or income generating assets will depend on many factors, including the following:

- the timing and availability of generic product or devices competition for our products or devices, and our licensees', borrowers' and royalty-agreement counterparties' products or devices;
- potential challenges or design arounds to product, use or manufacturing related patents which provide exclusivity for products and assets before their expiration by generic pharmaceutical manufacturers;
- the size of the market for our products or devices, and our licensees', borrowers' and royalty-agreement counterparties' products or devices;
- the extent and effectiveness of the sales and marketing and distribution support for our licensees', borrowers' and royalty-agreement counterparties' products or devices and commercial infrastructure with respect to our products or devices;
- the existence of novel or superior products or devices to our products or devices, or our licensees', borrowers' and royalty-agreement counterparties' products or devices;
- the availability of reduced pricing and discounts applicable to our licensees', borrowers' and royalty-agreement counterparties' products or devices;
- stocking and inventory management practices related to our products or our licensees', borrowers' and royalty-agreement counterparties' products or devices;
- limitations on indications for which our products or devices or our licensees', borrowers' and royalty-agreement counterparties' products or devices can be marketed; the competitive landscape for approved products or devices and developing therapies that compete with our products or devices or our licensees', borrowers' and royalty-agreement counterparties' products or devices;
- the ability of patients to be able to afford our products or devices, or our licensees', borrowers' and royalty-agreement counterparties' products or devices or obtain healthcare coverage that covers those products or devices;
- acceptance of, and ongoing satisfaction with, our products or devices and our licensees', borrowers' and royalty-agreement counterparties' products or devices by the care providers, patients receiving therapy and third-party payors; or
- the unfavorable outcome of any potential litigation relating to our products or devices and our licensees', borrowers' and royalty-agreement counterparties' products or devices.

For example, in mid-2015, Valeant announced two price increases on Glumetza, a royalty-bearing product under our Depomed Royalty Agreement. While the price increases would have been expected to increase revenues and thus our royalties, the entry of three generic manufacturers into this market in February 2016, August 2017 and July 2018 have resulted in a significant reduction in pricing and market share for Glumetza. Due to the uncertainties caused by changes in pricing by third parties that are outside our control, including as a result of generic competition, we may not be able to accurately estimate the impact on royalties on such sales paid to us for Glumetza or any other product.

Additionally, Noden's '111 Patent, expired in January of 2019, which was previously extended by virtue of pediatric testing requirements. While Noden has additional patent coverage related to drug formulation and manufacturing technology which relate to our commercialization of Tekturna in the United States and which expires later than 2019, the expiration of the composition of matter patents related to our Tekturna products will allow entry of competitors which have been able to design around the remaining formulation patents. For example, in 2018, Noden settled a paragraph IV challenge with Anchen Pharmaceuticals, Inc. which allowed entry into the market of a generic aliskiren product in March 2019. While we are unaware of the entry of any third-party generic product at the present time, we expect that a third-party generic version of aliskiren will be available in the future. We may face generic competition with respect to Tekturna in the United States earlier than the expiration of these latter patents. Further, in March 2019, under an agreement with Prasco Laboratories, we launched in the United States an authorized generic form of Tekturna. While we believe Noden is the first to commercialize a generic form of Tekturna ahead of potential competition for aliskiren, we may continue to face additional generic competition with respect to the authorized generic in the future.

### **We and our licensees must protect our and their intellectual property rights for us to succeed.**

Our success is dependent in significant part on our ability and the ability of third parties in control of the assets in which we've invested to protect the scope, validity and enforceability of our and their intellectual property, including the patents, SPCs and license agreements, all of which support our revenues. The scope, validity, enforceability and effective term of patents and SPCs can be highly uncertain and often involve complex legal and factual questions and proceedings. In addition, the legal principles applicable to patents in any given jurisdiction may be altered through changing court precedent and legislative action, and such changes may affect the scope, strength and enforceability of our patent rights or the nature of proceedings which may be brought related to the relevant patent rights. A finding in a proceeding related to patent rights which support our revenues which narrows

the scope or which affects the validity or enforceability of some or all of our patent rights could have a material impact on our ability to continue to collect royalty payments from our investments or collect revenue from our sales of our pharmaceutical products and medical devices.

**Our reliance on sole and single source suppliers could harm our ability to meet demand for our products or devices in a timely manner or within budget.**

Some of the components necessary for the assembly of our Medical Devices segment are currently provided to us by sole-sourced suppliers or single-sourced suppliers. We generally purchase components through purchase orders rather than long-term supply agreements and generally do not maintain large volumes of inventory. While alternative suppliers exist and could be identified for sole-sourced components, the disruption or termination of the supply of components could cause a significant increase in the costs of these components, which could affect our operating results. A disruption or termination in the supply of components could also result in our inability to meet demand for our products, which could harm our ability to generate revenues, lead to customer dissatisfaction and damage our reputation. Furthermore, if we are required to change the manufacturer of a key component of our products, we may be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer could delay our ability to manufacture our products in a timely manner or within budget, which may have a material adverse impact on our business, financial condition, results of operations, or cash flows.

**Recently enacted and future legislation is expected to increase the difficulty and costs to maintain revenues from our products, and in particular may negatively impact the pricing of our products.**

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, affect our ability to profitably sell our products.

For example, in the United States in March 2010, the ACA was enacted to increase access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and the health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The law has continued the downward pressure on pharmaceutical pricing, especially under the Medicare program, and increased the industry's regulatory burdens and operating costs. Among the provisions of the ACA of importance are the following:

- an annual, non-tax deductible fee payable by any entity that manufactures or imports specified branded prescription drugs payable to the federal government based on each company's market share of prior year total sales of branded products to certain federal healthcare programs;
- imposed an annual excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the United States, with limited exceptions (described in more detail below), although the effective rate paid may be lower. Through a series of legislative amendments, the tax was suspended for 2016 through 2019. Absent further legislative action, the device excise tax will be reinstated on medical device sales starting January 1, 2020;
- implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- extension of manufacturers' Medicaid rebate liability to individuals enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs in certain states;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries under their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D. Subsequent legislative amendments have increased the point-of-sale discounted to 70%, effective 2019;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

The potential financial impact of the ACA over the next few years will depend on a number of factors including policies reflected in implementing regulations and guidance and changes in sales volumes for products affected by the new system of rebates, discounts and fees. The taxes imposed by the ACA and the expansion in the government's role in the U.S. healthcare industry may result in decreased profits to us, lower reimbursement by payors for our products, and/or reduced medical procedure volumes, all of which may have a material adverse effect on our business, financial condition and results of operations. The Trump Administration and the U.S. Congress may take further action regarding the ACA, including, but not limited to, repeal or replacement. For example, the Tax Cuts and Jobs Act of 2017 (the "2017 Tax Act") was enacted, which, among other things, removes penalties for not complying with the individual mandate to carry health insurance. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that the individual mandate is a critical and inseparable feature of the ACA, and therefore, because it was repealed as part of the 2017 Tax Act, the remaining provisions of the ACA are invalid as well. While the Trump Administration and the Centers for Medicare & Medicaid Services have both stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, if any, and other efforts to repeal and replace the ACA will impact the ACA. There may be additional challenges and amendments to the ACA in the future, and all or a portion of the ACA and related subsequent legislation may be modified, repealed or otherwise invalidated through judicial challenge. We cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2025 unless additional action is taken by Congress. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers and increased the statute of limitations period in which the government may recover overpayments to providers from three to five years. In addition, recently there has been heightened governmental scrutiny over the manner in which drug manufacturers set prices for their commercial products. The implementation of cost containment measures or other healthcare reforms may limit us from being able to generate revenue, attain profitability, or commercializing our products, which could have a material adverse effect on business and results of operations.

In any event, we expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for pharmaceutical products, which could result in reduced demand for our products or our counterparties' products or additional pricing pressures on our products or our counterparties' products.

**Changes in the third-party coverage and reimbursement may affect sales of our products, product sales from which we receive royalty revenues and the products our borrowers sell to generate revenues. And the growth of managed care organizations ("MCOs") is expected to increase pricing pressures on our products in the United States.**

Sales of our products, product sales from which we receive royalties and the products our borrowers sell to generate revenues will depend significantly on the extent to which reimbursement for the cost of such products and related treatments will be available to physicians and patients from various levels of United States and international government health authorities, private health insurers and other organizations. Third-party payers and government health administration authorities increasingly attempt to limit and/or regulate the coverage and reimbursement of medical products and services, including branded prescription drugs. Changes in government legislation or regulation, such as the ACA, and changes in formulary or compendia listing or changes in private third-party payers' policies toward reimbursement for such products may reduce reimbursement of the cost of such products to physicians, pharmacies and distributors. Decreases in third-party reimbursement could reduce usage of such products and sales to collaborators, which may have a material adverse effect on our revenues derived from our products, those from which we receive royalties from the business of our borrowers. In addition, macroeconomic factors may affect the ability of patients to pay or co-pay for costs or otherwise pay for our products or the products from which we, our royalty counterparties and borrowers generate revenues by, for example, decreasing the number of patients covered by insurance policies or increasing costs associated with such policies.

In the United States in particular, the influence of MCOs has increased in recent years due to the growing number of patients receiving coverage through MCOs. The growth of MCOs has increased pressure on drug prices as well as revenues for pharmaceutical companies. One objective of MCOs is to contain and, where possible, reduce healthcare expenditures. MCOs typically use formularies as a means to negotiate prices with pharmaceutical providers; physician protocols requiring prior authorization for a branded product if a generic product is available or requiring the patient to first fail on one or more generic products before permitting access to a branded medicine; volume purchasing; and long-term contracts. In addition, by placing branded medicines on higher-tier status in their formularies or non-preferred tier status, MCOs transfer a portion of the cost of those medicines to the patient (through and increase in co-payment requirements), resulting in significant out-of-pocket expenses for the patient. This financial disincentive is a means by which MCOs manage drug costs and influence patients to use medicines

preferred by the MCOs.

Exclusion of a product from a formulary or other MCO-implemented restrictions can significantly impact drug usage in the MCO patient population. Consequently, pharmaceutical companies compete to gain access to formularies for their products. Unique product features, such as greater efficacy, better patient ease of use, or fewer side effects, are generally beneficial to achieving access to formularies. Larger pharmaceutical companies have the ability to bundle available products and discounts in an effort to place and maintain products on formulary. We will be responsible for meeting the requirements of MCO's in the United States and ensuring the competitive use of our products in a highly uncertain and changing environment. There can be no assurance that we will be able to maintain or increase the use of our products, and their inability to succeed could have a material adverse impact on the value of our investments.

### **Generic products may increase pricing pressures on our products.**

Although we believe that our products benefit from both issued and/or pending patents as well as proprietary manufacturing technology, one competitive challenge that our branded pharmaceuticals products face is or will be from generic pharmaceutical manufacturers. Upon the expiration or loss of patent protection for a product, especially a small molecule product, the major portion of revenues for that product may be dramatically reduced in a very short period of time. Several such competitors make a regular practice of challenging product patents before their expiration. Also, manufacturers of generic pharmaceutical products may file or have already filed an ANDA with the FDA seeking to market generic forms of our products prior to the expiration of relevant patents owned by Noden. In June 2018, Noden Pharma DAC entered into a settlement agreement with Anchen pursuant to which Anchen, the sole ANDA filer for Tekturna of which the Company is aware, was granted a license from Noden to commercialize its generic form of aliskiren starting March 1, 2019. Under their license, Anchen may commercialize their formulation of aliskiren, but is not permitted to commercialize a generic version of aliskiren which closely relates to the formulation of Tekturna. As a result of a settlement with Anchen, we expect that a third-party generic aliskiren will enter the market in the future. Further patent litigation and other challenges to Noden's patents would be costly and unpredictable, would require extensive management time and resources, and may ultimately deprive us of market exclusivity for our products in a given geographical territory. The FDA ANDA approval process exempts generics from costly and time-consuming clinical trials to demonstrate their safety and efficacy, allowing generic manufacturers to rely on the safety and efficacy data of the innovator's product. Generic competitors do not generally need to conduct clinical trials and can market a competing version of a product after the expiration or loss of patent or regulatory exclusivity and often charge significantly lower prices. In addition, as noted above, MCOs that focus primarily on the immediate cost of medicines often favor generics over branded drugs. Many governments also encourage the use of generics as alternatives to brand-name drugs in their healthcare programs. Additionally, certain foreign governments have indicated that compulsory licenses to patents may be granted in the case of national emergencies or in other circumstances, which could diminish or eliminate sales and profits from those regions, negatively affect our results of operations and cash flows, lead to an impairment charge of our long-lived assets or result in a material decline of our revenue.

In March 2019, under an agreement with Prasco Laboratories, we launched in the United States an authorized generic form of Tekturna. While we believe Noden is the first to commercialize a generic form of Tekturna ahead of potential competition for aliskiren, the entry into the market of a generic version of aliskiren by Anchen or any other competitor is likely to increase the pricing pressure on our authorized generic form of Tekturna.

### **We do not have experience commercializing an authorized generic product.**

In March 2019, we launched in the United States aliskiren hemifumarate tablets, 150 mg and 300 mg, an authorized generic of Tekturna, through Prasco Laboratories under an agreement with Noden Pharma DAC. This is the first authorized generic that we or our subsidiaries have launched. Accordingly, we do not have experience or expertise in the generic market. We rely significantly on Prasco Laboratories for matters relating to the authorized generic. Our ability to generate revenue related to our authorized generic may be limited for a number of reasons, including, without limitation, the entry into the market of additional generic products, the ratings for any existing or potential additional generic products, and the effect of increased generic competition on pricing. Our ability to supply quantities of our authorized generic may not be sufficient to meet Prasco Laboratories' demand, and such a failure to supply could have an adverse effect on the revenue we may be able to derive from the authorized generic. If we are unable to generate significant revenue from our authorized generic, our business, results of operations and financial condition may be affected.



**Our products may develop undesirable side effects or have other properties impacting safety or efficacy.**

Undesirable side effects caused by our products or similar products sold or developed by other companies, could reveal a high and unacceptable severity and prevalence of side effects or adverse events resulting in a number of potentially significant negative consequences, including:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could result in a material decline of our revenue negatively affecting our results of operations and cash flows and significantly harm our business and the value of our investments.

**We may have significant product liability exposure and our insurance may not cover all potential claims.**

We are exposed to product liability and other claims in the event that our technologies or products are alleged to have caused harm. We may not be able to obtain insurance for the potential liability on acceptable terms with adequate coverage or at reasonable costs. Any potential product liability claims could exceed the amount of our insurance coverage or may be excluded from coverage under the terms of our policies. Our insurance may not be renewed at a cost and level of coverage comparable to that then in effect. Any of these events could materially and adversely affect our business, results of operations and financial condition.

**Our third-party contractors as well as our own employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could result in significant liability for us and harm our reputation.**

We are exposed to the risk of fraud or other misconduct in connection with international business operations and our reliance on third-party contractors to manage and conduct those activities with respect to our products. These risks include potential failures to:

- comply with FDA regulations or similar regulations of comparable foreign regulatory authorities;
- provide accurate information to the FDA or comparable foreign regulatory authorities;
- comply with manufacturing standards applicable to our products;
- comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities;
- comply with the FCPA, the UK Bribery Act, and other anti-bribery laws;
- report financial information or data and our business affairs accurately;
- or disclose unauthorized activities to us.

**Our investment in Noden, an Irish entity, subjects us to both United States and international tax laws with respect to the structure and operations of our business and the business conducted by Noden, which are subject to continued scrutiny and change by governments and may result in additional liabilities that may affect our results of operations.**

Noden is incorporated in Ireland and maintains the performance of certain functions and ownership of certain assets in a more tax-efficient jurisdiction than the United States. Taxing authorities, such as the United States Internal Revenue Service (“IRS”), actively audit and otherwise challenge these types of arrangements, and have regularly done so in the pharmaceutical industry. We remain subject to reviews and audits by the IRS and other taxing authorities from time to time, and the IRS or other taxing authority may challenge our structure and intra-company arrangements through an audit or lawsuit. Responding to or defending against those and other challenges from taxing authorities could be expensive and, in any event, would consume time and other resources, and divert management’s time and focus from business operations. We generally cannot predict whether taxing authorities will conduct an audit or file a lawsuit challenging our current structure, the cost involved in responding to any inquiry or audit or lawsuit, or the outcome. If we are unsuccessful, we may be required to consolidate income and pay greater taxes as well as interest, fines or penalties, and may be obligated to pay increased taxes in the future, any of which could have a material adverse effect on our results of operations and could negatively affect our ability to be competitive in the acquisition of future, additional pharmaceutical products or devices.

**The regulatory clearance and approval processes of the FDA are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory clearance or approval for any new product candidates or modifications to existing products, our business will be substantially harmed.**

The time required to obtain approval or clearance of a drug or device, respectively, by the FDA is unpredictable but typically takes many years following the commencement of clinical trials, if required, and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval or clearance policies, regulations, or the type and amount of clinical data necessary to gain marketing authorization may change during the course of a product candidate's development and may vary among jurisdictions. We are not permitted to market any new product candidates in the United States until we receive regulatory approval of an NDA for any new drug product candidate or clearance of a 510(k) premarket notification (or approval of a PMA application) for any new medical device from the FDA, unless the device is exempt from such requirements.

Prior to obtaining approval to commercialize a drug product candidate in the United States or abroad, we or our collaborators must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA, that such product candidates are safe and effective for their intended uses. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we believe the preclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. The FDA may also require us to conduct additional preclinical studies or clinical trials for our product candidates either prior to or post-approval, or it may object to elements of our clinical development program.

In the United States, before we can market a new medical device, or a new use of, new claim for or significant modification to an existing product, we must first receive either clearance under Section 510(k) of the Federal Food, Drug, and Cosmetic Act ("FFDCA") or approval of a PMA application from the FDA, unless an exemption applies. In the 510(k) clearance process, before a device may be marketed, the FDA must determine that a proposed device is "substantially equivalent" to a legally-marketed "predicate" device, which includes a device that has been previously cleared through the 510(k) process, a device that was legally marketed prior to May 28, 1976 (pre-amendments device), a device that was originally on the U.S. market pursuant to an approved PMA and later down-classified, or a 510(k)-exempt device. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data are sometimes required to support substantial equivalence. In the PMA process, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, pre-clinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices.

Modifications to products that are approved through a PMA application generally require FDA approval. Similarly, certain modifications made to products cleared through a 510(k) may require a new 510(k) clearance. Both the PMA approval and the 510(k) clearance process can be expensive, lengthy and uncertain. The FDA's 510(k) clearance process usually takes from three to 12 months, but can last longer. The process of obtaining a PMA is much costlier and more uncertain than the 510(k) clearance process and generally takes from one to three years, or even longer, from the time the application is filed with the FDA. In addition, a PMA generally requires the performance of one or more clinical trials. Despite the time, effort and cost, we cannot assure you that any particular device will be approved or cleared by the FDA. Any delay or failure to obtain necessary regulatory approvals could harm our business.

In the United States, we have obtained 510(k) premarket clearance from the FDA to market the LENSAR device. An element of our strategy is to continue to add new features and seek new indications. We expect that any such modifications may require new 510(k) clearance; however, future modifications may be subject to the substantially more costly, time-consuming and uncertain PMA process. If the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing products than we had expected, product introductions or modifications could be delayed or canceled, which could cause our sales to decline.

The FDA can delay, limit or deny clearance or approval of our product candidates or require us to conduct additional preclinical or clinical testing or abandon a program for many reasons, including:

- the FDA's disagreement with the design or implementation of our clinical trials;
- negative or ambiguous results from our clinical trials;
- results that may not meet the level of statistical significance required by the FDA for approval or clearance;

- serious and unexpected drug-related adverse events experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates;
- our inability to demonstrate to the satisfaction of the FDA that our product candidates are safe and effective for the proposed indication or, in the case of our medical devices, are substantially equivalent to our proposed predicate device;
- the FDA’s disagreement with the interpretation of data from preclinical studies or clinical trials;
- our inability to demonstrate that the clinical and other benefits of our product candidates outweigh any safety or other perceived risks;
- the FDA’s requirement for additional preclinical studies or clinical trials;
- the FDA’s disagreement regarding the formulation, labeling or the specifications of our product candidates;
- the FDA’s agency’s failure to approve the manufacturing processes or facilities of third-party manufacturers with which we contract; or
- the potential for approval policies or regulations of the FDA to significantly change in a manner rendering our clinical data insufficient for approval.

Of the large number of products in development, only a small percentage successfully complete the FDA marketing authorization process and become commercialized. The lengthy process as well as the unpredictability of outcomes from future clinical trials may result in our failing to obtain regulatory authorization to market our product candidates.

Even if we eventually complete clinical testing and receive approval of an NDA, 510(k), or similar foreign marketing application for our product candidates, the FDA may grant approval contingent on the performance of costly additional clinical trials, including Phase 4 clinical trials, or in the case of our products, the implementation of a Risk Evaluation and Mitigation Strategy (“REMS”), which may be required to ensure safe use of the drug after approval. The FDA also may authorize a product candidate for a more limited indication or patient population than we originally requested, and the FDA may not authorize us to market the product with the labeling that we believe is necessary or desirable for the successful commercialization of a product candidate. Any delay in obtaining, or inability to obtain, applicable regulatory authorization would delay or prevent commercialization of that product candidate. In addition, our products may become subject to class-wide REMS that implicate all manufactures of a particular class of drugs, which could significantly impact our ability to commercialize our products and could reduce their market potential.

**The safety and efficacy of our medical device products is not yet supported by long-term clinical data, which could limit sales, and our products might therefore prove to be less safe or effective than initially thought.**

Our medical device products have received premarket clearance under Section 510(k) of the FDCA. In the 510(k) clearance process, before a device may be marketed the FDA must determine that a proposed device is “substantially equivalent” to a legally-marketed “predicate” device, which includes a device that has been previously cleared through the 510(k) process, a device that was legally marketed prior to May 28, 1976 (pre-amendments device), a device that was originally on the U.S. market pursuant to an approved PMA application and later down-classified, or a 510(k)-exempt device. This process is typically shorter and generally requires the submission of less supporting documentation than the FDA’s PMA application process and does not always require long-term clinical studies.

In the European Economic Area (“EEA”) manufacturers of medical devices are required by the Medical Devices Directive to collect post-marketing clinical data in relation to their CE marked medical devices. Post-market surveillance includes the conduct of post-market clinical follow-up studies permitting manufacturers to gather information concerning quality, safety or performance of medical devices after they have been placed on the market in the EEA. All information collected as part of the post-market surveillance process must be reviewed, investigated and analyzed on a regular basis in order to determine whether trending conclusions can be made concerning the safety or performance of the medical device and decisions must be taken in relation to the continued marketing of medical devices currently on the market. We expect to incur ongoing costs to comply with these post-market clinical obligations in EEA markets for so long as we continue to market and sell products in those markets. We anticipate that these costs will be immaterial going forward.

Given the foregoing regulatory environment in which we operate, we lack the breadth of published long-term clinical data supporting the safety and efficacy of our medical devices and the benefits they offer that might have been generated in connection with other approval processes. For these reasons, the market may be slow to adopt our products, we may not have comparative data that our competitors have or are generating, and we may be subject to greater regulatory and product liability risks.

In addition, while our LENSAR<sup>®</sup> Laser Systems were first approved in 2010 in the United States and in 2013 in EEA, we have limited complication or patient success rate data with respect to uses of our products. In addition, if future studies and experience indicate that our products cause unexpected or serious complications or other unforeseen negative effects, we could be subject to mandatory product recalls or suspension or withdrawal of clearance in the United States or the EEA, and our reputation with physicians, patients and healthcare providers may suffer.

**The misuse or off-label use of our products may harm our reputation in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business.**

Our products have been approved or cleared by the FDA for specific indications. Our marketing does not promote our products for uses outside of these cleared or approved indications for use, known as “off-label uses.” We cannot, however, prevent a physician from using or prescribing our products off-label, when in the physician’s independent professional medical judgment he or she deems it appropriate. There may be increased risk of injury to patients if physicians prescribe or use our products off-label. Furthermore, the use of our products for indications other than those cleared or approved by the FDA or any foreign regulatory body may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients.

If the FDA or any foreign regulatory body determines that our promotional materials or training constitute promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance or imposition of an untitled letter, which is used for violators that do not necessitate a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action under other regulatory authority, such as false claims laws, if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment of our operations.

Moreover, if our products are misused or used with improper technique, we may become subject to costly litigation. Product liability claims could divert management’s attention from our core business, be expensive to defend and result in sizeable damage awards against us that may not be covered by insurance. In addition, any of the events described above could harm our business.

**Even though we have received regulatory approval for our drug product candidates and clearance of a premarket notification for our devices, we are subject to ongoing regulatory obligations and continued regulatory review, which results in significant additional expense, and we may be subject to penalties, if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.**

Any regulatory approvals or clearances that we receive may be subject to limitations on the approved indicated uses for which the product may be marketed or the conditions of approval, or contain requirements for potentially costly post-market testing and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS as a condition of approval of our product candidates, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools.

In addition, once the FDA or a comparable foreign regulatory authority authorizes a product for marketing, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping are subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCP requirements for any clinical trials that we conduct post-approval. For example, we are subject to the medical device reporting requirements for our medical device products, which require us to report to the FDA when we receive or become aware of information that reasonably suggests that one or more of our medical devices may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, it could cause or contribute to a death or serious injury. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the product. If we fail to comply with our reporting obligations, the FDA could take enforcement action against us. We are subject to similar post-market reporting requirements with respect to our drug products.

Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of approvals;
- product seizure or detention, or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could impact our business. For example, in December 2016, the 21st Century Cures Act "(Cures Act)" was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and medical devices and spur innovation, but its ultimate implementation remains unclear. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may fail to obtain any marketing approvals, lose any marketing approval that we have obtained and we may not achieve or sustain profitability.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. If these executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

**Our acquisition of pharmaceutical products, including the Noden Products, and acquisition of a medical device with the LENSAR<sup>®</sup> laser system, will make us subject to more extensive healthcare laws, regulation and enforcement and our failure to comply with those laws could have a material adverse effect on our results of operations and financial condition.**

The acquisition of pharmaceutical products and medical devices, and our sales and marketing efforts with respect to our products and/or medical devices, will increase our potential risk of civil and criminal enforcement by the federal government and the states and foreign governments. Our business practices and relationships with providers are subject to scrutiny under these laws. We may also be subject to privacy and security regulation related to patient, customer, employee and other third-party information by both the federal government and the states and foreign jurisdictions in which we conduct our business. The laws, regulations and codes that may affect us in the United States include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. The U.S. government has interpreted this law broadly to apply to the marketing and sales activities of manufacturers. Moreover, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Violations of the federal Anti-Kickback Statute may result in civil monetary penalties up to \$74,792 for each violation, plus up to three times the remuneration involved. Civil penalties for such conduct can further be assessed under the federal False Claims Act. Violations can also result in criminal penalties, including criminal fines of up to \$100,000 and imprisonment of up to 10 years. Similarly, violations can result in exclusion from participation in government healthcare programs, including Medicare and Medicaid;
- federal civil and criminal false claims laws and civil monetary penalty 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. Private individuals can bring False Claims Act "qui tam" actions, on behalf of the government and such individuals, commonly known as "whistleblowers," may share in amounts paid by the entity to the government in fines or settlement. When an entity is determined to have violated the federal civil False Claims Act, the government may impose civil fines and penalties ranging from \$11,181 to \$22,363 for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;

- the federal Civil Monetary Penalties Law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier;
- The Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- HIPAA, as amended by the Health Information for Economic and Clinical Health Act of 2009 ("HITECH"), and its implementing regulations, which imposes certain requirements on certain covered healthcare providers, health plans and healthcare clearinghouses as well as their business associates that perform services for them that involve individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information, without appropriate authorization, including mandatory contractual terms as well as directly applicable privacy and security standards and requirements. Failure to comply with the HIPAA privacy and security standards can result in civil monetary penalties up to \$55,910 per violation, not to exceed \$1.68 million per calendar year for non-compliance of an identical provision, and, in certain circumstances, criminal penalties with fines up to \$250,000 per violation and/or imprisonment. State attorneys general can also bring a civil action to enjoin a HIPAA violation or to obtain statutory damages on behalf of residents of his or her state;
- the federal physician sunshine requirements under the ACA, which requires manufacturers of drugs, devices, biologics, and medical supplies to report annually to the Centers for Medicare and Medicaid Services ("CMS"), information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members. Applicable manufacturers are required to submit annual reports to CMS. Failure to submit required information may result in civil monetary penalties of \$11,052 per failure up to an aggregate of \$165,786 per year (or up to an aggregate of \$1.105 million per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests that are not timely, accurately, and completely reported in an annual submission, and may result in liability under other federal laws or regulations;
- guidelines promulgated by the Office of Inspector General of the U.S. Department of Health and Human Services related to pharmaceutical company regulatory compliance programs and the PhRMA Code on Interactions with Healthcare Professionals, as amended;
- foreign and state law equivalents of each of the above federal laws, such as the FCPA, anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers;
- state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources;
- state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and
- state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts.

These laws and regulations, among other things, constrain our business, marketing and other promotional activities by limiting the kinds of financial arrangements, including sales programs, we may have with hospitals, physicians or other potential purchasers of our products. Due to the breadth of these laws, the narrowness of statutory exceptions and regulatory safe harbors available, and the range of interpretations to which they are subject, it is possible that some of our current or future practices might be challenged under one or more of these laws.

To enforce compliance with the healthcare regulatory laws, certain enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time- and resource-consuming and can divert management's attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may have to agree to additional compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity, and be costly to respond to.

We do not have experience in establishing the compliance programs necessary to comply with this complex and evolving regulatory environment and our reliance on Noden and LENSAR to operate and address these requirements appropriately increases the risks that we may be found to violate the applicable laws and regulations. If we are found to be in violation of any of

such laws or any other governmental regulations, we may be subject to penalties, including administrative, civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, the exclusion from participation in federal and state healthcare programs, imprisonment, contractual damages, reputational harm, disgorgement and the curtailment or restructuring of our operations, any of which could materially and adversely affect interests in our products, including having a material adverse effect on our financial results.

**Our common stock may lose value, our common stock could be delisted from Nasdaq and our business may be liquidated due to several factors, including the failure to acquire additional sources of revenue, decrease in revenues from of our income generating assets, the failure to continue to produce revenues for our existing assets in our Pharmaceutical or Medical Devices segments and the failure to meet analyst expectations.**

Prior to 2017, our revenues consisted mostly of royalties from licensees of our Queen et al. patents, which patents expired in December of 2014 and most related licenses expired in the first quarter of 2016.

Prospectively, we expect to focus on the acquisition of additional pharmaceutical products and companies and anticipate that over time, as a result of these new acquisitions, more of our revenues will come from our Pharmaceutical segment and less of our revenues will come from our Income Generating Assets and Medical Devices segments. If we are unable to successfully execute all or any elements of our strategy, our financial performance could be adversely affected, and the price of our common stock may fall. If the price of our common stock were to fall and remain below Nasdaq listing standards, our common stock may be delisted. If our common stock were delisted, market liquidity for our common stock could be severely affected and our stockholders' ability to sell securities in the secondary market could be limited. Delisting from Nasdaq would negatively affect the value of our common stock. Delisting could also have other negative results, including, but not limited to, the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities.

**An impairment charge with respect to intangible assets could have a material impact on our results of operations.**

We periodically evaluate our intangible assets to determine whether all or a portion of their carrying values may be impaired, in which case a charge to earnings may be necessary. The occurrence of certain events, changes in business strategy, government regulations or economic or market conditions may cause us to remeasure the fair value of certain assets and liabilities. Our judgments regarding the existence of impairment indicators are based on, among other things, legal factors, market conditions, and operational performance. If an event or events occur that would cause us to revise our estimates and assumptions used in analyzing the value of our intangible assets, such revision could result in an impairment charge that could have a material impact on our results of operations in the period in which the impairment occurs. For example, at June 30, 2018, we recorded an impairment charge of \$152.3 million for the Noden intangible assets related to the increased probability of a generic version of aliskiren being launched in the United States. As a result of this impairment charge, which was based on the estimated fair value of the assets, the remaining carrying value of these intangible assets were determined to be \$40.1 million. For additional information on the impairment charge, see Note 13, *Intangible Assets*.

**The lack of liquidity for the assets in our acquisitions may materially and adversely affect our business and, if we need to sell any of our acquired assets, we may not be able to do so at a favorable price. As a result, we may suffer losses.**

We generally acquire patents, royalty rights and debt instruments that have limited secondary resale markets. The illiquidity of most of our assets may make it difficult for us to dispose of them at a favorable price and, as a result, we may suffer losses if we are required to dispose of any or all such assets in a liquidation or otherwise. In addition, if we liquidate all or a portion of our assets quickly or in connection with a liquidation, we may realize significantly less than the value at which we had previously recorded these assets.

**We may use a certain amount of cash from time to time in order to satisfy the obligations relating to our convertible notes. The maturity or conversion of any of our convertible notes could materially and adversely affect our business, results of operations and financial condition.**

On February 1, 2018, we repaid our 4.0% Convertible Senior Notes due February 1, 2018 (the "February 2018 Notes") in full at their stated maturity. In addition, we are required to repay the full principal amount of \$150.0 million in principal amount outstanding under the 2.75% Convertible Senior Notes due December 1, 2021 (the "December 2021 Notes") if not previously converted.

Our ability to make scheduled payments of the principal of, to pay interest on, to pay any cash due upon conversion of, or to refinance, our indebtedness, depends on our future performance, which is subject to economic, financial, competitive and other

factors beyond our control. Our business may not generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

Holders of the December 2021 Notes may convert their notes at their option under the following conditions at any time prior to the close of business on the business day immediately preceding June 1, 2021: (i) during any fiscal quarter (and only during such fiscal quarter) commencing after the fiscal quarter ending March 31, 2017, if the last reported sale price of our common stock for at least 20 trading days (whether or not consecutive), in the period of 30 consecutive trading days, ending on, and including, the last trading day of the immediately preceding fiscal quarter, exceeds 130% of the conversion price for the notes on each applicable trading day; (ii) during the five business day period immediately after any five consecutive trading-day period (the measurement period), in which the trading price per \$1,000 principal amount of the December 2021 Notes for each trading day of that measurement period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate for the notes for each such trading day; or (iii) upon the occurrence of specified corporate events.

The December 2021 Notes may be settled by paying or delivering, as applicable, cash, shares of our common stock or a combination of cash and shares of our common stock, at our election, although it is the current intention that they will be net-share settled. If one or more holders elect to convert their notes when conversion is permitted, we would be required to make cash payments to satisfy up to the face value of our conversion obligation in respect of each note, which could adversely affect our liquidity.

We may use a certain amount of cash from time to time in order to satisfy repurchase or other obligations relating to our convertible notes which could adversely affect the amount or timing of any distribution to our stockholders or any income generating transactions. In addition, we may redeem, repurchase or otherwise acquire the convertible notes in the open market in the future, any of which could adversely affect the amount or timing of any cash distribution to our stockholders.

**The conversion or any future exchanges of any of the December 2021 Notes into shares of our common stock would have a dilutive effect that could cause our stock price to go down.**

Until June 1, 2021, the December 2021 Notes are convertible into shares of our common stock only if specified conditions are met and thereafter convertible at any time, at the option of the holder. We have reserved shares of our authorized common stock for issuance upon conversion of these convertible notes. Upon conversion, the principal amount is due in cash, and to the extent that the conversion value exceeds the principal amount, the difference is due in shares of common stock. If any or all of these convertible notes are converted into shares of our common stock, our existing stockholders will experience immediate dilution of voting rights and our common stock price may decline. Furthermore, the perception that such dilution could occur may cause the market price of our common stock to decline.

**We entered into a capped call transaction in connection with the issuance of our December 2021 Notes that may affect the value of our common stock and any desired dilution mitigation will be limited to the extent that our stock price rises above the cap price of the capped call transaction.**

In connection with the issuance of our December 2021 Notes, we entered into a capped call transaction, with a hedge counterparty, which we expect to reduce the potential dilution upon conversion of the December 2021 Notes in the event that the market price per share of our common stock, as measured under the terms of the capped call transaction, at the time of exercise is greater than the strike price of the capped call transaction, which corresponds to the initial conversion price of the notes and is subject to certain adjustments similar to those contained in the December 2021 Notes. If, however, the market price per share of our common stock, as measured under the terms of the capped call transaction, exceeds the cap price (\$4.88 per share) of the capped call transaction, there would nevertheless be dilution to the extent that such market price exceeds the cap price of the capped call transaction.

In connection with hedging the capped call transaction, the hedge counterparty or its affiliates:

- expect to purchase our common stock in the open market and/or enter into various derivatives and/or enter into various derivative transactions with respect to our common stock; and
- may enter into or unwind various derivatives and/or purchase or sell our common stock in secondary market transactions.



These activities could have the effect of increasing or preventing a decline in the price of our common stock concurrently with or following the pricing of the December 2021 Notes and could have the effect of decreasing the price of our common stock during the period immediately prior to a conversion of the December 2021 Notes.

The hedge counterparty or its affiliates are likely to modify their hedge positions in relation to the capped call transaction from time to time prior to conversion or maturity of the December 2021 Notes by purchasing and selling our common stock, other of our securities, or other instruments they may wish to use in connection with such hedging.

In addition, we intend to exercise options we hold under the capped call transaction whenever the December 2021 Notes are converted. In order to unwind its hedge positions with respect to those exercised options, the counterparty or affiliates thereof expect to sell our common stock in secondary market transactions or unwind various derivative transactions with respect to our common stock during the period immediately prior to conversion of the December 2021 Notes. We have also agreed to indemnify the hedge counterparty and affiliates thereof for losses incurred in connection with a potential unwinding of their hedge positions under certain circumstances.

The effect, if any, of any of these transactions and activities on the market price of our common stock will depend in part on market conditions and cannot be ascertained at this time, but any of these activities could adversely affect the value of our common stock. For further information regarding the mechanics of our capped call transaction refer to our discussion in the Liquidity and Capital Resources section of Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations and Note 16, *Term Loan and Convertible Senior Notes*, to the Consolidated Financial Statements included in Item 8.

**Despite our current debt levels, we may still incur additional debt; if we incur substantial additional debt, these higher levels of debt may affect our ability to pay the principal of and interest on our convertible notes.**

We and our subsidiaries may be able to incur substantial additional debt in the future, some of which may be secured debt. The indenture governing the convertible notes do not restrict our ability to incur additional indebtedness or require us to maintain financial ratios or specified levels of net worth or liquidity. If we incur substantial additional indebtedness in the future, these higher levels of indebtedness may affect our ability to pay the principal of and interest on our convertible notes, or any fundamental change in purchase price or any cash due upon conversion, and our creditworthiness generally.

**We have implemented a corporate structure taking into consideration our limited operations and potentially applicable tax impact on our royalty and other income, and any changes in applicable tax laws and regulations or enforcement positions of tax authorities may negatively impact our financial condition and operating results.**

We have established our corporate structure to be closely aligned with the financial nature of our business. There can be no assurance that the applicable tax laws and regulations will continue in effect or that the taxing authorities in any or all of the applicable jurisdictions will not challenge one or more aspects or characterizations of our corporate structure and the treatment of transactions or agreements within our corporate structure, or determine that the manner in which we operate our business is not consistent with our corporate structure. For example, recently-enacted U.S. tax legislation may result in an increased tax liability as a result of our current corporate structure. We may also have disputes with one or more state tax authorities regarding whether we are subject to that state's tax and, if we are subject to such state's tax, what proportion of our revenues is subject to taxation in such state. For example, we are currently subject to an audit by the California Franchise Tax Board and, while we may disagree with their conclusions regarding such issues, the proceedings extend over long periods of time and we may ultimately be required to pay taxes either in a settlement or upon a final decision of an agency or court. Any unfavorable changes in laws and regulations or positions by tax authorities could harm our financial position, results of operations and cash flows.

**We may have exposure to additional tax liabilities.**

We are subject to taxes in the United States and other jurisdictions. Tax rates in these jurisdictions may be subject to significant change due to economic and/or political conditions. A number of other factors may also impact our future effective tax rate including:

- the jurisdictions in which profits are determined to be earned and taxed;
- the resolution of issues arising from tax audits with various tax authorities;
- changes in valuation of our deferred tax assets and liabilities;
- increases in expenses not deductible for tax purposes, including write-offs of acquired intangibles and impairment of goodwill in connection with acquisitions;
- changes in availability of tax credits, tax holidays, and tax deductions;

- changes in share-based compensation; and
- changes in tax laws or the interpretation of such tax laws and changes in generally accepted accounting principles.

On December 22, 2017, the U.S. federal government enacted the 2017 Tax Act. The 2017 Tax Act significantly changed the existing U.S. corporate income tax laws by, among other things, lowering the corporate tax rate (from a top rate of 35% to a flat rate of 21%), implementing elements of a territorial tax system, and imposing a one-time deemed repatriation transition tax on cumulative undistributed foreign earnings, for which we have not previously paid U.S. taxes. The Company recognized in its Consolidated Financial Statements for the year ended December 31, 2017 estimated tax impacts related to the revaluation of deferred tax assets and liabilities. The ultimate impact did not differ materially from these provisional amounts after additional analysis, changes in interpretations and assumptions the Company made and additional regulatory guidance that was issued. The accounting was completed when the Company's 2017 U.S. corporate income tax return was filed in 2018. We have made a policy election with respect to our treatment of potential GILTI to account for taxes on GILTI as a current-period expense as incurred.

In addition, certain activities conducted by our foreign subsidiaries may give rise to United States corporate income tax, even if there are no distributions to the United States. These taxes would be imposed on us when our subsidiaries that are controlled foreign corporations generate income that is subject to Subpart F of the U.S. Internal Revenue Code ("Subpart F") or Global intangible low-taxed income ("GILTI"). Passive income, such as rents, royalties, interest and dividends, is among the types of income subject to taxation under Subpart F. Any income taxable under Subpart F or GILTI is taxable in the United States at federal corporate income tax rates of 21%. Subpart F income that is taxable to us, even if it is not distributed to us, may also include income from intercompany transactions between our U.S. and non-U.S. subsidiaries, or where our non-U.S. subsidiaries make an "investment in U.S. property," within the meaning of Subpart F, such as holding the stock in, or making a loan to, a U.S. corporation.

While we may mitigate this increase in our effective tax rate through claiming a foreign tax credit against our U.S. federal income taxes or potentially have foreign or U.S. taxes reduced under applicable income tax treaties, we are subject to various limitations on claiming foreign tax credits and we may lack treaty protections in certain jurisdictions that will potentially limit any reduction of the increased effective tax rate. A higher effective tax rate may also result to the extent that losses are incurred in non-U.S. subsidiaries that do not reduce our U.S. taxable income.

**Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.**

At December 31, 2018, we had federal, state and foreign net operating loss carryforwards of \$101.7 million, \$285.9 million and \$73.0 million, respectively, and federal and state tax credit carryforwards of \$2.2 million and \$19.3 million, respectively. There may be limitations on our ability to use our net operating loss carryforwards or other tax assets. For example, under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change" (generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. We or our subsidiaries may have experienced, or may in the future experience, "ownership changes" as a result of shifts in stock ownership. Tax attributes acquired from LENSAR may be subject to separate return limitations ("SRLY") that may limit the corporation's ability to use the acquired net operating losses and credits. Any limitations on our ability to use our net operating loss carryforwards and other tax assets could materially and adversely impact our financial condition and results of operations. Furthermore, under the 2017 Tax Act, although the treatment of tax losses generated in taxable years ending before December 31, 2017 has generally not changed, tax losses generated in taxable years beginning after December 31, 2017 may only be utilized to offset 80% of taxable income annually. This change may require us to pay additional federal income taxes in future years.

**We depend on our licensees and royalty-agreement counterparties for the determination of royalty payments. While we have rights to audit our licensees and royalty-agreement counterparties, the independent auditors may have difficulty determining the correct royalty calculation, we may not be able to detect errors and payment calculations may call for retroactive adjustments. We may have to exercise legal remedies to resolve any disputes resulting from the audit or otherwise related to non-performance by a licensee or royalty counterparty.**

The royalty payments we receive are determined by our licensees based on their reported sales. Each licensee's calculation of the royalty payments is subject to and dependent upon the adequacy and accuracy of its sales and accounting functions, and errors may occur from time to time in the calculations made by a licensee. Our license and royalty agreements provide us the right to audit the calculations and sales data for the associated royalty payments; however, our right to conduct such audits may be limited in terms of the covered periods, and such audits may occur many months following our recognition of the royalty revenue, may require us to adjust our royalty revenues in later periods and may require incurring additional expenses on our part. Further, our

licensees and royalty-agreement counterparties may be uncooperative or have insufficient records, which may complicate and delay the audit process.

Although we regularly exercise our royalty audit rights, and reference publicly available information in the assessment of the paid royalties, we rely in the first instance on our licensees and royalty-agreement counterparties to accurately report sales and calculate and pay applicable royalties and, upon exercise of such royalty audit rights, we rely on licensees' and royalty-agreement counterparties' cooperation in performing such audits. In the absence of such cooperation, we may be forced to exercise legal remedies to enforce our agreements.

**We may experience increases and decreases in our revenues due to fluctuations in foreign currency exchange rates and we may be unsuccessful in our attempts to mitigate this risk.**

Our operating results are subject to volatility due to fluctuations in foreign currency exchange rates. Our primary exposure to fluctuations in foreign currency exchange rates relates to revenue and operating expenses denominated in currencies other than the U.S. dollar. Fluctuations in foreign currency rates, particularly the Euro, relative to the U.S. dollar can significantly affect our revenues and operating results. While foreign currency conversion terms vary by license agreement, generally most agreements require that royalties first be calculated in the currency of sale and then converted into U.S. dollars using the average daily exchange rates for that currency for a specified period at the end of the calendar quarter. For example, when the U.S. dollar weakens in relation to other currencies, the converted amount is greater than it would have been had the U.S. dollar exchange rates remained unchanged. Our revenues may fluctuate due to changes in foreign currency exchange rates and is subject to foreign currency exchange risk.

To compensate for Euro currency fluctuations, we may hedge Euro currency exposures with Euro forward and option contracts, to offset the risks associated with these Euro currency exposures. We may suspend the use of these contracts from time to time or we may be unsuccessful in our attempt to hedge our Euro currency risk. We will continue to experience foreign currency related fluctuations in our royalty revenues in certain instances when we do not enter into foreign currency exchange contracts or where it is not possible or cost effective to hedge our foreign currency related exposures. Currency related fluctuations in our royalty revenues will vary based on the currency exchange rates associated with these exposures and changes in those rates, whether we have entered into foreign currency exchange contracts to offset these exposures and other factors. All of these factors could materially impact our results of operations, financial position and cash flows, the timing of which is variable and generally outside of our control.

**Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.**

The ability of the FDA to review and approve new products or devices can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new products or devices to be reviewed and/or approved by necessary government agencies, which could adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our or our companies' regulatory submissions, which could have a material adverse effect on our business.

**We must attract, retain and integrate key employees in order to succeed. It may be difficult to recruit, retain and integrate key employees.**

To be successful, we must attract, retain and integrate qualified personnel. Our business focus is on the acquisition of, and investing in, pharmaceutical products, devices and/or income generating assets and maximizing the value of our patent portfolio and related assets. The acquisition of additional products or companies may require us to recruit, retain or integrate additional qualified personnel. If we are unsuccessful in attracting, retaining and integrating qualified personnel, our business could be adversely impacted.

**Our agreements with Facet may not reflect terms that would have resulted from arm’s-length negotiations between unaffiliated third parties.**

The agreements associated with the spin-off of Facet Biotech Corporation (“Facet”) in December 2008 (the “Spin-Off”), including the Separation and Distribution Agreement, Tax Sharing and Indemnification Agreement and Cross License Agreement, were negotiated in the context of the Spin-Off while Facet was still part of us and, accordingly, may not reflect more favorable terms that may have resulted from arm’s-length negotiations between unaffiliated third parties.

**We may have obligations for which we may not be able to collect under our indemnification rights from Facet.**

Under the terms of the Separation and Distribution agreement with Facet, we and Facet agreed to indemnify the other from and after the Spin-Off with respect to certain indebtedness, liabilities and obligations that were retained by our respective companies. These indemnification obligations could be significant. The ability to satisfy these indemnities, if called upon to do so, will depend upon our future financial strength. We cannot assure you that, if Facet has to indemnify us for any substantial obligations, Facet will have the ability to satisfy those obligations. If Facet does not have the ability to satisfy those obligations, we may be required to satisfy those obligations instead. For example, in connection with the Spin-Off, we entered into amendments to the leases for the facilities in Redwood City, California, which formerly served as our corporate headquarters, under which Facet was added as a co-tenant under the leases and a Co-Tenancy Agreement under which Facet agreed to indemnify us for all matters related to the leases attributable to the period after the Spin-Off date. Should Facet default under its lease obligations, we would be held liable by the landlord as a co-tenant and, thus, we have in substance guaranteed the payments under the lease agreements for the Redwood City facilities, the disposition of which could have a material adverse effect on the amount or timing of any distribution to our stockholders. As of December 31, 2018, the total lease payments for the duration of the guarantee, which runs through December 2021, are approximately \$33.8 million. We would also be responsible for lease-related payments including utilities, property taxes and common area maintenance that may be as much as the actual lease payments. In April 2010, Abbott Laboratories acquired Facet and renamed the company Abbott Biotherapeutics Corp., and in January 2013, Abbott Biotherapeutics Corp. was renamed AbbVie Biotherapeutics, Inc. and spun off from Abbott as a subsidiary of AbbVie Inc. We do not know how Abbott’s acquisition of Facet will impact our ability to collect under our indemnification rights or whether Facet’s ability to satisfy its obligations will change. In addition, we have limited information rights under the Co-Tenancy Agreement. As a result, we are unable to determine definitively whether Facet continues to occupy the space and whether it has subleased the space to another party or the basis upon which our potential co-tenant obligation may be triggered. See “Item 2—Properties.”

**As we continue to develop our business, our mix of assets and sources of income may require that we register with the SEC as an “investment company” in accordance with the Investment Company Act of 1940.**

We are not registered and have no intention to register as an “investment company” under the Investment Company Act of 1940 (the “40 Act”). As a result, we are not and do not expect to become subject to regulation under the 40 Act, including its reporting and corporate governance requirements and restrictions on leverage and affiliate transactions.

Generally, to avoid being regulated as an “investment company” under the 40 Act an issuer must:

- not be engaged or hold itself out as being engaged primarily in the business of investing, reinvesting or trading in securities and not own or propose to acquire “investment securities” with a value of more than 40% of the value of its total assets (exclusive of U.S. government securities and cash items) on an unconsolidated basis; or
- be able to rely on an exception from the definition of “investment company” under the ’40 Act or an exemptive rule.

“Investment securities” are any securities other than U.S. government securities and securities issued by a majority-owned subsidiary that is not itself either an “investment company” or a private investment company, meaning a company that is excluded from the definition of “investment company” by Section 3(c)(1) or Section 3(c)(7) of the 40 Act.

We have in the past and may in the future rely on one or more exceptions to the definition of “investment company” under the 40 Act, including the exception under Section 3(c)(5) of the 40 Act. To rely on Section 3(c)(5), as interpreted by the staff of the SEC, we would be required to have at least 55% of our total assets in certain qualifying assets. In a no-action letter issued to Royalty Pharma on August 13, 2010, the SEC staff stated that certain royalty interests of the type we own can be treated as qualifying assets.

Our board of directors has determined and resolved that we not engage in the business of investing, reinvesting, owning, holding or trading in securities and is implementing a plan to restructure our business and the composition of our assets to make clear that we are not an “investment company” within the meaning of the 40 Act. This may limit our ability to make certain investments

(including divesting certain assets), or require us to take or forego certain actions, that could materially and adversely affect our financial condition and results of operation. In addition, if the SEC, its staff or the courts changes their interpretation of certain provisions of the 40 Act, including Section 3(c)(5), we may need to take additional steps in order to avoid becoming subject to regulation under the 40 Act, which could materially and adversely affect our financial condition and results of operation.

If we were required to register as an “investment company,” the obligations imposed on us by the 40 Act would likely require substantial changes in the way we do business and would result in significant additional regulatory and administrative burdens and costs. In order to remain outside the scope of regulation under the 40 Act, we may need to take various actions which we might otherwise not pursue. These actions may include restructuring our company and modifying our mixture of assets and income, including divesting certain desirable assets immediately, and could have a material and adverse effect on us.

**We have in the past and are currently involved in, and expect that in the future we will from time to time be involved in, litigation, either as a defendant or a plaintiff, which could have a negative impact on our operations and results.**

Monitoring and defending against or prosecuting legal actions is time-consuming for our management and may detract from our ability to fully focus our internal resources on our core business goal of acquiring and managing income generating assets. In addition, legal fees and costs incurred in connection with such activities may be significant. Depending on the nature of the lawsuit, a decision adverse to our interests could result in the payment of substantial damages and could have a material adverse effect on our cash flow, results of operations and financial position or impact our rights in an adverse way.

**Failure in our information technology and storage systems could significantly disrupt the operation of our business.**

Our ability to execute our business plan depends, in part, on the continued and uninterrupted performance of our information technology (“IT”) systems. IT systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious human acts and natural disasters. Moreover, despite network security and back-up measures, some of our servers may be vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our IT systems, sustained or repeated system failures that interrupt our ability to generate and maintain data could adversely affect our ability to operate our business.

**Changes to financial accounting standards may affect our reported results of operations**

A change in accounting standards or practices can have a significant effect on our reported results and may even affect our reporting of transactions completed before the change is effective. New accounting pronouncements and varying interpretations of accounting pronouncements have occurred and may occur in the future. Changes to existing standards or the reevaluation of current practices may adversely affect our reported financial results or the way we conduct our business.

**We use estimates, make judgments, and apply certain methods in measuring the progress of our business in determining our financial results and in applying our accounting policies. As these estimates, judgments, and methods change, our assessment of the progress of our business and our results of operations could vary.**

The methods, estimates, and judgments we use in applying our accounting policies have a significant impact on our results of operations. Such methods, estimates, and judgments are, by their nature, subject to substantial risks, uncertainties, and assumptions, and factors may arise over time may lead us to change our methods, estimates, and judgments. Changes in any of our assumptions may adversely affect our reported financial results.

**If we fail to maintain an effective system of internal control over financial reporting in the future, we may not be able to accurately report our financial condition, results of operations or cash flows, which may adversely affect investor confidence in us and, as a result, the value of our common stock.**

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. We are required, under Section 404 of the Sarbanes-Oxley Act (“Section 404”), to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment must include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. A material weakness is a control deficiency, or combination of control deficiencies, in internal control over financial reporting that results in more than a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis. Section 404 also generally requires an attestation from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting.

Our compliance with Section 404 requires that we incur substantial accounting expense and expend significant management efforts. Our acquired businesses may have limited experience complying with Section 404 and if in the future we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal control over financial reporting is effective. Furthermore, we cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

#### **ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

#### **ITEM 2. PROPERTIES**

##### *Pharmaceutical Segment*

Noden Pharma DAC leases approximately 3,100 square feet of office space in Dublin, Ireland, which serves as the office managing all pharmaceutical operations. The lease expires in September 2025. Noden Pharma DAC has the option to terminate the lease in September 2021.

##### *Medical Devices Segment*

LENSAR leases an office and manufacturing facility of approximately 33,900 square feet in Orlando, Florida, which serves as the office managing all medical device operations. The lease expires in July 2021.

##### *Income Generating Assets Segment*

We lease approximately 5,900 square feet of office space in Incline Village, Nevada, which serves as our corporate headquarters. The lease expires in May 2020.

In July 2006, we entered into two leases and a sublease for facilities in Redwood City, California, which formerly served as our corporate headquarters and cover approximately 450,000 square feet of office space. Under the amendments to the leases entered into in connection with the Spin-Off, Facet was added as a co-tenant under the leases. As a co-tenant, Facet is bound by all of the terms and conditions of the leases. We and Facet are jointly and severally liable for all obligations under the leases, including the payment of rental obligations. The guarantee runs through December 2021. We also entered into a Co-Tenancy Agreement with Facet in connection with the Spin-Off and the lease amendments under which we assigned to Facet all rights under the leases, including, but not limited to, the right to amend the leases, extend the lease terms or terminate the leases, and Facet assumed all of our obligations under the leases. Under the Co-Tenancy Agreement, we also relinquished any right or option to regain possession, use or occupancy of these facilities. Facet agreed to indemnify us for all matters associated with the leases attributable to the period after the Spin-Off date and we agreed to indemnify Facet for all matters associated with the leases attributable to the period before the Spin-Off date. In addition, in connection with the Spin-Off, we assigned the sublease to Facet. In April 2010, Abbott Laboratories acquired Facet and later renamed the entity AbbVie Biotherapeutics, Inc. (“AbbVie”). To date, AbbVie has satisfied all obligations under the Redwood City leases.

We believe that our existing facilities are adequate to meet our business requirements for the reasonably foreseeable future and that additional space will be available on commercially reasonable terms, if required.

#### **ITEM 3. LEGAL PROCEEDINGS**

The information set forth in Note 25, *Legal Proceedings*, to the Consolidated Financial Statements included in Item 8, “Financial Statements and Supplementary Data” of this Annual Report is incorporated by reference herein.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

## PART II

### ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

As of February 25, 2019, we had approximately 127 common stockholders of record. Most of our outstanding shares of common stock are held of record by one stockholder, Cede & Co., as nominee for the Depository Trust Company. Many brokers, banks and other institutions hold shares of common stock as nominees for beneficial owners that deposit these shares of common stock in participant accounts at the Depository Trust Company. The actual number of beneficial owners of our stock is likely significantly greater than the number of stockholders of record; however, we are unable to reasonably estimate the total number of beneficial owners.

#### Equity Compensation Plan Information

See Part III, Item 12, "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters" for information regarding securities authorized for issuance under equity compensation plans.

#### Recent Sales of Unregistered Securities

None.

#### Issuer purchases of Equity Securities

The following table contains information relating to the repurchases of our common stock made by us in the three months ended December 31, 2018 (in thousands, except per share amounts):

<b>Fiscal Period</b>	<b>Total Number of Shares Repurchased</b>	<b>Average Price Paid Per Share</b>	<b>Total Number of Shares Purchased As Part of a Publicly Announced Program</b>	<b>Approximate Dollar Amount of Shares That May Yet be Purchased Under the Program</b>
October 1, 2018 to October 31, 2018 .....	—	\$ —	—	\$ 100,000 <sup>(1)</sup>
November 1, 2018 to November 30, 2018 .....	3,475	\$ 2.99	3,475	\$ 89,597
December 1, 2018 to December 31, 2018.....	5,199	\$ 2.91	5,199	\$ 74,465
Total during three months ended December 31, 2018.....	8,674	\$ 2.94	8,674	\$ 74,465

<sup>(1)</sup> On September 24, 2018, the Company announced that its board of directors authorized the repurchase of issued and outstanding shares of our common stock having an aggregate value of up to \$100.0 million pursuant to a share repurchase program. Repurchases under the new share repurchase program will be made from time to time in the open market or in privately negotiated transactions and funded from our working capital. The amount and timing of such repurchases will depend upon the price and availability of shares, general market conditions and the availability of cash. Repurchases may also be made under a trading plan under Rule 10b5-1, which would permit shares to be repurchased when the Company might otherwise be precluded from doing so because of self-imposed trading blackout periods or other regulatory restrictions. All shares of common stock repurchased under the Company's new share repurchase program are expected to be retired and restored to authorized but unissued shares of common stock. This repurchase program may be suspended or discontinued at any time without notice.

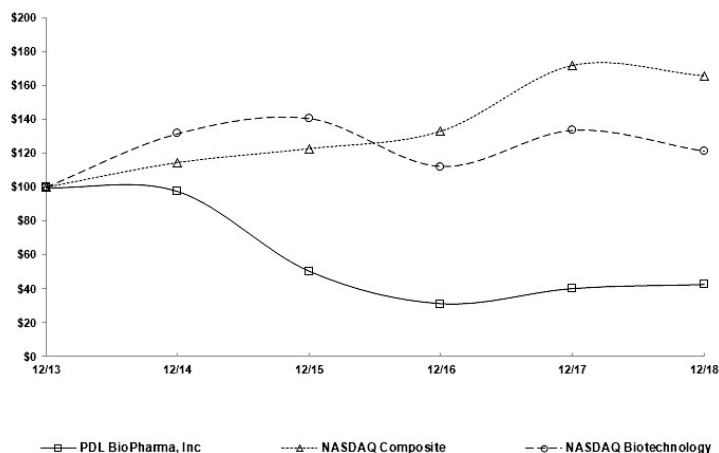
#### Comparison of Stockholder Returns

The line graph below compares the cumulative total stockholder return on our common stock between December 31, 2013, and December 31, 2018, with the cumulative total return of (i) the Nasdaq Biotechnology Index and (ii) the Nasdaq Composite Index over the same period. This graph assumes that \$100.00 was invested on December 31, 2013, in our common stock at the closing sales price for our common stock on that date and at the closing sales price for each index on that date and that all dividends were reinvested. Stockholder returns over the indicated period should not be considered indicative of future stockholder returns and are



not intended to be a forecast.

**COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN\***  
 Among PDL BioPharma, Inc. the NASDAQ Composite Index  
 and the NASDAQ Biotechnology Index



\*\$100 invested on 12/31/13 in stock or index, including reinvestment of dividends.  
 Fiscal year ending December 31.

	12/31/2013	12/31/2014	12/31/2015	12/31/2016	12/31/2017	12/31/2018
PDL BioPharma, Inc.....	\$ 100.00	\$ 97.68	\$ 50.20	\$ 30.98	\$ 40.04	\$ 42.38
Nasdaq Biotechnology Index .....	\$ 100.00	\$ 131.71	\$ 140.56	\$ 112.25	\$ 133.67	\$ 121.24
Nasdaq Composite Index.....	\$ 100.00	\$ 114.62	\$ 122.81	\$ 133.19	\$ 172.11	\$ 165.84

The information in this section shall not be deemed to be “soliciting material” or to be “filed” with the SEC, nor shall such information be incorporated by reference into any future filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except to the extent that we specifically incorporate it by reference in such filing.

**ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA**

The following selected consolidated financial information has been derived from our consolidated financial statements. The information below is not necessarily indicative of the results of future operations and should be read in conjunction with Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” Item 1A, “Risk Factors” and the consolidated financial statements and related notes thereto included in Item 8, “Financial Statements and Supplementary Data” in order to fully understand factors that may affect the comparability of the information presented below.

**Consolidated Statements of Operations Data**

<i>(in thousands, except per share data)</i>	<b>For the Years Ended December 31,</b>				
	<b>2018</b>	<b>2017</b>	<b>2016</b>	<b>2015</b>	<b>2014</b>
Revenues:					
Royalties from Queen et al. patents.....	\$ 4,536	\$ 36,415	\$ 166,158	\$ 485,156	\$ 486,888
Royalty rights - change in fair value .....	85,256	162,327	16,196	68,367	45,742
Interest revenue .....	2,337	17,744	30,404	36,202	48,020
Product revenue, net .....	105,448	84,123	31,669	—	—
License and other.....	533	19,451	(126)	723	575
Total revenues .....	<u>198,110</u>	<u>320,060</u>	<u>244,301</u>	<u>590,448</u>	<u>581,225</u>

<i>(in thousands, except per share data)</i>	<b>For the Years Ended December 31,</b>				
	<b>2018</b>	<b>2017</b>	<b>2016</b>	<b>2015</b>	<b>2014</b>
Operating expenses:					
Cost of product revenue, (excluding amortization and impairment of intangible assets).....	48,460	30,537	4,065	—	—
Amortization of intangible assets .....	15,831	24,689	12,028	—	—
General and administrative expenses .....	45,420	45,641	39,790	36,090	34,914
Sales and marketing.....	17,139	17,683	538	—	—
Research and development.....	2,955	7,381	3,820	—	—
Impairment of intangible assets.....	152,330	—	—	—	—
Asset impairment loss.....	8,200	—	3,735	—	—
Acquisition-related costs .....	—	—	3,564	—	—
Loss on extinguishment of notes receivable.....	—	—	51,075	3,979	—
Change in fair value of anniversary payment and contingent consideration.....	(41,631)	349	(3,716)	—	—
Total operating expenses.....	<u>248,704</u>	<u>126,280</u>	<u>114,899</u>	<u>40,069</u>	<u>34,914</u>
Operating (loss) income .....	<u>(50,594)</u>	<u>193,780</u>	<u>129,402</u>	<u>550,379</u>	<u>546,311</u>
Non-operating expense, net:					
Gain on bargain purchase .....	—	9,309	—	—	—
Other non-operating expense, net.....	(5,328)	(18,562)	(20,032)	(20,241)	(45,039)
Non-operating expense, net .....	<u>(5,328)</u>	<u>(9,253)</u>	<u>(20,032)</u>	<u>(20,241)</u>	<u>(45,039)</u>
(Loss) income before income taxes.....	(55,922)	184,527	109,370	530,138	501,272
Income tax expense .....	12,937	73,826	45,711	197,343	179,028
Net (loss) income .....	<u>(68,859)</u>	<u>110,701</u>	<u>63,659</u>	<u>332,795</u>	<u>322,244</u>
Less: Net (loss) income attributable to noncontrolling interests	—	(47)	53	—	—
Net (loss) income attributable to PDL's stockholders.....	<u>\$ (68,859)</u>	<u>\$ 110,748</u>	<u>\$ 63,606</u>	<u>\$ 332,795</u>	<u>\$ 322,244</u>
Net (loss) income per basic share:					
Net (loss) income.....	\$ (0.47)	\$ 0.71	\$ 0.39	\$ 2.04	\$ 2.04
Net (loss) income per diluted share:					
Net (loss) income.....	\$ (0.47)	\$ 0.71	\$ 0.39	\$ 2.03	\$ 1.86
Dividends per share:					
Cash dividends declared and paid .....	\$ —	\$ —	\$ 0.10	\$ 0.60	\$ 0.60

### Consolidated Balance Sheet Data

<i>(in thousands)</i>	<b>December 31,</b>				
	<b>2018</b>	<b>2017</b>	<b>2016</b>	<b>2015</b>	<b>2014</b>
Cash, cash equivalents, short-term investments and restricted investments.....	\$ 394,590	\$ 532,114	\$ 242,141	\$ 220,352	\$ 293,687
Working capital .....	\$ 464,747	\$ 447,334	\$ 267,716	\$ 245,969	\$ 167,914
Total assets .....	\$ 963,736	\$ 1,243,123	\$ 1,215,387	\$ 1,012,205	\$ 954,946
Long-term obligations, less current portion .....	\$ 181,487	\$ 204,124	\$ 329,649	\$ 279,512	\$ 306,977
Retained earnings .....	\$ 828,547	\$ 945,614	\$ 857,116	\$ 810,036	\$ 575,740
Total stockholders' equity .....	\$ 729,779	\$ 845,890	\$ 755,423	\$ 695,952	\$ 460,437

## 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 “Selected Consolidated Financial Data” and the Consolidated Financial Statements and related Notes included elsewhere in this Report.

### Overview

We seek to provide a significant return for our stockholders by acquiring commercial stage pharmaceutical assets with multiple year revenue growth potential as well as late clinical stage pharmaceutical products. Our leadership team has extensive experience in acquiring, commercializing and managing the life cycle of therapeutic products domestically and internationally across a number of indications and modalities. We intend to leverage this experience by pursuing the acquisition, growth and potential monetization of pharmaceutical products and companies.

Historically, we generated a substantial portion of our revenues through the license agreements related to patents covering the humanization of antibodies, which we refer to as the Queen et al. patents. In 2012, we began providing alternative sources of capital through royalty monetizations and debt facilities, and, in 2016, we began acquiring commercial-stage products and launching specialized companies dedicated to the commercialization of these products. To date, we have consummated seventeen such transactions, the following ten of which are active and outstanding:

Investment	Investment Type	Segment	Deployed Capital <sup>5</sup> (in millions)
Noden <sup>1</sup> .....	Equity and loan	Pharmaceutical	\$ 191.2
LENSAR, Inc. (“LENSAR”).....	Converted equity and loan	Medical Devices	\$ 47.0
CareView Communications, Inc. (“CareView”).....	Debt	Income Generating Assets	\$ 20.0
Direct Flow Medical, Inc. (“DFM”) <sup>2</sup> .....	Debt	Income Generating Assets	\$ 59.0
Wellstat Diagnostics <sup>3</sup> .....	Royalty/debt hybrid	Income Generating Assets	\$ 44.0
Assertio <sup>4</sup> .....	Royalty	Income Generating Assets	\$ 260.5
The Regents of the University of Michigan (“U-M”) .....	Royalty	Income Generating Assets	\$ 65.6
AcelRx Pharmaceuticals, Inc. (“AcelRx”).....	Royalty	Income Generating Assets	\$ 65.0
Viscogliosi Brothers, LLC (“VB”).....	Royalty	Income Generating Assets	\$ 15.5
KYBELLA <sup>®</sup> .....	Royalty	Income Generating Assets	\$ 9.5

<sup>1</sup> Noden Pharma DAC and Noden Pharma USA, Inc. (together, and including their respective subsidiaries, “Noden”).

<sup>2</sup> DFM ceased operations in December 2016 and we subsequently foreclosed upon and obtained most of the assets of DFM and impaired them by \$51.1 million. Since taking over the DFM assets, we have collected \$8.7 million in cash and, as of December 31, 2018 an intangible asset with a carrying value of \$1.6 million remains on our books. For further detail see Note 9, *Notes and Other Long-term Receivables*, and Note 13, *Intangible Assets*, to the Consolidated Financial Statements included in Item 8.

<sup>3</sup> Wellstat Diagnostics, LLC (also known as Defined Diagnostic, LLC) (“Wellstat Diagnostics”).

<sup>4</sup> Assertio Therapeutics, Inc., formerly Depomed, Inc. Hereafter referred to as “Assertio”.

<sup>5</sup> Excludes transaction costs.

Based on the composition of our existing investment portfolio, we currently operate in three segments designated as Pharmaceutical, Medical Devices and Income Generating Assets.

Our Pharmaceutical segment consists of revenue derived from branded prescription medicine products sold under the name Tekturna<sup>®</sup> and Tekturna HCT<sup>®</sup> in the United States, and Rasilez<sup>®</sup> and Rasilez HCT<sup>®</sup> in the rest of the world (collectively, the “Noden Products”). Our Medical Devices segment consists of revenue derived from the LENSAR<sup>®</sup> Laser System sales. Our Income Generating Assets segment consists of revenue derived from (i) notes and other long-term receivables, (ii) royalty rights

and hybrid notes/royalty receivables, (iii) equity investments and (iv) royalties from issued patents in the United States and elsewhere covering the humanization of antibodies, which we refer to as the Queen et al. patents.

Prospectively, we expect to focus on the acquisition of additional pharmaceutical products and companies. We anticipate that over time more of our revenues will come from our Pharmaceutical and Medical Devices segments and less of our revenues will come from our Income Generating Assets segment. We will remain opportunistic looking for later stage products and companies with which to invest with growing revenues and the potential for value creation for our shareholders.

### **Critical Accounting Policies and Significant Estimates**

The preparation of financial statements and related disclosures in conformity with U.S. Generally Accepted Accounting Principles (“GAAP”) and the discussion and analysis of our financial condition and operating results require our management to make judgments, assumptions and estimates that affect the amounts reported in its consolidated financial statements and accompanying notes. Note 2, *Summary of Significant Accounting Policies*, to the Consolidated Financial Statements included in Item 8 describes the significant accounting policies and methods used in the preparation of our consolidated financial statements. Management bases its estimates on historical experience and on various other assumptions it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates and such differences may be material.

While our significant accounting policies are more fully described in the notes to our Consolidated Financial Statements appearing elsewhere in this Annual Report, management believes that the following accounting policies related to notes receivable and other long-term receivables, inventory, intangible assets, convertible notes, product revenue, royalty rights - at fair value, income taxes, and business combination are critical because they are both important to the portrayal of our financial condition and operating results, and they require management to make judgments and estimates about inherently uncertain matters.

#### ***Notes Receivable and Other Long-Term Receivables***

We account for our notes receivable at amortized cost, net of unamortized origination fees, if any, and adjusted for any impairment losses. Interest is accreted or accrued to “Interest revenue” using the effective interest method. When and if supplemental payments are received from certain of these notes and other long-term receivables, an adjustment to the estimated effective interest rate is affected prospectively.

We evaluate the collectability of both interest and principal for each note receivable or loan to determine whether it is impaired. A note receivable or loan is considered to be impaired when, based on current information and events, we determine it is probable that it will be unable to collect amounts due according to the existing contractual terms. When a note receivable or loan is considered to be impaired, the amount of loss is calculated by comparing the carrying value of the financial asset to the value determined by discounting the expected future cash flows at the loan’s effective interest rate or to the estimated fair value of the underlying collateral, less costs to sell, if the loan is collateralized and we expect repayment to be provided solely by the collateral. Impairment assessments require significant judgments and are based on significant assumptions related to the borrower’s credit risk, financial performance, expected sales, and estimated fair value of the collateral.

We record interest on an accrual basis and recognize it as earned in accordance with the contractual terms of the applicable credit agreement, to the extent that the underlying note receivable or loan is not impaired and such amounts are expected to be collected. When a note receivable or loan becomes past due, or if management otherwise does not expect that principal, interest, and other obligations due will be collected in full, we will generally place the note receivable or loan on an impaired status and cease recognizing interest income on that note receivable or loan until all principal and interest due has been paid or until such time that we believe the borrower has demonstrated the ability to repay its current and future contractual obligations. Any uncollected interest related to prior periods is reversed from income in the period that collection of the interest receivable is determined to be doubtful. However, we may make exceptions to this policy if the investment has sufficient collateral value and is in the process of collection.

As of December 31, 2018, we had three notes receivable investments which we determined to be impaired with a cumulative investment cost and fair value of approximately \$62.8 million and \$70.0 million, respectively, compared to three note receivable investments which we determined to be impaired as of December 31, 2017 with a cumulative investment cost and fair value of approximately \$70.7 million and \$71.3 million, respectively. We did not recognize any losses on extinguishment of notes receivable during the years ended December 31, 2018 and 2017. During the year ended December 31, 2016, we recognized a loss on extinguishment of notes of \$51.1 million. During the year ended December 31, 2018, we recorded an impairment loss of \$8.2

million related to the CareView note receivable. There were no impairment losses on notes receivable for the years ended December 31, 2017 and 2016. For the years ended December 31, 2018 and 2017, we recognized \$2.3 million and \$3.1 million, respectively, of interest revenue for the CareView note receivable investment as result of cash interest payments made during the respective fiscal years. For the year ended December 31, 2016, we did not recognize any interest income for note receivable investments on an impaired status.

### ***Inventory***

Inventory, which consists of raw material, work-in-process and finished goods, is stated at the lower of cost or market value. We determine cost using the first-in, first-out method. Inventory levels are analyzed periodically and written down to their net realizable value if they have become obsolete, have a cost basis in excess of its expected net realizable value or are in excess of expected requirements. During the year ended December 31, 2018 we recognized a reduction in the inventory reserve of \$1.2 million. During the years ended December 31, 2017 and 2016, we recognized inventory write-downs of approximately \$2.0 million and \$0.3 million, respectively.

### ***Intangible Assets***

Intangible assets with finite useful lives consist primarily of acquired product rights and acquired technology and are amortized on a straight-line basis over their estimated useful lives (eight to 15 years). The estimated useful lives associated with finite-lived intangible assets are consistent with the estimated lives of the associated products and may be modified when circumstances warrant. Such assets are reviewed for impairment when events or circumstances indicate that the carrying value of an asset may not be recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset and its eventual disposition are less than its carrying amount. The amount of any impairment is measured as the difference between the carrying amount and the fair value of the impaired asset.

In June 2018, a settlement agreement with Anchen was reached that granted Anchen a nonexclusive royalty-free license to manufacture and commercialize a generic version of aliskiren in the United States. In return, Anchen agreed not to commercialize its generic version of aliskiren prior to March 1, 2019. As a result of this settlement agreement we performed an impairment assessment of our Noden asset group and concluded that the sum of undiscounted cash flows was not greater than the carrying value of the assets. Therefore, we performed a discounted cash flow analysis to estimate the fair value of the asset group in accordance with Accounting Standard Codification (“ASC”) Topic 360, Impairment or Disposal of Long-lived Assets, resulting in an impairment charge of \$152.3 million in the second quarter of 2018.

On March 4, 2019, we announced the U.S. commercial launch of an authorized generic of Tekturna, with the same drug formulation as Tekturna. We performed an impairment assessment of our Noden asset group at this time by estimating the undiscounted future cash flows with respect to the asset against its carrying value and concluded a further impairment was not required.

Future events, such as FDA approval of a third-party generic version of aliskiren or publicly announced plans of a launch of a generic version of aliskiren, may be further indicators of impairment which may require us to perform additional impairment testing.

### ***Convertible Notes***

We perform an assessment of all embedded features of a debt instrument to determine if (i) such features should be bifurcated and separately accounted for, and (ii) if bifurcation requirements are met, whether such features should be classified and accounted for as equity or debt instruments. If the embedded feature meets the requirements to be bifurcated and accounted for as a liability, the fair value of the embedded feature is measured initially, included as a liability on the Consolidated Balance Sheets, and re-measured to fair value at each reporting period. Any changes in fair value are recorded in the Consolidated Statement of Operations. We monitor, on an ongoing basis, whether events or circumstances could give rise to a change in our classification of embedded features.

We issued the February 2018 Notes with a net share settlement feature, meaning that upon any conversion, the principal amount will be settled in cash and the remaining amount, if any, will be settled in shares of our common stock. We issued the December 2021 Notes with an option to settle conversions by paying or delivering, as applicable, cash, shares of our common stock or a combination of cash and shares of our common stock, at our election. In accordance with accounting guidance for convertible debt instruments that may be settled in cash or other assets on conversion, we separated the principal balance between the fair

value of the liability component and the common stock conversion feature using a market interest rate for a similar nonconvertible instrument at the date of issuance.

The fair value of the liability component of the December 2021 Notes was estimated at \$109.1 million at issuance. Therefore, the difference between the face value of the December 2021 Notes at issuance and the estimated fair value of the liability component will be amortized to interest expense over the term of the December 2021 Notes using the effective interest method.

The estimated fair value of the liability components at the date of issuance for the February 2018 Notes and December 2021 Notes were determined using valuation models and are complex and subject to judgment. Significant assumptions within the valuation models included an implied credit spread, the expected volatility and dividend yield of our common stock and the risk-free interest rate for notes with a similar term.

On February 1, 2018, upon maturity of the February 2018 Notes, the Company repaid the remaining principal and accrued interest in cash and the February 2018 Notes were retired.

## ***Product Revenue***

### *General*

In accordance with ASC 606, revenue is recognized from the sale of products and services when a customer obtains control of such promised products and services. The amount of revenue recognized reflects the consideration to which the Company expects to be entitled to receive in exchange for these products and services. A five-step model is utilized to achieve the core principle and includes the following steps: (1) identify the customer contract; (2) identify the contract's performance obligations; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations; and (5) recognize revenue when the performance obligations are satisfied.

The following is a description of principal activities - separated by reportable segments - from which we generate our revenue.

### ***Pharmaceutical***

We principally generate revenue in our Pharmaceutical segment from products sold to wholesalers and distributors. Customer orders are generally fulfilled within a few days of receipt resulting in minimal order backlog. Contractual performance obligations are usually limited to transfer of the product to the customer. The transfer occurs either upon shipment or upon receipt of the product in certain countries outside the United States after considering when the customer obtains control of the product. In addition, for some non-U.S. countries, we sell product on a consignment basis where control is not transferred until the customer resells the product to an end user. At these points, customers are able to direct the use of and obtain substantially all of the remaining benefits of the product.

Sales to customers are initially invoiced at contractual list prices. Payment terms are typically 30 to 90 days based on customary practice in each country. Revenue is reduced from the list price at the time of recognition for expected chargebacks, discounts, rebates, sales allowances and product returns, which are referred to as gross-to-net adjustments. These reductions are attributed to various commercial agreements, managed healthcare organizations and government programs such as Medicare, Medicaid, and the 340B Drug Pricing Program containing various pricing implications such as mandatory discounts, pricing protection below wholesaler list price and other discounts when Medicare Part D beneficiaries are in the coverage gap. These various reductions in the transaction price have been estimated using either a most likely amount, in the case of prompt pay discounts, or expected value method for all other variable consideration and have been reflected as liabilities and are settled through cash payments, typically within time periods ranging from a few months to one year. Significant judgment is required in estimating gross-to-net adjustments considering legal interpretations of applicable laws and regulations, historical experience, payer channel mix, current contract prices under applicable programs, unbilled claims, processing time lags and inventory levels in the distribution channel.

Reserves for chargebacks, discounts, rebates, sales allowances and product returns are included within current liabilities in our Consolidated Balance Sheets.

For the period from July 1, 2016 through October 4, 2016, all of the Noden Products were distributed by Novartis under the terms of the Noden Purchase Agreement while transfer of the marketing authorization rights were pending. We present revenue under the Novartis transition arrangement on a "net" basis and established a reserve for retroactive adjustment to the profit split with Novartis.

Beginning on October 5, 2016, Noden Pharma USA, Inc. distributed the Noden Products in the United States. We presented revenue for all sales in the United States on a “gross” basis and established a reserve for allowances.

For the period from October 5, 2016 to August 31, 2017, Novartis continued to distribute the Noden products outside of the United States. Beginning on September 1, 2017, Noden Pharma DAC began distributing the Noden Products to select countries outside the United States. We present revenue for Noden Products sold by Novartis outside of the United States on a “net” basis. As of the third quarter of 2018, Noden Pharma DAC completed the MA transfers for all territories.

### ***Medical Devices***

We principally generate revenue in our Medical Devices segment from the sale and lease of the LENSAR<sup>®</sup> Laser System, which may include equipment, Patient Interface Devices (“PIDs”), procedure licenses, and training, installation, warranty and maintenance agreements.

For bundled packages, we account for individual products and services separately if they are distinct - i.e. if a product or service is separately identifiable from other promises in the bundled package and if the customer can benefit from it on its own or with other resources that are readily available to the customer. The LENSAR<sup>®</sup> Laser system, training and installation services are one performance obligation. All other elements are separate performance obligations. PIDs, procedure licenses, warranty and maintenance services are also sold on a stand-alone basis.

As we both sell and lease the LENSAR<sup>®</sup> Laser System, the consideration (including any discounts) is first allocated between lease and non-lease components and then allocated between the separate products and services based on their stand-alone selling prices. The stand-alone selling prices for the PIDs and procedure licenses are determined based on the prices at which we separately sell the PIDs and procedure licenses. The LENSAR<sup>®</sup> Laser System and warranty stand-alone selling prices are determined using the expected cost plus a margin approach.

For LENSAR<sup>®</sup> Laser System sales, we recognize revenue in product revenue when a customer takes possession of the system. This usually occurs after the customer signs a contract, LENSAR installs the system, and LENSAR performs the requisite training for use of the system. For LENSAR<sup>®</sup> Laser System leases, we recognize revenue in product revenue over the length of the lease in accordance with ASC Topic 840, *Leases*.

The LENSAR<sup>®</sup> Laser System requires both a consumable, a PID, and a procedure license to perform each procedure. We recognize revenue for PIDs in product revenue when the customer takes possession of the PID. PIDs are sold by the case. We recognize revenue for procedure licenses in product revenue when a customer purchases a procedure license from the web portal. Typically, consideration for PIDs and procedure licenses is considered fixed consideration except for certain customer agreements that provide for tiered volume discount pricing which is considered variable consideration.

We offer an extended warranty that provides additional services beyond the standard warranty. We recognize revenue from the sale of extended warranties in product revenue over the warranty period. Customers have the option of renewing the warranty period, which is considered a new and separate contract.

### ***Income Generating Assets***

#### ***Royalty Rights - At Fair Value***

Currently, we account for our investments in royalty rights at fair value with changes in fair value presented in earnings. The fair value of the investments in royalty rights is determined by using a discounted cash flow analysis related to the expected future cash flows to be received. These assets are classified as Level 3 assets within the fair value hierarchy, as our valuation estimates utilize significant unobservable inputs, including estimates as to the probability and timing of future sales of the related products. Transaction-related fees and costs are expensed as incurred.

The changes in the estimated fair value from investments in royalty rights along with cash receipts in each reporting period are presented together on our Consolidated Statements of Operations as a component of revenue under the caption, “Royalty rights - change in fair value.”

Realized gains and losses on Royalty Rights are recognized as they are earned and when collection is reasonably assured. Royalty Rights revenue is recognized over the respective contractual arrangement period. Critical estimates may include product demand and market growth assumptions, inventory target levels, product approval and pricing assumptions. Factors that could cause a

change in estimates of future cash flows include a change in estimated market size, market share of the products on which we receive royalties, a change in pricing strategy or reimbursement coverage, a delay in obtaining regulatory approval, changes to forecast volume and pricing as a result of generic competition, a change in dosage of the product, and a change in the number of treatments. For each arrangement, we are entitled to royalty payments based on revenue generated by the net sales of the product.

### ***Income Taxes***

The provision for income taxes is determined using the asset and liability approach. Tax laws require items to be included in tax filings at different times than the items are reflected in the financial statements. A current liability is recognized for the estimated taxes payable for the current year. Deferred taxes represent the future tax consequences expected to occur when the reported amounts of assets and liabilities are recovered or paid. Deferred taxes are adjusted for enacted changes in tax rates and tax laws. Valuation allowances are recorded to reduce deferred tax assets when it is more likely than not that a tax benefit will not be realized.

We recognize tax benefits from uncertain tax positions only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the financial statements from such positions are then measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement. We adjust the level of the liability to reflect any subsequent changes in the relevant facts surrounding the uncertain positions. Any interest and penalties on uncertain tax positions are included within the tax provision.

The Tax Cuts and Jobs Act of 2017 (the "2017 Tax Act") significantly changed the existing U.S. corporate income tax laws by, among other things, lowering the corporate tax rate (from a top rate of 35% to a flat rate of 21%), implementing elements of a territorial tax system, and imposing a one-time deemed repatriation transition tax on cumulative undistributed foreign earnings, for which we have not previously paid U.S. taxes. Due to the complexities involved in accounting for the 2017 Tax Act, the SEC staff issued Staff Accounting Bulletin No. 118 ("SAB 118") to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Act. SAB 118 provided a measurement period of up to one year after the enactment date of the 2017 Tax Act to finalize the recording of the related tax impacts.

Our accounting for the following elements of the 2017 Tax Act is complete:

- *Change in federal corporate tax rate from a top rate of 35% to a flat rate of 21% ("Rate Adjustment")*: The December 31, 2017 provisional estimate and December 31, 2018 additional measurement-period adjustment related to the Rate Adjustment on our deferred tax assets and liabilities impacted our income tax rate by less than 1% for each of the years ended December 31, 2017 and 2018.
- *Global intangible low-taxed income ("GILTI")*: We did not recognize any GILTI for the year ended December 31, 2017. No provisional estimate or additional measurement-period adjustments were recorded for the years ended December 31, 2017 and 2018. We have made a policy election with respect to our treatment of potential GILTI to account for taxes on GILTI as a current-period expense as incurred.
- *Foreign-derived intangible income ("FDII")*: We did not recognize any FDII benefit for the year ended December 31, 2017. No provisional estimate or additional measurement-period adjustments were recorded for the years ended December 31, 2017 and 2018.
- *Deemed repatriation transition tax ("Transition Tax")*: The December 31, 2017 provisional estimate and December 31, 2018 additional measurement-period adjustment to the Transition Tax obligation impacted our income tax rate by less than 1% for each of the years ended December 31, 2017 and 2018.
- *Base-erosion and anti-abuse tax ("BEAT")*: We did not recognize any BEAT obligation for the year ended December 31, 2017. No provisional estimate or additional measurement-period adjustments were recorded for the years ended December 31, 2017 and 2018.

### ***Business Combination***

We apply ASC 805, *Business combinations*, pursuant to which the cost of an acquisition is measured as the aggregate of the fair values at the date of exchange of the assets given, liabilities incurred, and equity instruments issued. The costs directly attributable to the acquisition are expensed as incurred. Identifiable assets, liabilities and contingent liabilities acquired or assumed are measured separately at their fair value as of the acquisition date, irrespective of the extent of any noncontrolling interests. The excess of the (i) the total of cost of acquisition, fair value of the noncontrolling interests and acquisition date fair value of any



previously held equity interest in the acquiree over (ii) the fair value of the identifiable net assets of the acquiree is recorded as goodwill. If the cost of acquisition is less than the fair value of the net assets of the subsidiary acquired, the difference is recognized directly in the Consolidated Statements of Operations.

The determination and allocation of fair values to the identifiable assets acquired and liabilities assumed is based on various assumptions and valuation methodologies requiring considerable management judgment. The most significant variables in these valuations are discount rates, terminal values, the number of years on which to base the cash flow projections, as well as the assumptions and estimates used to determine the cash inflows and outflows. Management determines discount rates to be used based on the risk inherent in the related activity's current business model and industry comparisons. Terminal values are based on the expected life of products and forecasted life cycle and forecasted cash flows over that period. Although management believes that the assumptions applied in the determination are reasonable based on information available at the date of acquisition, actual results may differ from the forecasted amounts and the difference could be material.

## **Recent Developments**

### *Share Repurchase*

From January 1, 2019 to March 13, 2019, we repurchased approximately 10.7 million shares of our common stock at a weighted-average price of \$3.32 per share for a total of \$35.5 million. The total amounts repurchased by us under the \$100.0 million share repurchase program authorized by the Company's board of directors equal approximately 19.4 million shares of its common stock for an aggregate purchase price of \$61.0 million, or an average cost of \$3.15 per share, including trading commissions.

### *CareView Modification Agreement*

As further discussed in Note 9, *Notes and Other Long-Term Receivables*, to the Consolidated Financial Statements included in Item 8, the first principal payment and the scheduled interest payment due December 31, 2018 that were previously deferred until January 31, 2019 were subsequently deferred until March 31, 2019 under additional amendments.

### *Authorized Generic*

As further discussed in Note 13, *Intangible Assets*, to the Consolidated Financial Statements included in Item 8, on March 4, 2019, we announced the U.S. commercial launch of an authorized generic of Tekturna, with the same drug formulation as Tekturna.

## **Summary of 2018, 2017 and 2016 Financial Results**

- Our net (loss) income for the years ended December 31, 2018, 2017 and 2016 was \$(68.9) million, \$110.7 million and \$63.6 million, respectively;
- At December 31, 2018, we had cash, cash equivalents and short-term investments of \$394.6 million as compared with \$532.1 million at December 31, 2017;
- At December 31, 2018, we had \$963.7 million in total assets as compared with \$1,243.1 million at December 31, 2017; and
- At December 31, 2018, we had \$234.0 million in total liabilities as compared with \$397.2 million at December 31, 2017.

## Revenues

A summary of our revenues for the years ended December 31, 2018, 2017 and 2016, is presented below:

<i>(Dollars in thousands)</i>	2018	2017	Change from Prior Year %	2016	Change from Prior Year %
Revenues:					
Royalties from Queen et al. patents.....	\$ 4,536	\$ 36,415	(88)%	\$ 166,158	(78)%
Royalty rights - change in fair value .....	85,256	162,327	(47)%	16,196	902 %
Interest revenue .....	2,337	17,744	(87)%	30,404	(42)%
Product revenue, net .....	105,448	84,123	25 %	31,669	166 %
License and other .....	533	19,451	(97)%	(126)	N/M
Total revenues .....	<u>\$ 198,110</u>	<u>\$ 320,060</u>	(38)%	<u>\$ 244,301</u>	31 %

*N/M = Not meaningful*

Total revenues were \$198.1 million, \$320.1 million and \$244.3 million for the years ended December 31, 2018, 2017 and 2016, respectively.

*For the year ended December 31, 2018, compared to December 31, 2017*

Our total revenues decreased by 38%, or \$122.0 million, for the year ended December 31, 2018, when compared to the year ended December 31, 2017. The decrease was primarily due to:

- a larger increase in the estimated fair value of the Assertio royalty asset recognized in Royalty rights - change in fair value revenues in 2017 than in 2018,
- lower 2018 sales of Tysabri manufactured prior to the patent expiry date reflected in Royalties from Queen et al. patents,
- decreased interest revenues due to the sale of the kaléo note receivable asset in 2017 presented in Interest revenue,
- a payment in 2017 from Merck recognized in License and other revenues as part of the previously announced settlement agreement to resolve the patent infringement lawsuits related to Keytruda® (the “Merck settlement payment”), partially offset by
- an increase in product revenues derived from sales of the Noden Products and sales of the LENSAR® Laser System.

Revenue from our Pharmaceutical segment for the year ended December 31, 2018 was \$80.8 million, an increase of 17% when compared to the same period in 2017. All revenues from our Pharmaceutical segment were derived from sales of the Noden Products. We acquired the exclusive worldwide rights to manufacture, market, and sell the Noden Products from Novartis on July 1, 2016. Novartis remained the primary obligor for ex-U.S. sales for most of 2017. As a result, the majority of ex-U.S. revenue was presented on a “net” basis in 2017 while being presented “gross” in 2018.

We record revenue net of estimated product returns, pricing discounts, including rebates offered pursuant to mandatory federal and state government programs, chargebacks, prompt pay discounts, distribution fees and co-pay assistance for product sales each period.

The following table provides a summary of activity with respect to our sales allowances and accruals for the year ended December 31, 2018:

<i>(in thousands)</i>	Discount and Distribution Fees	Government Rebates and Chargebacks	Assistance and Other Discounts	Product Return	Total
Balance at January 1, 2018.....	\$ 3,422	\$ 8,709	\$ 4,178	\$ 3,304	\$ 19,613
Allowances for current period sales .....	9,403	18,583	8,206	2,367	38,559
Allowances for prior period sales.....	—	38	—	61	99
Credits/payments for current period sales .....	(6,313)	(10,045)	(4,963)	—	(21,321)
Credits/payments for prior period sales.....	(3,418)	(8,384)	(3,964)	(1,051)	(16,817)
Balance at December 31, 2018.....	<u>\$ 3,094</u>	<u>\$ 8,901</u>	<u>\$ 3,457</u>	<u>\$ 4,681</u>	<u>\$ 20,133</u>

Revenue from our Medical Devices segment for the year ended December 31, 2018 was \$24.7 million, an increase of 63% compared to the year ended December 31, 2017. The increase is attributable to a full year of revenue recognized in 2018 as compared to a partial year in 2017. Revenue from LENSAR product sales include LENSAR® Laser Systems, disposable consumables, procedures, training, installation, warranty and maintenance services.

Revenue from our Income Generating Assets segment for the year ended December 31, 2018 was \$92.7 million, a decrease of 61%, or \$143.3 million, when compared to the same period in 2017. The decrease was due to a larger increase in the estimated fair value of the Assertio royalty asset in 2017, decreasing royalties from the Queen et al. patents as sales of Tysabri manufactured prior to patent expiry, decreased interest revenue due to the sale of the kaléo note in 2017 and as a result of the Merck settlement that occurred in 2017.

The following tables provides a summary of activity with respect to our royalty rights - change in fair value for the year ended December 31, 2018:

<i>(in thousands)</i>	<b>Cash Royalties</b>	<b>Change in Fair Value</b>	<b>Total</b>
Assertio (formerly Depomed).....	\$ 71,502	\$ 12,333	\$ 83,835
VB.....	1,062	(272)	790
U-M.....	4,631	(1,174)	3,457
AcelRx.....	249	(2,514)	(2,265)
Avinger.....	366	(396)	(30)
KYBELLA.....	159	(690)	(531)
	<u>\$ 77,969</u>	<u>\$ 7,287</u>	<u>\$ 85,256</u>

The following table summarizes the percentage of our total revenues earned, which individually accounted for 10% or more of our total revenues for the years ended December 31, 2018, 2017 and 2016:

<b>Licensee</b>	<b>Product Name</b>	<b>Year Ended December 31,</b>		
		<b>2018</b>	<b>2017</b>	<b>2016</b>
Genentech.....	<i>Avastin</i> .....	—%	—%	16%
	<i>Herceptin</i> .....	—%	—%	16%
Biogen.....	<i>Tysabri</i> .....	2%	11%	24%
Assertio.....	<i>Glumetza, Janumet XR, Jentaduo XR, Invokamet XR and Synjardy XR</i> .....	42%	52%	13%
LENSAR.....	<i>Laser System</i> .....	12%	5%	—%
Noden.....	<i>Tekturna, Tekturna HCT, Rasilez and Rasilez HCT</i> .....	41%	22%	13%

Foreign currency exchange rates also impact our reported revenues from royalty assets and product sales. Our revenues may fluctuate due to changes in foreign currency exchange rates and are subject to foreign currency exchange risk. While foreign currency conversion terms vary by license agreement, generally most agreements require that royalties first be calculated in the currency of sale and then converted into U.S. dollars using the average daily exchange rates for that currency for a specified period at the end of the calendar quarter. Accordingly, when the U.S. dollar weakens against other currencies, the converted amount is greater than it would have been had the U.S. dollar not weakened. In addition, our Noden Product sales in markets outside the United States are typically denominated in foreign currencies and can cause fluctuations in our reported revenue from period to period. The impact of changes in foreign currency exchange rates to our reported revenue was insignificant for the year ended December 31, 2018.

For the year ended December 31, 2017, compared to December 31, 2016

Our total revenues increased by 31%, or \$75.8 million, for the year ended December 31, 2017, when compared to the same period of 2016. The increase was primarily due to:

- the increase in estimated fair value of the Assertio royalty asset recognized in 2017 Royalty rights - change in fair value revenues as compared to 2016,
- higher product revenues from the Noden Products and LENSAR in 2017, and
- a one time, lump-sum payment of \$19.5 million in connection with the Merck settlement payment received in 2017 recognized in License and other revenues.

Revenue from our Pharmaceutical segment in 2017 and 2016 were derived exclusively from sales of the Noden Products. Product revenue for the year ended December 31, 2017 was \$69.0 million, an increase of 118% compared to the year ended December 31, 2016, due primarily to having a full year's revenue in 2017 compared to a partial year in 2016. We acquired the exclusive worldwide rights to manufacture, market, and sell the Noden Products from Novartis at the beginning of the third quarter of 2016. Novartis remained the primary obligor through the third quarter of 2016 for sales in the United States and through most of the fourth quarter of 2016 for sales outside of the United States. Therefore, revenue is presented on a "net" basis for the third quarter of 2016 for sales in the United States and on a gross basis for sales in the United States for the fourth quarter of 2016 and for all of 2017. This change partially contributed to increased Product revenue in 2017.

Revenue from our Income Generating Assets segment for the year ended December 31, 2017 was \$235.9 million, an increase of 11%, or \$23.3 million, when compared to the year ended December 31, 2016. The increase was primarily due to:

- increased cash royalty payments, including a one-time settlement payment from Valeant resulting from a royalty audit of Glumetza,
- the increased fair value of the Assertio royalty asset, and
- the Merck settlement payment, partially offset by
- lower royalties from our licensees related to the Queen et al. patents, which expired during the first quarter of 2016, and reduced royalty payments from Tysabri as a result of the product supply having been extinguished in the United States and reduced in other countries during 2017, as well as
- the decrease in interest revenues from the early repayment of the Paradigm Spine, LLC note receivable and the sale of the kaléo, Inc. note receivable.

The following tables provides a summary of activity with respect to our royalty rights - change in fair value for the year ended December 31, 2017:

<i>(in thousands)</i>	<b>Cash Royalties</b>	<b>Change in Fair Value</b>	<b>Total</b>
Assertio.....	\$ 97,644	\$ 67,968	\$ 165,612
VB.....	1,276	(617)	659
U-M.....	3,662	(8,617)	(4,955)
ARIAD.....	3,081	(462)	2,619
AcelRx.....	120	5,411	5,531
Avinger.....	1,220	(1,242)	(22)
KYBELLA.....	250	(7,367)	(7,117)
	<u>\$ 107,253</u>	<u>\$ 55,074</u>	<u>\$ 162,327</u>

For the year ended December 31, 2016, we hedged certain Euro-denominated currency exposures related to our licensees' product sales with Euro forward contracts. We designated foreign currency exchange contracts used to hedge royalty revenues based on underlying Euro-denominated sales as cash flow hedges. The aggregate unrealized gain or loss, net of tax, on the effective portion of the hedge was recorded in stockholders' equity as "Accumulated other comprehensive income (loss)." Gains or losses on cash flow hedges were recognized as an adjustment to royalty revenue in the same period that the hedged transaction impacted earnings. For the year ended December 31, 2016, we recognized income of \$2.8 million in revenues from our Euro forward contracts.

## Operating Expenses

A summary of our operating expenses for the years ended December 31, 2018, 2017 and 2016, is presented below:

<i>(Dollars in thousands)</i>	<b>2018</b>	<b>2017</b>	<b>Change from Prior Year %</b>	<b>2016</b>	<b>Change from Prior Year %</b>
Costs of product revenue (excluding amortization and impairment of intangible assets) .....	\$ 48,460	\$ 30,537	59 %	\$ 4,065	651 %
Amortization of intangible assets .....	15,831	24,689	(36)%	12,028	105 %
General and administrative .....	45,420	45,641	0 %	39,790	15 %
Sales and marketing .....	17,139	17,683	(3)%	538	3,187 %
Research and development .....	2,955	7,381	(60)%	3,820	93 %
Impairment of intangible assets .....	152,330	—	<i>N/M</i>	—	<i>N/M</i>
Asset impairment loss .....	8,200	—	<i>N/M</i>	3,735	<i>N/M</i>
Acquisition-related costs .....	—	—	<i>N/M</i>	3,564	<i>N/M</i>
Loss on extinguishment of notes receivable .....	—	—	<i>N/M</i>	51,075	<i>N/M</i>
Change in fair value of anniversary payment and contingent consideration .....	(41,631)	349	<i>N/M</i>	(3,716)	(109)%
Total operating expenses .....	<u>\$ 248,704</u>	<u>\$ 126,280</u>	97 %	<u>\$ 114,899</u>	10 %
Percentage of total revenues .....	126 %	39%		47 %	

*N/M = Not meaningful*

*For the year ended December 31, 2018, compared to December 31, 2017*

Total operating expenses increased by 97%, or \$122.4 million for the year ended December 31, 2018, when compared to the year ended December 31, 2017. The increase was primarily a result of:

- the impairment of intangible assets related to the Noden Products due to the increased probability of a third-party generic version of aliskiren being launched in the United States,
- an \$8.2 million impairment loss on the CareView note, partially offset by
- the elimination of the contingent liability related to changes in the probabilities of a third-party generic version of aliskiren being launched in the United States,
- lower research and development expenses due to reduce clinical trial expenses related to the pediatric trial for Tekturna, and
- the decrease in the amortization of the related intangible assets as a result of the impairment.

*For the year ended December 31, 2017, compared to December 31, 2016*

Total operating expenses increased by 10%, or \$11.4 million for the year ended December 31, 2017 compared to the year ended December 31, 2016. The increase in operating expenses was a result of the acquisitions in the Pharmaceutical and Medical Devices segments, contributing an additional \$26.5 million of cost of product revenue, \$12.7 million of amortization of intangible assets, \$17.1 million in sales and marketing expenses, and \$3.6 million in research and development costs for the completion of a pediatric trial for Tekturna. General administrative expenses increased by \$5.9 million of which \$7.5 million was related to the Pharmaceutical segment and \$3.2 million was related to the Medical Devices segment, partially offset by decreased \$51.1 million in loss on extinguishment for the Direct Flow Medical notes receivable, decreased professional consulting service expenses, and decreased asset purchase expenses.

General and administrative expenses for the years ended December 31, 2018, 2017 and 2016 by segment are summarized in the tables below:

<b>Year Ended December 31, 2018</b>				
<i>(in thousands)</i>	<b>Pharmaceutical</b>	<b>Medical Devices</b>	<b>Income Generating Assets</b>	<b>Total</b>
Compensation .....	\$ 1,971	\$ 3,627	\$ 10,204	\$ 15,802
<i>Salaries and Wages (including taxes)</i> .....	1,506	1,871	6,193	9,570
<i>Bonuses (including accruals)</i> .....	325	991	(203)	1,113
<i>Stock-based compensation</i> .....	140	765	4,214	5,119
Asset management .....	—	—	5,386	5,386
Business development .....	203	—	1,168	1,371
Accounting and tax services .....	1,528	39	4,288	5,855
Other professional services .....	3,891	825	1,921	6,637
Other .....	3,781	1,399	5,189	10,369
Total general and administrative .....	<u>\$ 11,374</u>	<u>\$ 5,890</u>	<u>\$ 28,156</u>	<u>\$ 45,420</u>
<b>Year Ended December 31, 2017</b>				
<i>(in thousands)</i>	<b>Pharmaceutical</b>	<b>Medical Devices</b>	<b>Income Generating Assets</b>	<b>Total</b>
Compensation .....	\$ 1,949	\$ 1,714	\$ 12,831	\$ 16,494
<i>Salaries and Wages (including taxes)</i> .....	1,563	1,031	5,729	8,323
<i>Bonuses (including accruals)</i> .....	235	657	4,126	5,018
<i>Stock-based compensation</i> .....	151	26	2,976	3,153
Asset management .....	—	—	7,403	7,403
Business development .....	—	—	2,174	2,174
Accounting and tax services .....	1,453	50	3,763	5,266
Other professional services .....	4,139	302	2,860	7,301
Other .....	2,009	1,091	3,903	7,003
Total general and administrative .....	<u>\$ 9,550</u>	<u>\$ 3,157</u>	<u>\$ 32,934</u>	<u>\$ 45,641</u>
<b>Year Ended December 31, 2016</b>				
<i>(in thousands)</i>	<b>Pharmaceutical</b>	<b>Medical Devices</b>	<b>Income Generating Assets</b>	<b>Total</b>
Compensation .....	\$ 707	\$ —	\$ 14,015	\$ 14,722
<i>Salaries and Wages (including taxes)</i> .....	350	—	4,139	4,489
<i>Bonuses (including accruals)</i> .....	104	—	6,410	6,514
<i>Stock-based compensation</i> .....	253	—	3,466	3,719
Asset management .....	—	—	8,761	8,761
Business development .....	—	—	3,668	3,668
Accounting and tax services .....	15	—	2,852	2,867
Other professional services .....	998	—	5,440	6,438
Other .....	348	—	2,986	3,334
Total general and administrative .....	<u>\$ 2,068</u>	<u>\$ —</u>	<u>\$ 37,722</u>	<u>\$ 39,790</u>

## Non-Operating Expense, Net

A summary of our non-operating expense, net, for the years ended December 31, 2018, 2017 and 2016, is presented below:

<i>(Dollars in thousands)</i>	2018	2017	Change from Prior Year %	2016	Change from Prior Year %
Interest and other income, net.....	\$ 6,065	\$ 1,659	266 %	\$ 588	182 %
Interest expense.....	(12,157)	(20,221)	(40)%	(18,267)	11 %
Gain on bargain purchase.....	—	9,309	N/M	—	N/M
Loss on extinguishment of debt.....	—	—	N/M	(2,353)	N/M
Gain on sale of investments.....	764	—	N/M	—	N/M
Total non-operating expense, net.....	<u>\$ (5,328)</u>	<u>\$ (9,253)</u>	(42)%	<u>\$ (20,032)</u>	(54)%

*N/M = Not meaningful*

*For the year ended December 31, 2018, compared to December 31, 2017*

Total non-operating expenses, net, decreased by 42%, or \$3.9 million for the year ended December 31, 2018, compared to the year ended December 31, 2017. Non-operating expense, net, decreased due to:

- the reduction in interest expense after the February 2018 Notes were repaid,
- increased investment income as compared to the prior year, and
- the gain on sale of investments in 2018, partially offset by
- the bargain purchase gain recognized in 2017.

*For the year ended December 31, 2017, compared to December 31, 2016*

Total non-operating expenses, net, decreased by 54%, or \$10.8 million for the year ended December 31, 2017 compared to the year ended December 31, 2016. Non-operating expense, net, decreased, due to:

- the bargain purchase gain recognized upon the acquisition of LENSAR
- a reduction in interest expense due to the partial repayment of the February 2018 Notes in November 2016,
- the loss on the extinguishment of debt recognized in 2016,
- an increase in interest and other income, partially offset by
- the increase in interest expense from the December 2021 Note issued during the fourth quarter of 2016. The increase in interest expense for the year ended December 31, 2017, as compared to 2016, consisted primarily of non-cash interest expense as we are required to compute interest expense using the interest rate for similar nonconvertible instruments in accordance with the accounting guidance for convertible debt instruments that may be settled in cash or other assets on conversion.

## Income Taxes

Income tax expense for the years ended December 31, 2018, 2017, and 2016, was \$12.9 million, \$73.8 million and \$45.7 million, respectively, which resulted primarily from applying the federal statutory income tax rate to (loss) income before income taxes. The tax rate of (23.1)% in 2018 and 40.0% in 2017 differs from the statutory tax rate of 21% and 35%, respectively, primarily as a result of Subpart F and GILTI income, the foreign rate differential on income or loss at our foreign subsidiaries and the increase in our valuation allowance in 2018.

During 2018 the amount of our unrecognized tax benefits increased by \$1.6 million. The future impact of the unrecognized tax benefits of \$80.8 million, if recognized, is comprised of \$59.5 million, which would affect the effective tax rate, and \$21.3 million, which would result in adjustments to deferred tax assets.

Estimated interest and penalties associated with unrecognized tax benefits increased our income tax expense in the Consolidated Statements of Operations by \$1.0 million during each of the years ended December 31, 2018, 2017, and 2016, respectively. In general, our income tax returns are subject to examination by U.S. federal, state and local tax authorities for tax years 2000 forward. Interest and penalties associated with unrecognized tax benefits accrued on the balance sheet were \$8.0 million and \$7.0 million as of December 31, 2018 and 2017, respectively. We are currently under income tax examination by the State of

California for tax years 2009 through 2015 and by the Internal Revenue Service for the tax year 2016. Although the timing of the resolution of income tax examinations is highly uncertain, and the amounts ultimately paid, if any, upon resolution of the issues raised by the taxing authorities may differ materially from the amounts accrued for each year, except as noted above, we do not anticipate any material change to the amount of our unrecognized tax benefit over the next 12 months.

### ***Net (Loss) Income per Share***

Net (loss) income per share for the years ended December 31, 2018, 2017 and 2016, is presented below:

	<b>Year Ended December 31,</b>		
	<b>2018</b>	<b>2017</b>	<b>2016</b>
<b>Net (loss) income per basic share</b> .....	\$ (0.47)	\$ 0.71	\$ 0.39
<b>Net (loss) income per diluted share</b> .....	\$ (0.47)	\$ 0.71	\$ 0.39

### **Liquidity and Capital Resources**

We finance our operations primarily through royalty and other license-related revenues, public and private placements of debt and equity securities, interest income on invested capital and revenues from pharmaceutical and medical device product sales. We currently have 18 full-time employees at PDL managing our intellectual property, our asset acquisitions, operations and other corporate activities as well as providing for certain essential reporting and management functions of a public company. In addition, we have 20 full-time employees at our operating subsidiary, Noden, who manage Noden's business and operations, and 67 full time employees at our operating subsidiary, LENSAR, who manage the medical device business and operations.

Our future capital requirements are difficult to forecast and will depend upon many factors, including our ability to identify and acquire pharmaceutical products, the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, the resources we devote to developing and supporting our products and other factors. Additionally, we will continue to evaluate possible acquisitions of new products, royalty revenues or other income generating assets, which may require the use of cash or additional financing.

The general cash needs of our Pharmaceutical, Medical Devices and Income Generating Assets segments can vary significantly. In our Pharmaceutical segment, cash needs tend to be driven primarily by material purchases and anticipated near term capital expenditures. In our Medical Devices segment, the primary factor determining cash needs is the funding of our operations. The cash needs of our Income Generating Assets segment tend to be driven by legal and professional service fees as well as the funding of potential repurchases of our common stock.

We had cash, cash equivalents and investments in the aggregate of \$394.6 million and \$532.1 million at December 31, 2018 and 2017, respectively. The decrease was primarily attributable to the repayment of the February 2018 Notes for \$126.4 million, the repurchase of stock of \$49.1 million, the purchase of the Assertio royalty asset reversionary interest for \$20.0 million, purchase of fixed assets of \$4.5 million and cash used in operating activities of \$13.4 million, partially offset by cash received from royalties of \$78.0 million and proceeds from the sale of available-for-sale securities of \$4.1 million.

On March 1, 2017, we announced that our board of directors authorized the repurchase of up to \$30.0 million of our common stock through March 2018 pursuant to a share repurchase program. The repurchases under the share repurchase program were made from time to time in the open market or in privately negotiated transactions and were funded from our working capital. All shares of common stock repurchased under this share repurchase program were retired and restored to authorized but unissued shares of common stock as of June 30, 2017. We repurchased 13.3 million shares of common stock under the share repurchase program during the year ended December 31, 2017 for an aggregate purchase price of \$30.0 million, or an average cost of \$2.25 per share, including trading commissions.

On September 25, 2017, we announced that our board of directors authorized the repurchase of issued and outstanding shares of our common stock having an aggregate value of up to \$25.0 million pursuant to a share repurchase program. The repurchases under the share repurchase program were made from time to time in the open market or in privately negotiated transactions and were funded from our working capital. All shares of common stock repurchased under this share repurchase program were retired and restored to authorized but unissued shares of common stock at July 5, 2018. We repurchased 8.7 million shares of its common stock for an aggregate purchase price of \$25.0 million, or an average cost of \$2.86 per share, including trading commissions.

On September 24, 2018, we announced that our board of directors authorized the repurchase of issued and outstanding shares of our common stock having an aggregate value of up to \$100.0 million pursuant to a new share repurchase program. Repurchases



under the new share repurchase program will be made from time to time in the open market or in privately negotiated transactions and funded from our working capital. The amount and timing of such repurchases will depend upon the price and availability of shares, general market conditions and the availability of cash. Repurchases may also be made under a trading plan under Rule 10b5-1, which would permit shares to be repurchased when we might otherwise be precluded from doing so because of self-imposed trading blackout periods or other regulatory restrictions. All shares of common stock repurchased under our new share repurchase program are expected to be retired and restored to authorized but unissued shares of common stock. As of December 31, 2018, we have repurchased 8.7 million shares of its common stock under this share repurchase program for an aggregate purchase price of \$25.5 million, or an average cost of \$2.94 per share, including trading commissions. The program may be suspended or discontinued at any time without notice.

We believe that cash from future revenues from acquired pharmaceutical products, medical devices and/or income generating assets, net of operating expenses, debt service and income taxes, plus cash on hand, will be sufficient to fund our operations over the next several years. However, our acquired pharmaceutical products, medical devices and/or income generating assets will not result in cash flows to us, in the near term, that will replace the cash flows we received from our license agreements related to the Queen et al. patents. In the second quarter of 2016, our cash flows materially decreased after we stopped receiving payments from certain of the Queen et al. patent licenses and our legal settlements. Our continued success is dependent on our ability to acquire new additional pharmaceutical products, medical devices and/or income generating assets, and the timing of these transactions, in order to provide recurring cash flows going forward that support our business model, and service our debt.

We continuously evaluate alternatives to increase return for our stockholders, including, for example, by acquiring and managing companies and/or products in the pharmaceutical and medical device industries, purchasing income generating assets, selling certain assets, buying back our convertible notes, repurchasing our common stock or potentially selling our company.

We may consider additional debt or equity financings to support growth if cash flows from our existing business are not sufficient to fund future product or income generating asset opportunities and acquisitions.

### ***Off-Balance Sheet Arrangements***

As of December 31, 2018, we did not have any off-balance sheet arrangements, as defined under SEC Regulation S-K Item 303(a)(4)(ii).

### **Contractual Obligations**

#### *Convertible Note*

As of December 31, 2018, our convertible note obligation consisted of our December 2021 Notes, which totaled \$150.0 million in principal.

We expect that our debt service obligations over the next several years will consist of interest payments and repayment of our December 2021 Notes. We may further seek to exchange, repurchase or otherwise acquire the convertible notes in the open market in the future, which could adversely affect the amount or timing of any distributions to our stockholders. We would make such exchanges or repurchases only if we deemed it to be in our stockholders' best interest. We may finance such repurchases with cash on hand and/or with public or private equity or debt financings if we deem such financings to be available on favorable terms.

#### *Noden Purchase Agreement*

Pursuant to the Noden Purchase Agreement, Noden is required to pay up to \$95.0 million in milestone payments, subject to the occurrence of such milestones. If the milestones are achieved, which we no longer believe is probable, we would fund at least \$38.0 million in the form of additional equity contributions to Noden.

#### *Kybella Royalty Agreement*

On July 8, 2016, we entered into a royalty purchase and sales agreement with an individual, whereby we acquired that individual's rights to receive certain royalties on sales of KYBELLA by Allergan plc, in exchange for a \$9.5 million cash payment and up to a \$1.0 million future milestone payment based upon product sales targets.

The following table summarizes our contractual obligations and commercial commitments as of December 31, 2018:

<i>(in thousands)</i>	Payments Due by Period				
	2019	2020	2021	Thereafter	Total
Operating leases <sup>(1)</sup>	\$ 1,140	\$ 1,003	\$ 559	\$ —	\$ 2,702
Convertible notes <sup>(2)</sup>	4,125	4,125	154,125	—	162,375
Inventory <sup>(3)</sup>	57,458	37,070	36,798	—	131,326
Contingent consideration <sup>(4)</sup>	55,000	—	40,000	—	95,000
Total contractual obligations	<u>\$ 117,723</u>	<u>\$ 42,198</u>	<u>\$ 231,482</u>	<u>\$ —</u>	<u>\$ 391,403</u>

<sup>(1)</sup> Amounts represent the lease for our headquarters in Incline Village, Nevada, the lease for the Noden Pharma DAC office in Dublin, Ireland, the lease for the LENSAR office and manufacturing facility in Orlando, Florida and operating leases for office equipment.

<sup>(2)</sup> Amounts represent principal and cash interest payments due on the December 2021 Notes.

<sup>(3)</sup> Consist of minimum purchase obligation under the Novartis supply agreement for bulk tablets and API and inventory components for LENSAR.

<sup>(4)</sup> Pursuant to the terms of the Noden Purchase Agreement, Noden Pharma DAC is committed to pay Novartis up to an additional \$95.0 million contingent on achievement of milestones based on sales targets and the timing of the launch of a generic drug containing the pharmaceutical ingredient aliskiren. While we do not believe we will be required to pay these amounts, they are included above as the outcome is not final.

## Guarantees

### *Redwood City Lease Guarantee*

In connection with the spin-off (the “Spin-Off”) of Facet Biotech Corporation (“Facet”) in December 2008, we entered into amendments to the leases for our former facilities in Redwood City, California, under which Facet was added as a co-tenant. As a co-tenant, Facet is bound by all of the terms and conditions of the leases. We and Facet are jointly and severally liable for all obligations under the leases, including the payment of rental obligations. The guarantee runs through December 2021. For further information, see Note 15, *Commitments and Contingencies*.

## Purchase Commitments

Noden and Novartis entered into a supply agreement pursuant to which Novartis manufactures and supplies to Noden a bulk tableted form of the Noden Products, and for the additional supply of the API, for specified periods of time prior to the transfer of manufacturing responsibilities for the Noden Products to another manufacturer. The supply agreement may be terminated by either party for material breach that remains uncured for a specified time period. Noden has placed firm orders for bulk product of \$12.3 million, which will be fulfilled within the next twelve months. Under the terms of the supply agreement, Noden is committed to purchase certain minimum quantities of bulk product and API that would amount to approximately \$54.0 million and \$127.6 million over the next twelve and thirty-six months, respectively, unless otherwise negotiated. While the supply agreement provides that the parties will agree to reasonable accommodations with respect to changes in firm orders, we expect that Noden will meet the requirements of the supply agreement. The commitments in the supply agreement terminate upon transfer to another manufacturer.

LENSAR entered into various supply agreements for the manufacture and supply of certain components. The supply agreements commit LENSAR to a minimum purchase obligation of approximately \$3.8 million over the next twenty-four months of which \$3.5 million is due in the next 12 months. LENSAR expects to meet these requirements.

## Escrow Receivable

On September 21, 2017, we entered into an agreement (the “kaléo Note Sale Agreement”) with MAM-Kangaroo Lender, LLC, a Delaware limited liability company (the “kaléo Purchaser”), pursuant to which we sold our entire interest in the notes issued by Accel 300, LLC (“Accel 300”) pursuant to that certain Indenture, dated as of April 1, 2014, by and between Accel 300 and U.S. Bank National Association, as the current trustee of the notes described therein (the “kaléo Note”).

Pursuant to the kaléo Note Sale Agreement, the kaléo Purchaser paid to us an amount equal to 100% of the then outstanding principal, a premium of 1% of such amount and accrued interest under the kaléo Notes, for an aggregate cash purchase price of \$141.7 million.

\$1.4 million of the aggregate purchase price was deposited into an escrow account as a potential payment against certain contingencies for 18 months, after which the escrow agent is required to release any funds remaining in the escrow account to us.

We do not believe that the funds will be subject to claims contemplated under the escrow agreement. However, in the event that such a claim is made, and if successful, the amount of such a claim up to \$1.4 million would be released from the escrow to the kaléo Purchaser, which may reduce the amount ultimately returned to us when the 18 month escrow period has ended. As of December 31, 2018, we are not aware of any claims by the kaléo Purchaser that would reduce the escrow receivable.

### Recently Issued Accounting Pronouncements

See Note 2, *Summary of Significant Accounting Policies*, to the Consolidated Financial Statements included in Item 8, for information regarding recently issued accounting pronouncements.

## ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

### Interest Rate Sensitive Financial Instruments

Our investment portfolio has a fair value of approximately \$226.7 million at December 31, 2018, and \$422.4 million at December 31, 2017, and consisted primarily of investments in Rule 2a-7 money market funds. If market interest rates were to have increased by 1% in either of these years, there would have been no material impact on the fair value of our portfolio.

The aggregate fair value of our convertible notes was estimated to be \$151.4 million at December 31, 2018, and \$274.2 million at December 31, 2017, based on available pricing information. At December 31, 2018 our convertible notes consisted of the December 2021 Notes, which have a fixed interest rate of 2.75%. As of December 31, 2017, our convertible notes consisted of the December 2021 Notes and the February 2018 Notes, which had a fixed interest rate of 4.0%. Changes in interest rates do not affect interest expense on fixed rate debt. While changes in interest rates do not impact the amount of interest we pay, these obligations are subject to interest rate risk because changes in interest rates would affect the fair values of fixed rate debt.

The following table presents information about our material debt obligation that is sensitive to changes in interest rates. The table presents principal amounts and related interest rates by year of expected maturity for our debt obligations or the earliest year in which the holders may put the debt to us. The convertible notes may be converted to our common stock prior to the maturity date.

<i>(in thousands)</i>	<b>2019</b>	<b>2020</b>	<b>2021</b>	<b>Total</b>	<b>Fair Value</b>
<b>Convertible notes</b>					
Fixed Rate.....	\$ —	\$ —	\$ 150,000	\$ 150,000	\$ 151,356 <sup>(1)</sup>
Average Interest Rate.....	2.75%	2.75%	2.75%		

(1) The fair value of the remaining payments under our December 2021 Notes was estimated based on the trading value of these notes at December 31, 2018.

### Foreign Currency Sensitive Financial Instruments

Our international operations are affected by fluctuations in the value of the U.S. dollar as compared to foreign currencies, predominantly the euro. Increases and decreases in our international product sales from movements in foreign currency exchange rates are offset partially by the corresponding increases or decreases in our international operating expenses. Our revenues, expenses and cash flows may fluctuate due to changes in foreign currency exchange rates and are subject to foreign currency exchange risk. While foreign currency conversion terms vary by agreement, generally most agreements require that royalties first be calculated in the currency of sale and then converted into U.S. dollars using the average daily exchange rates for that currency for a specified period at the end of the calendar quarter. Similarly, sales of our Noden Products and expenses of our Irish subsidiary are denominated in currencies other than the U.S. dollar. Accordingly, when the U.S. dollar weakens against other currencies, the converted amount is greater than it would have been had the U.S. dollar not weakened.

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

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## **Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Stockholders of PDL BioPharma, Inc.

### ***Opinions on the Financial Statements and Internal Control over Financial Reporting***

We have audited the accompanying consolidated balance sheets of PDL BioPharma, Inc. and its subsidiaries (the “Company”) as of December 31, 2018 and December 31, 2017, and the related consolidated statements of operations, comprehensive (loss) income, stockholders’ equity and cash flows for each of the three years in the period ended December 31, 2018, including the related notes (collectively referred to as the “consolidated financial statements”). We also have audited the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

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

### ***Basis for Opinions***

The Company's management is responsible for these consolidated 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 Management's Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on the Company’s consolidated financial statements and 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 consolidated 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 consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated 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 consolidated 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 consolidated 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 (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) 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 (iii) 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/ PricewaterhouseCoopers LLP

San Francisco, California  
March 14, 2019

We have served as the Company's auditor since 2014.

**PDL BIOPHARMA, INC.**  
**CONSOLIDATED BALANCE SHEETS**  
(In thousands, except per share data)

	December 31,	
	2018	2017
<b>Assets</b>		
Current assets:		
Cash and cash equivalents .....	\$ 394,590	\$ 527,266
Short-term investments .....	—	4,848
Accounts receivable, net .....	21,648	31,183
Notes receivable .....	63,042	53,613
Inventory .....	18,942	9,147
Prepaid and other current assets .....	18,995	14,386
Total current assets .....	517,217	640,443
Property and equipment, net .....	7,387	7,222
Royalty rights - at fair value .....	376,510	349,223
Notes and other receivables, long-term .....	771	17,124
Long-term deferred tax assets .....	1,539	2,432
Intangible assets, net .....	51,319	215,823
Other assets .....	8,993	10,856
<b>Total assets</b> .....	<b>\$ 963,736</b>	<b>\$ 1,243,123</b>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable .....	\$ 13,142	\$ 19,785
Accrued liabilities .....	39,312	45,881
Accrued income taxes .....	16	1,377
Convertible notes payable .....	—	126,066
Total current liabilities .....	52,470	193,109
Convertible notes payable .....	124,644	117,415
Contingent consideration .....	—	42,000
Other long-term liabilities .....	56,843	44,709
Total liabilities .....	233,957	397,233
Commitments and contingencies (Note 15)		
Stockholders' equity:		
Preferred stock, par value \$0.01 per share, 10,000 shares authorized; no shares issued and outstanding .....	—	—
Common stock, par value \$0.01 per share, 350,000 shares authorized; 136,513 and 153,775 shares issued and outstanding at December 31, 2018 and 2017, respectively .....	1,365	1,538
Additional paid-in capital .....	(98,030)	(102,443)
Treasury stock, at cost (750 and zero shares held) .....	(2,103)	—
Accumulated other comprehensive income .....	—	1,181
Retained earnings .....	828,547	945,614
Total PDL's stockholders' equity .....	729,779	845,890
Total stockholders' equity .....	729,779	845,890
<b>Total liabilities and stockholders' equity</b> .....	<b>\$ 963,736</b>	<b>\$ 1,243,123</b>

See accompanying notes.

**PDL BIOPHARMA, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
(In thousands, except per share amounts)

	<b>Year Ended December 31,</b>		
	<b>2018</b>	<b>2017</b>	<b>2016</b>
<b>Revenues:</b>			
Royalties from Queen et al. patents .....	\$ 4,536	\$ 36,415	\$ 166,158
Royalty rights - change in fair value .....	85,256	162,327	16,196
Interest revenue .....	2,337	17,744	30,404
Product revenue, net .....	105,448	84,123	31,669
License and other .....	533	19,451	(126)
<b>Total revenues</b> .....	<b>198,110</b>	<b>320,060</b>	<b>244,301</b>
<b>Operating expenses</b>			
Cost of product revenue (excluding amortization and impairment of intangible assets) .....	48,460	30,537	4,065
Amortization of intangible assets .....	15,831	24,689	12,028
General and administrative .....	45,420	45,641	39,790
Sales and marketing .....	17,139	17,683	538
Research and development .....	2,955	7,381	3,820
Impairment of intangible assets .....	152,330	—	—
Asset impairment loss .....	8,200	—	3,735
Acquisition-related costs .....	—	—	3,564
Loss on extinguishment of notes receivable .....	—	—	51,075
Change in fair value of anniversary payment and contingent consideration ...	(41,631)	349	(3,716)
<b>Total operating expenses</b> .....	<b>248,704</b>	<b>126,280</b>	<b>114,899</b>
<b>Operating (loss) income</b> .....	<b>(50,594)</b>	<b>193,780</b>	<b>129,402</b>
<b>Non-operating expense, net</b>			
Interest and other income, net .....	6,065	1,659	588
Interest expense .....	(12,157)	(20,221)	(18,267)
Gain on bargain purchase .....	—	9,309	—
Gain on investments .....	764	—	—
Loss on extinguishment of debt .....	—	—	(2,353)
<b>Total non-operating expense, net</b> .....	<b>(5,328)</b>	<b>(9,253)</b>	<b>(20,032)</b>
(Loss) income before income taxes .....	(55,922)	184,527	109,370
Income tax expense .....	12,937	73,826	45,711
<b>Net (loss) income</b> .....	<b>(68,859)</b>	<b>110,701</b>	<b>63,659</b>
Less: Net (loss) income attributable to noncontrolling interests .....	—	(47)	53
<b>Net (loss) income attributable to PDL's stockholders</b> .....	<b>\$ (68,859)</b>	<b>\$ 110,748</b>	<b>\$ 63,606</b>
<b>Net (loss) income per share</b>			
Basic .....	\$ (0.47)	\$ 0.71	\$ 0.39
Diluted .....	\$ (0.47)	\$ 0.71	\$ 0.39
<b>Weighted-average shares outstanding</b>			
Basic .....	145,669	155,394	163,805
Diluted .....	145,669	156,257	164,192
<b>Cash dividends declared per common share</b> .....	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 0.10</b>

See accompanying notes.



**PDL BIOPHARMA, INC.**  
**CONSOLIDATED STATEMENTS OF COMPREHENSIVE (LOSS) INCOME**  
(In thousands)

	Year Ended December 31,		
	2018	2017	2016
<b>Net (loss) income</b> .....	\$ (68,859)	\$ 110,701	\$ 63,659
<b>Other comprehensive (loss) income, net of tax</b>			
Change in unrealized gains on investments in available-for-sale securities:			
Change in fair value of investments in available-for-sale securities, net of tax .....	(578)	1,181	122
Adjustment for net (gains) losses realized and included in net (loss) income, net of tax .....	(603)	—	(557)
Total change in unrealized gains (losses) on investments in available-for-sale securities, net of tax <sup>(a)</sup> .....	(1,181)	1,181	(435)
Change in unrealized gains (losses) on cash flow hedges:			
Adjustment to royalties from Queen et al. patents for net losses (gains) realized and included in net (loss) income, net of tax .....	—	—	(1,821)
Total change in unrealized losses on cash flow hedges, net of tax <sup>(b)</sup> .....	—	—	(1,821)
Total other comprehensive (loss) income, net of tax .....	(1,181)	1,181	(2,256)
<b>Comprehensive (loss) income</b> .....	(70,040)	111,882	61,403
Less: Comprehensive (loss) income attributable to noncontrolling interests .....	—	(47)	53
<b>Comprehensive (loss) income attributable to PDL's stockholders</b> .....	\$ (70,040)	\$ 111,929	\$ 61,350

<sup>(a)</sup> Net of tax of (\$314), \$314 and (\$234) for the years ended December 31, 2018, 2017 and 2016, respectively.

<sup>(b)</sup> Net of tax of (\$981) for the year ended December 31, 2016.

See accompanying notes.

**PDL BIOPHARMA, INC.**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**  
(In thousands, except share amounts)

	PDL's Stockholders Equity							Total Stockholders' Equity
	Common Stock		Treasury Stock	Additional Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Income (Loss)	Non- controlling Interest	
	Shares	Amount						
<b>Balance at December 31, 2015</b> .....	164,286,615	\$ 1,643	\$ —	\$(117,983)	\$810,036	\$ 2,256	\$ —	\$ 695,952
Common stock issued and forfeited, net .....	1,251,832	12	—	(12)	—	—	—	—
Issuance of convertible debt .....	—	—	—	25,465	—	—	—	25,465
Purchase of purchased call options, net of tax ...	—	—	—	(14,400)	—	—	—	(14,400)
Sale of subsidiary shares to non-controlling interest .....	—	—	—	(3,977)	—	—	4,227	250
Stock-based compensation expense .....	—	—	—	3,741	—	—	—	3,741
Tax benefit from stock options .....	—	—	—	(462)	—	—	—	(462)
Dividends declared .....	—	—	—	—	(16,526)	—	—	(16,526)
Comprehensive income:								
Net income .....	—	—	—	—	63,606	—	53	63,659
Change in unrealized gains and losses on investments in available-for-sale securities, net of tax .....	—	—	—	—	—	(435)	—	(435)
Changes in unrealized gains and losses on cash flow hedges, net of tax .....	—	—	—	—	—	(1,821)	—	(1,821)
Total comprehensive income .....								61,403
<b>Balance at December 31, 2016</b> .....	165,538,447	1,655	—	(107,628)	857,116	—	4,280	755,423
Common stock issued and forfeited, net .....	1,582,698	16	—	(16)	—	—	—	—
Stock-based compensation expense .....	—	—	—	3,138	—	—	—	3,138
Repurchase and retirement of common stock ....	(13,346,389)	(133)	—	—	(29,867)	—	—	(30,000)
Acquisition of Noden common stock .....	—	—	—	2,063	—	—	(4,233)	(2,170)
Cumulative effect from change in accounting principles .....	—	—	—	—	7,617	—	—	7,617
Comprehensive income:								
Net income .....	—	—	—	—	110,748	—	(47)	110,701
Change in unrealized gains and losses on investments in available-for-sale securities, net of tax .....	—	—	—	—	—	1,181	—	1,181
Total comprehensive income .....								111,882
<b>Balance at December 31, 2017</b> .....	153,774,756	1,538	—	(102,443)	945,614	1,181	—	845,890
Common stock issued and forfeited, net of shares withheld for employee taxes.....	(601,668)	(6)	—	6	58	—	—	58
Stock-based compensation expense .....	—	—	—	4,407	—	—	—	4,407
Repurchase and retirement of common stock ....	(16,660,566)	(167)	(2,103)	—	(48,266)	—	—	(50,536)
Comprehensive loss:								
Net loss .....	—	—	—	—	(68,859)	—	—	(68,859)
Change in unrealized gains and losses on investments in available-for-sale securities, net of tax .....	—	—	—	—	—	(1,181)	—	(1,181)
Total comprehensive loss .....								(70,040)
<b>Balance at December 31, 2018</b> .....	136,512,522	\$ 1,365	\$ (2,103)	\$ (98,030)	\$828,547	\$ —	\$ —	\$ 729,779

See accompanying notes.

**PDL BIOPHARMA, INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(In thousands)

	Year Ended December 31,		
	2018	2017	2016
<b>Cash flows from operating activities</b>			
Net (loss) income .....	\$ (68,859)	\$ 110,701	\$ 63,659
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:			
Amortization of convertible notes and term loan offering costs .....	7,609	11,038	10,009
Amortization of intangible assets .....	15,831	24,689	12,028
Impairment of intangible asset .....	152,330	—	—
Asset impairment loss .....	8,200	—	3,735
Change in fair value of royalty rights - at fair value .....	(85,256)	(162,327)	(16,196)
Change in fair value of derivative asset .....	(33)	49	906
Change in fair value of anniversary payment and contingent consideration .....	(41,631)	349	(3,716)
Other amortization, depreciation and accretion of embedded derivative .....	3,696	2,366	18
Inventory obsolescence .....	(1,203)	2,012	342
Provision for bad debts .....	8	76	—
Loss on extinguishment of notes receivable .....	—	—	51,075
Loss on extinguishment of convertible notes .....	—	—	2,353
Gain on sale of available-for-sale securities .....	(764)	(108)	(882)
Loss on disposal of property and equipment .....	66	—	—
Escrow receivable .....	—	(1,400)	—
Bargain purchase gain .....	—	(9,309)	—
Stock-based compensation expense .....	4,758	3,138	3,742
Deferred income taxes .....	13,846	39,172	(10,676)
Changes in assets and liabilities:			
Accounts receivable .....	9,341	5,877	(34,120)
Receivables from licensees and other .....	—	5,055	(6,000)
Prepaid and other current assets .....	(5,025)	(9,100)	(1,526)
Accrued interest on notes receivable .....	—	1,475	(2,764)
Inventory .....	(8,305)	(1,120)	(3,227)
Other assets .....	(2,120)	(1,400)	(757)
Accounts payable .....	(6,642)	10,840	6,621
Accrued liabilities .....	(7,449)	13,120	22,729
Accrued income taxes .....	(1,361)	(3,346)	1,352
Deferred tax liability .....	—	—	(787)
Other long-term liabilities .....	(462)	(1,223)	3,800
Net cash (used in) provided by operating activities .....	<u>(13,425)</u>	<u>40,624</u>	<u>101,718</u>
<b>Cash flows from investing activities</b>			
Acquisition of business, net of cash .....	—	—	(109,938)
Purchases of investments .....	—	(23,213)	(22,952)
Purchase of investments - other .....	—	—	(75,000)
Maturities of investments - other .....	—	75,000	—
Payment of contingent consideration .....	(858)	—	—
Proceeds from sales of available-for-sale securities .....	4,116	39,956	4,680
Purchase of royalty rights - at fair value .....	(20,000)	—	(59,500)
Proceeds from royalty rights - at fair value .....	77,969	107,253	72,582
Sale of royalty rights - at fair value .....	—	108,169	—
Purchase of notes receivable .....	—	—	(9,010)
Repayment of notes receivable .....	—	144,829	54,653
Proceeds from sales of assets held for sale .....	—	8,190	—
Purchase of property and equipment .....	(4,523)	(1,297)	(25)
Net cash provided by (used in) investing activities .....	<u>56,704</u>	<u>458,887</u>	<u>(144,510)</u>
<b>Cash flows from financing activities</b>			
Repayment of term loan .....	—	—	(25,000)
Repurchase of convertible notes .....	—	—	(120,000)
Repayment of convertible notes .....	(126,447)	—	—
Payment of debt issuance costs .....	—	—	(3,204)
Proceeds from issuance of convertible notes .....	—	—	150,000
Purchase of call options .....	—	—	(14,400)
Payment of anniversary payment .....	—	(87,007)	—
Cash received from noncontrolling interest holder .....	—	—	250
Cash paid for purchase of noncontrolling interest .....	—	(2,170)	—
Repurchase of Company common stock .....	(49,109)	(30,000)	—
Cash dividends paid .....	(48)	(222)	(16,583)
Net settlement of stock-based compensation awards .....	(351)	—	—
Net cash used in financing activities .....	<u>(175,955)</u>	<u>(119,399)</u>	<u>(28,937)</u>
Net (decrease) increase in cash and cash equivalents .....	(132,676)	380,112	(71,729)
Cash and cash equivalents at beginning of the year .....	527,266	147,154	218,883
Cash and cash equivalents at end of the year .....	<u>\$ 394,590</u>	<u>\$ 527,266</u>	<u>\$ 147,154</u>

See accompanying notes

**PDL BIOPHARMA, INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS, continued**  
**(In thousands)**

	Year Ended December 31,		
	2018	2017	2016
<b>Supplemental cash flow information</b>			
Cash paid for income taxes .....	\$ 3,805	\$ 43,366	\$ 50,000
Cash paid for interest.....	\$ 6,654	\$ 9,286	\$ 11,410
<b>Supplemental schedule of non-cash investing and financing activities</b>			
Assets held for sale reclassified from other assets to intangible assets.....	\$ 1,811	\$ —	\$ —
Warrants received for notes receivable.....	\$ —	\$ —	\$ 2,342
Accrued Anniversary Payment associated with the acquisition of a business .....	\$ —	\$ —	\$ 87,007
Accrued contingent consideration associated with the acquisition of a business .....	\$ —	\$ —	\$ 47,360
Asset held for sale reclassified from notes receivable to other assets.....	\$ —	\$ 10,000	\$ —
Extinguishment of notes receivable .....	\$ —	\$ 43,909	\$ —

See accompanying notes

**PDL BIOPHARMA, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**December 31, 2018**

## **1. Organization and Business**

PDL BioPharma, Inc. and its subsidiaries (collectively, the “Company”) seeks to provide a significant return for its stockholders by acquiring commercial stage pharmaceutical assets with multiple year revenue growth potential as well as late clinical stage pharmaceutical products.

Historically, the Company generated a substantial portion of its revenues through the license agreements related to patents covering the humanization of antibodies, which it refers to as the Queen et al. patents. In 2012, the Company began providing alternative sources of capital through royalty monetizations and debt facilities, and, in 2016, the Company began acquiring commercial-stage products and launching specialized companies dedicated to the commercialization of these products. To date, the Company has consummated seventeen such transactions, ten of which are active and outstanding.

Based on the composition of its existing investment portfolio, the Company currently operates in three segments designated as Pharmaceutical, Medical Devices and Income Generating Assets.

The Company’s Pharmaceutical segment consists of revenue derived from branded prescription medicine product sold under the name Tekturna<sup>®</sup> and Tekturna HCT<sup>®</sup> in the United States and Rasilez<sup>®</sup> and Rasilez HCT<sup>®</sup> in the rest of the world (collectively, the “Noden Products”). The Company’s Medical Devices segment consists of revenue derived from the LENSAR<sup>®</sup> Laser System sales. The Company’s Income Generating Assets segment consists of revenue derived from (i) notes and other long-term receivables, (ii) royalty rights - at fair value, (iii) equity investments and (iv) royalties from the Queen et al. patents.

## **2. Summary of Significant Accounting Policies**

### ***Basis of Presentation***

The accompanying Consolidated Financial Statements of the Company have been prepared in accordance with U.S. Generally Accepted Accounting Principles (“GAAP”).

### ***Principles of Consolidation***

The Consolidated Financial Statements include the accounts of the Company and its subsidiaries. All significant intercompany balances and transactions have been eliminated upon consolidation.

A subsidiary is an entity in which the Company, directly or indirectly, controls more than one half of the voting power; has the power to appoint or remove the majority of the members of the board of directors; to cast a majority of votes at the meeting of the board of directors or to govern the financial and operating policies of the investee under a statute or agreement among the stockholders or equity holders.

The Company applies the guidance codified in Accounting Standard Codification (“ASC”) 810, *Consolidations*, which requires certain variable interest entities to be consolidated by the primary beneficiary of the entity in which it has a controlling financial interest. The Company identifies an entity as a variable interest entity if either: (1) the entity does not have sufficient equity investment at risk to permit the entity to finance its activities without additional subordinated financial support, or (2) the entity’s equity investors lack the essential characteristics of a controlling financial interest. The Company performs ongoing qualitative assessments of its variable interest entities to determine whether the Company has a controlling financial interest in any variable interest entity and therefore is the primary beneficiary, and if it has the power to direct activities that impact the activities of the entity.

### ***Use of Estimates***

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the Consolidated Financial Statements and accompanying Notes to the Consolidated Financial Statements. The accounting estimates that require management’s most significant, difficult and subjective judgments include the valuation of royalty rights - at fair value, revenue recognition and allowance for customer credits, the valuation of notes receivable and inventory, the assessment of recoverability of intangible assets and their estimated useful lives, the valuation and

recognition of share-based compensation, the recognition and measurement of current and deferred income tax assets and liabilities, and contingent consideration estimates. Actual results could differ from those estimates.

### ***Segment Reporting***

Under ASC 280, *Segment Reporting*, operating segments are defined as components of an enterprise about which separate financial information is available that is regularly evaluated by the entity's chief operating decision maker, in deciding how to allocate resources and in assessing performance. The Company has evaluated its operating segments in accordance with ASC 280 as of December 31, 2018, and has identified three reportable segments: Pharmaceutical, Medical Devices and Income Generating Assets.

### ***Cash Equivalents***

The Company considers all highly liquid investments with initial maturities of three months or less at the date of purchase to be cash equivalents. The Company places its cash and cash equivalents with high credit quality financial institutions and, by policy, limits the amount of credit exposure in any one financial instrument.

### ***Accounts Receivable***

As of December 31, 2018 and 2017, the Company had \$78,000 and \$76,000 in its allowance for doubtful accounts, respectively. The Company provides an allowance for doubtful accounts based on experience and specifically identified risks. Accounts receivable are carried at fair value and charged off against the allowance for doubtful accounts when the Company determines that recovery is unlikely and the Company ceases collection efforts.

### ***Investments***

As of December 31, 2018, the Company's investments comprised an investment in a privately-held company. As of December 31, 2017, the Company's investments also included available-for-sale investments.

All marketable securities were classified as available-for-sale. Available-for-sale securities are carried at fair value, based on quoted market prices and observable inputs, with unrealized gains and losses, net of tax, reported as a separate component of stockholders' equity. The Company classifies marketable securities that are available for use in current operations as current assets in the Consolidated Balance Sheets. Realized gains and losses and declines in value judged to be other than temporary for available-for-sale securities are included in "Interest and other income, net." The cost of securities sold is based on the specific identification method.

On July 1, 2016, Noden Pharma DAC entered into an asset purchase agreement ("Noden Purchase Agreement") whereby it purchased from Novartis Pharma AG ("Novartis") the exclusive worldwide rights to manufacture, market, and sell the Noden Products and certain related assets and assumed certain related liabilities (the "Noden Transaction"). Upon the consummation of the Noden Transaction, a noncontrolling interest holder acquired a 6% equity interest in Noden. The equity interest of the noncontrolling interest holder was subject to vesting and repurchase rights over a four-year period. In May 2017, the Company repurchased this equity interest for \$2.2 million in cash. The Company accounted for the repurchase in accordance with ASC 810 and recognized the difference between the fair value of the consideration paid and the amount by which the noncontrolling interest is adjusted for in equity attributable to the Company. The Company consolidates Noden under the voting interest model as of December 31, 2018 and 2017. For additional information about the consolidation of Noden, see Note 23, *Business Combinations*.

### ***Fair Value Measurements***

The fair value of the Company's financial instruments are estimates of the amounts that would be received if the Company were to sell an asset or the Company paid to transfer a liability in an orderly transaction between market participants at the measurement date or exit price. The assets and liabilities are categorized and disclosed in one of the following three categories:

Level 1 – based on quoted market prices in active markets for identical assets and liabilities;

Level 2 – based on quoted market prices for similar assets and liabilities, using observable market based inputs or unobservable market based inputs corroborated by market data, and

Level 3 – based on unobservable inputs using management’s best estimate and assumptions when inputs are unavailable.

### ***Notes Receivable and Other Long-Term Receivables***

The Company accounts for its notes receivable at amortized cost, net of unamortized origination fees, if any, and adjusted for any impairment losses. Interest is accreted or accrued to “Interest revenue” using the effective interest method. When and if supplemental payments are received from certain of these notes and other long-term receivables, an adjustment to the estimated effective interest rate is affected prospectively.

The Company evaluates the collectability of both interest and principal for each note receivable and loan to determine whether it is impaired. A note receivable or loan is considered to be impaired when, based on current information and events, the Company determines it is probable that it will be unable to collect amounts due according to the existing contractual terms. When a note receivable or loan is considered to be impaired, the amount of loss is calculated by comparing the carrying value of the financial asset to the value determined by discounting the expected future cash flows at the loan’s effective interest rate or to the estimated fair value of the underlying collateral, less costs to sell, if the loan is collateralized and the Company expects repayment to be provided solely by the collateral. Impairment assessments require significant judgments and are based on significant assumptions related to the borrower’s credit risk, financial performance, expected sales, and estimated fair value of the collateral.

The Company records interest on an accrual basis and recognizes it as earned in accordance with the contractual terms of the credit agreement, to the extent that such amounts are expected to be collected. When a note receivable or loan becomes past due, or if management otherwise does not expect that principal, interest, and other obligations due will be collected in full, the Company will generally place the note receivable or loan on an impaired status and cease recognizing interest income on that note receivable or loan on an accrual basis until all principal and interest due has been paid or until such time that the Company believes the borrower has demonstrated the ability to repay its current and future contractual obligations. Any uncollected interest related to prior periods is reversed from income in the period that collection of the interest receivable is determined to be doubtful. However, the Company may make exceptions to this policy if the investment has sufficient collateral value and is in the process of collection. Any interest payments received for notes receivable or loans on an impaired status are recognized as interest income on a cash basis.

For the years ended December 31, 2018 and 2017, the Company recognized \$2.3 million and \$3.1 million, respectively, of interest revenue for the CareView note receivable while on impaired status as a result of cash interest payments made during these years. For the year ended December 31, 2016, the Company did not recognize any interest income for notes receivable or loans which were impaired.

As of December 31, 2018, the Company had three notes receivable investments which were determined to be impaired with a cumulative investment cost and fair value of approximately \$62.8 million and \$70.0 million, respectively, compared to three note receivable investments which were determined to be impaired as of December 31, 2017 with a cumulative investment cost and fair value of approximately \$70.7 million and \$71.3 million, respectively. During the years ended December 31, 2018 and 2017, the Company did not recognize any losses on extinguishment of notes receivable. During the year ended December 31, 2016, the Company recognized a loss on extinguishment of notes receivable of \$51.1 million.

During the year ended December 31, 2018 the Company recorded an impairment loss of \$8.2 million related to the CareView note receivable. There were no impairment losses on notes receivable for the years ended December 31, 2017 and 2016. For additional information about the impairment loss recorded on the CareView note receivable, see Note 9, *Notes and Other Long-Term Receivables*.

### ***Inventory***

Inventory, which consists of raw material, work-in-process and finished goods, is stated at the lower of cost or market value. The Company determines cost using the first-in, first-out method. Inventory levels are analyzed periodically and written down to their net realizable value if they have become obsolete, have a cost basis in excess of its expected net realizable value or are in excess of expected requirements. The Company evaluates for potential excess inventory by analyzing current and future product demand relative to the remaining product shelf life. The Company builds demand forecasts by considering factors such as, but not limited to, overall market potential, market share, market acceptance and patient usage. The Company classifies inventory as current on the Consolidated Balance Sheets when the Company expects inventory to be consumed for commercial use within the next twelve months.

## ***Intangible Assets***

Intangible assets with finite useful lives consist primarily of acquired product rights and acquired technology and are amortized on a straight-line basis over their estimated useful lives, over eight years to 15 years. The estimated useful lives associated with finite-lived intangible assets are consistent with the estimated lives of the associated products and may be modified when circumstances warrant. Such assets are reviewed for impairment when events or circumstances indicate that the carrying value of an asset may not be recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset and its eventual disposition are less than its carrying amount. The amount of any impairment is measured as the difference between the carrying amount and the fair value of the impaired asset.

## ***Goodwill***

Goodwill represents the excess of the acquisition consideration over the fair value of assets acquired and liabilities assumed. The annual test for goodwill impairment is a two-step process. The first step is a comparison of the fair value of the reporting unit with its carrying amount, including goodwill. If this step indicates impairment, then, in the second step, the loss is measured as the excess of recorded goodwill over its implied fair value. Implied fair value is the excess of the fair value of the reporting unit over the fair value of all identified assets and liabilities. The Company tests goodwill for impairment annually in December and when events or changes in circumstances indicate that the carrying value may not be recoverable. After completing the Company's impairment review for the Noden reporting unit during the fourth quarter of 2016, the Company concluded that the goodwill of the Noden reporting unit was impaired. The Company recognized a goodwill impairment loss of \$3.7 million as of December 31, 2016. There is no remaining goodwill recorded on the Consolidated Balance Sheets as of December 31, 2018 or 2017.

## ***Property and Equipment***

Property and equipment are stated at cost less accumulated depreciation. Depreciation is computed using the straight-line method over the following estimated useful lives:

Leasehold improvements.....	Lesser of useful life or term of lease
Manufacturing equipment .....	3-5 years
Computer and office equipment.....	3 years
Transportation equipment.....	3 years
Furniture and fixtures .....	7 years
Equipment under lease .....	Greater of lease term or 5-10 years

## ***Convertible Notes***

The Company issued the December 2021 Notes with a settlement feature that allows the Company to settle the notes by paying or delivering, as applicable, cash, shares of the Company's common stock or a combination of cash and shares of our common stock, at the Company's election. In accordance with accounting guidance for convertible debt instruments that may be settled in cash or other assets on conversion, the Company separated the principal balance between the fair value of the liability component and the common stock conversion feature using a market interest rate for a similar nonconvertible instrument at the date of issuance.

## ***Financing Costs Related to Long-term Debt***

Costs associated with obtaining long-term debt are deferred and amortized over the term of the related debt using the effective interest method. Such costs are presented as reductions from the carrying amount of the long-term debt liability, consistent with debt discounts, on the Company's Consolidated Balance Sheets.

## ***Revenue Recognition***

### ***Adoption of New Revenue Recognition Standard***

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers* that supersedes Accounting Standards Codification ("ASC") Topic 605, *Revenue Recognition* ("ASC 605"). Subsequently, the FASB issued several updates to ASU No. 2014-09, codified in ASC Topic 606 ("ASC 606"). ASC 606 also includes new guidance on costs related to a contract, which is codified in ASC Subtopic 340-40. The Company adopted ASC 606 on January 1, 2018 using the modified retrospective method



for all contracts not substantially completed as of the date of adoption. The cumulative impact of the adoption of ASC 606 was not material to the Company; therefore, the Company did not record any adjustments to retained earnings. The reported results for 2018 reflect the application of ASC 606 guidance while the reported results for 2017 were prepared under the guidance of ASC 605, which is also referred to herein as “legacy GAAP” or the “previous guidance”.

#### *Policy Elections and Practical Expedients Taken*

Taxes assessed by a governmental authority that are both imposed on and concurrent with a specific revenue-producing transaction, that are collected by the Company from a customer, are excluded from revenue.

Shipping and handling costs associated with outbound freight after control over a product has transferred to a customer are accounted for as a fulfillment cost and are included in cost of product revenue.

Sales commissions and other incremental costs of obtaining contracts are expensed as incurred as the amortization periods are less than one year.

#### *General*

In accordance with ASC 606, revenue is recognized from the sale of products when a customer obtains control of promised products and services. The amount of revenue recognized reflects the consideration to which the Company expects to be entitled to receive in exchange for these products and services. A five-step model is utilized to achieve the core principle and includes the following steps: (1) identify the customer contract; (2) identify the contract’s performance obligations; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations; and (5) recognize revenue when the performance obligations are satisfied.

The following is a description of principal activities - separated by reportable segments - from which the Company generates its revenue. For more detailed information about reportable segments, see Note 24, *Segment Information*.

#### *Pharmaceutical*

The Pharmaceutical segment of the Company principally generates revenue from products sold to wholesalers and distributors. Customer orders are generally fulfilled within a few days of receipt resulting in minimal order backlog. Contractual performance obligations are usually limited to transfer of the product to the customer. The transfer occurs either upon shipment or upon receipt of the product in certain countries outside the United States after considering when the customer obtains control of the product. In addition, for some non-U.S. countries, the Company sells product on a consignment basis where control is not transferred until the customer resells the product to an end user. At these points, customers are able to direct the use of and obtain substantially all of the remaining benefits of the product.

Sales to customers are initially invoiced at contractual list prices. Payment terms are typically 30 to 90 days based on customary practice in each country. Revenue is reduced from the list price at the time of recognition for expected chargebacks, discounts, rebates, sales allowances and product returns, which are referred to as gross-to-net adjustments. A description of gross-to-net adjustments are described below.

*Customer Credits:* The Company’s customers are offered various forms of consideration, including allowances, service fees and prompt payment discounts. The Company expects the customers will earn prompt payment discounts and, therefore, the Company deducts the full amount of these discounts from total product sales when revenues are recognized. Service fees are also deducted from total product sales as they are earned.

*Rebates and Discounts:* Allowances for rebates include mandated discounts under the Medicaid Drug Rebate Program in the United States and mandated discounts in the European Union in markets where government-sponsored healthcare systems are the primary payers for healthcare. Rebates are amounts owed after the final dispensing of the product to a benefit plan participant and are based upon contractual agreements or legal requirements with public sector benefit providers. The accrual for rebates is based on negotiated discount rates and expected utilization as well as historical data. Estimates for expected utilization of rebates are based on data received from the customers. Rebates are generally invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter’s activity, plus an accrual balance for known prior quarters’ unpaid rebates. If actual future rebates vary from estimates, the Company may need to adjust prior period accruals, which would affect revenue in the period of adjustment.

*Chargebacks:* Chargebacks are discounts that occur when certain contracted customers, which currently consist primarily of group purchasing organizations, Public Health Service institutions, non-profit clinics, and Federal government entities purchasing via the Federal Supply Schedule, purchase directly from the Company's wholesalers. Contracted customers generally purchase the product at a discounted price. The wholesalers, in turn, charges back to the Company the difference between the price initially paid by the wholesalers and the discounted price paid by the contracted customers. In addition to actual chargebacks received, the Company maintains an accrual for chargebacks based on the estimated contractual discounts on products sold for which the chargeback has not been billed. If actual future chargebacks vary from these estimates, the Company may need to adjust prior period accruals, which would affect revenue in the period of adjustment.

*Medicare Part D Coverage Gap:* Medicare Part D prescription drug benefit mandates manufacturers to fund 50% of the Medicare Part D insurance coverage gap for prescription drugs sold to eligible patients. Estimates for the expected Medicare Part D coverage gap are based on historical invoices received and in part from data received from the Company's customers. Funding of the coverage gap is generally invoiced and paid in arrears so that the accrual balance consists of an estimate of the amount expected to be incurred for the current quarter's activity, plus an accrual balance for known prior quarters. If actual future funding varies from estimates, the Company may need to adjust prior period accruals, which would affect revenue in the period of adjustment.

*Co-payment Assistance:* Patients who have commercial insurance and meet certain eligibility requirements may receive co-payment assistance. The Company accrues a liability for co-payment assistance based on actual program participation and estimates of program redemption using data provided by third-party administrators.

*Returns:* Returns are generally estimated and recorded based on historical sales and returns information. Products that exhibit unusual sales or return patterns due to dating, competition or other marketing matters are specifically investigated and analyzed as part of the accounting for sales returns accruals.

Reserves for chargebacks, discounts, rebates, sales allowances and product returns are included within current liabilities in the Company's Consolidated Balance Sheets.

For the period from July 1, 2016 through October 4, 2016, all of the Noden Products were distributed by Novartis under the terms of the Noden Purchase Agreement while transfer of the marketing authorization rights were pending. The Company presents revenue under the Novartis transition arrangement on a "net" basis and established a reserve for retroactive adjustment to the profit transfer with Novartis.

Beginning on October 5, 2016, Noden Pharma USA, Inc. distributed the Noden Products in the United States. The Company presented revenue for all sales in the United States on a "gross" basis and established a reserve for allowances.

For the period from October 5, 2016 to August 31, 2017, Novartis continued to distribute the Noden products outside of the United States. Beginning on September 1, 2017, Noden Pharma DAC began distributing the Noden Products to select countries outside the United States. The Company presents revenue for Noden Products sold by Novartis outside of the United States on a "net" basis. As of the third quarter of 2018, Noden Pharma DAC completed the marketing authorization transfers for all territories.

For licenses that are bundled with other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front license fees. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

### *Medical Devices*

The Medical Devices segment of the Company principally generates revenue from the sale and lease of the LENSAR® Laser System, which may include equipment, Patient Interface Devices ("PIDs"), procedure licenses, and training, installation, warranty and maintenance agreements.

For bundled packages, the Company accounts for individual products and services separately if they are distinct - i.e. if a product or service is separately identifiable from other items in the bundled package and if the customer can benefit from it on its own or with other resources that are readily available to the customer. The LENSAR® Laser system, standard warranty training and

installation services are one performance obligation. All other elements are separate performance obligations. PIDs, procedure licenses, warranty and maintenance services are also sold on a stand-alone basis.

As the Company both sells and leases the LENSAR<sup>®</sup> Laser System, the consideration (including any discounts) is first allocated between lease and non-lease components and then allocated between the separate products and services based on their stand-alone selling prices. The stand-alone selling prices for the PIDs and procedure licenses are determined based on the prices at which the Company separately sells the PIDs and procedure licenses. The LENSAR<sup>®</sup> Laser System and warranty stand-alone selling prices are determined using the expected cost plus a margin approach.

For LENSAR<sup>®</sup> Laser System sales, the Company recognizes revenue in product revenue when a customer takes possession of the system. This usually occurs after the customer signs a contract, LENSAR installs the system, and LENSAR performs the requisite training for use of the system. For LENSAR<sup>®</sup> Laser System leases, the Company recognizes revenue in product revenue over the length of the lease in accordance with ASC Topic 840, *Leases*.

The LENSAR<sup>®</sup> Laser System requires both a consumable, a PID, and a procedure license to perform each procedure. The Company recognizes revenue for PIDs in product revenue when the customer takes possession of the PID. PIDs are sold by the case. The Company recognizes revenue for procedure licenses in product revenue when a customer purchases a procedure license from the web portal. Typically, consideration for PIDs and procedure licenses is considered fixed consideration except for certain customer agreements that provide for tiered volume discount pricing which is considered variable consideration.

The Company offers an extended warranty that provides additional services beyond the standard warranty. The Company recognizes revenue from the sale of extended warranties in product revenue over the warranty period. Customers have the option of renewing the warranty period, which is considered a new and separate contract.

#### *Income Generating Assets*

Licenses of intellectual property: If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license.

In January 2018, DFM, LLC, a wholly-owned subsidiary of the Company, granted an exclusive license related to certain Direct Flow Medical assets in exchange for \$0.5 million in cash and up to \$2.0 million in royalty payments. The \$0.5 million payment was accounted for in accordance with ASC 606 under which the full cash payment was recognized as revenue in the first quarter of 2018 as DFM, LLC had fulfilled its performance obligation under the agreement.

#### *Queen et al. Royalty Revenues*

Under the Company's license agreements related to patents covering the humanization of antibodies, which it refers to as the Queen et al. patents, the Company receives royalty payments based upon its licensees' net sales of covered products. Royalties qualify for the sales-and-usage exemption under ASC 606 as (i) royalties are based strictly on the sales-and-usage by the licensee; and (ii) a license of intellectual property is the sole or predominant item to which such royalties relate. Based on this exemption, these royalties are earned under the terms of a license agreement in the period the products are sold by the Company's partner and the Company has a present right to payment. Generally, under these agreements, the Company receives royalty reports from its licensees approximately one quarter in arrears; that is, generally in the second month of the quarter after the licensee has sold the royalty-bearing product. The Company recognizes royalty revenues when it can reliably estimate such amounts and collectability is reasonably assured. Under this accounting policy, the royalty revenues the Company reports are not based upon estimates, and such royalty revenues are typically reported in the same period in which the Company receives payment from its licensees.

Although the last of the Queen et al. patents expired in December 2014, the Company has received royalties beyond expiration based on the terms of its licenses and its legal settlement. Under the terms of the legal settlement between Genentech, Inc. ("Genentech") and the Company, the first quarter of 2016 was the last period for which Genentech paid royalties to the Company for Avastin<sup>®</sup>, Herceptin<sup>®</sup>, Xolair<sup>®</sup>, Perjeta<sup>®</sup> and Kadcyla<sup>®</sup>. Other products from the Queen et al. patent licenses, such as Tysabri<sup>®</sup>, entitle the Company to royalties following the expiration of its patents with respect to sales of licensed product manufactured prior to patent expiry in jurisdictions providing patent protection licenses. In November 2017, the Company was notified by Biogen, Inc. that product supply for Tysabri<sup>®</sup> that was manufactured prior to patent expiry, and for which the Company would receive royalties on, had been extinguished in the United States and was rapidly being reduced in other countries. As a result, royalties from product sales of Tysabri were substantially lower in 2018 and no additional royalties are expected.

### ***Royalty Rights - At Fair Value***

Currently, the Company accounts for its investments in royalty rights at fair value with changes in fair value presented in earnings. The fair value of the investments in royalty rights is determined by using a discounted cash flow analysis related to the expected future cash flows to be received. These assets are classified as Level 3 assets within the fair value hierarchy, as the Company's valuation estimates utilize significant unobservable inputs, including estimates as to the probability and timing of future sales of the related products. Transaction-related fees and costs are expensed as incurred.

The changes in the estimated fair value from investments in royalty rights along with cash receipts in each reporting period are presented together on the Company's Consolidated Statements of Operations as a component of revenue under the caption, "Royalty rights - change in fair value."

Realized gains and losses on royalty rights are recognized as they are earned and when collection is reasonably assured. Royalty Rights revenue is recognized over the respective contractual arrangement period. Critical estimates may include product demand and market growth assumptions, inventory target levels, product approval, pricing assumptions and the impact of competition from other branded or generic products. Factors that could cause a change in estimates of future cash flows include a change in estimated market size, a change in pricing strategy or reimbursement coverage, a delay in obtaining regulatory approval, a change in dosage of the product a change in the number of treatments and the entrants of new competitors or generic products. For each arrangement, the Company is entitled to royalty payments based on revenue generated by the net sales of the product.

### ***Foreign Currency Hedging***

From time to time, the Company may enter into foreign currency hedges to manage exposures arising in the normal course of business and not for speculative purposes.

The Company hedged certain Euro-denominated currency exposures related to royalties associated with its licensees' product sales with Euro forward contracts. In general, those contracts were intended to offset the underlying Euro market risk in the Company's royalty revenues. The last of those contracts expired in the fourth quarter of 2015 and was settled in the first quarter of 2016. The Company designated foreign currency exchange contracts used to hedge royalty revenues based on underlying Euro-denominated licensee product sales as cash flow hedges.

The fair value of the Euro forward contracts was estimated using pricing models with readily observable inputs from actively quoted markets and was disclosed on a gross basis. The aggregate unrealized gains or losses, net of tax, on the effective component of the hedge was recorded in stockholders' equity as "Accumulated other comprehensive income." Realized gains or losses on cash flow hedges are recognized as an adjustment to royalty revenue in the same period that the hedged transaction impacts earnings as royalty revenue. Any gain or loss on the ineffective portion of these hedge contracts is reported in "Interest and other income, net" in the period the ineffectiveness occurs.

### ***Foreign Currency Translation***

The Company uses the U.S. dollar predominately as the functional currency of its foreign subsidiaries. For foreign subsidiaries where the U.S. dollar is the functional currency, gains and losses from remeasurement of foreign currency balances into U.S. dollars are included in the Consolidated Statements of Operations. The aggregate net gains (losses) resulting from foreign currency transactions and remeasurement of foreign currency balances into U.S. dollars that were included in the Consolidated Statements of Operations amounted to a \$0.7 million loss, \$0.1 million gain and less than \$0.1 million gain for the years ended December 31, 2018, 2017 and 2016, respectively.

### ***Comprehensive (Loss) Income***

Comprehensive (loss) income comprises net (loss) income adjusted for other comprehensive (loss) income, using the specific identification method, which includes the changes in unrealized gains and losses on cash flow hedges and changes in unrealized gains and losses on the Company's investments in available-for-sale securities, all net of tax, which are excluded from the Company's net (loss) income.

## ***Income Taxes***

The provision for income taxes is determined using the asset and liability approach. Tax laws require items to be included in tax filings at different times than the items are reflected in the Consolidated Financial Statements. A current liability is recognized for the estimated taxes payable for the current year. Deferred taxes represent the future tax consequences expected to occur when the reported amounts of assets and liabilities are recovered or paid. Deferred taxes are adjusted for enacted changes in tax rates and tax laws. Valuation allowances are recorded to reduce deferred tax assets when it is more likely than not that a tax benefit will not be realized.

The Company recognizes tax benefits from uncertain tax positions only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the consolidated financial statements from such positions are then measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement. The Company adjusts the level of the liability to reflect any subsequent changes in the relevant facts surrounding the uncertain positions. Any interest and penalties on uncertain tax positions are included within the tax provision.

The Tax Cuts and Job Act of 2017 (the “2017 Tax Act”) significantly changed the existing U.S. corporate income tax laws by, among other things, lowering the corporate tax rate (from a top rate of 35% to a flat rate of 21%), implementing elements of a territorial tax system, and imposing a one-time deemed repatriation transition tax on cumulative undistributed foreign earnings, for which we have not previously paid U.S. taxes. The Company recognized the estimated tax impact related to the revaluation of deferred tax assets and liabilities in its Consolidated Financial Statements for the year ended December 31, 2017. The ultimate impact did not differ materially from these provisional amounts after additional analysis, changes in interpretations and assumptions the Company made and additional regulatory guidance that was issued. The accounting was completed when the Company’s 2017 U.S. corporate income tax return was filed in 2018. The Company has made a policy election with respect to its treatment of potential global intangible low-taxed income (“GILTI”) to account for taxes on GILTI as a current-period expense as incurred.

## ***Business Combination***

The Company applies ASC 805, *Business combinations* (“ASC 805”), pursuant to which the cost of an acquisition is measured as the aggregate of the fair values at the date of exchange of the assets given, liabilities incurred, and equity instruments issued. The costs directly attributable to the acquisition are expensed as incurred. Identifiable assets, liabilities and contingent liabilities acquired or assumed are measured separately at their fair value as of the acquisition date, irrespective of the extent of any noncontrolling interests. The excess of the (i) the total of cost of acquisition, fair value of the noncontrolling interests and acquisition date fair value of any previously held equity interest in the acquiree over (ii) the fair value of the identifiable net assets of the acquiree is recorded as goodwill. If the cost of an acquisition is less than the fair value of the net assets of the subsidiary acquired, the difference is recognized directly in the Consolidated Statements of Operations as a bargain purchase gain.

## ***Lease Accounting and Lease Guarantee***

The Company accounts for operating leases by recording rent expense on a straight-line basis over the expected life of the lease, commencing on the date the Company gains possession of leased property. The Company includes tenant improvement allowances and rent holidays received from landlords and the effect of any rent escalation clauses as adjustments to straight-line rent expense over the expected life of the lease.

Capital leases are reflected as a liability at the inception of the lease based on the present value of the minimum lease payments or, if lower, the fair value of the property. Assets under capital leases are recorded in property and equipment, net on the Company’s Consolidated Balance Sheets and depreciated in a manner consistent with other property and equipment.

## ***Adopted Accounting Pronouncements***

In October 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2016-01, *Recognition and Measurement of Financial Assets and Financial Liabilities*. The new standard requires equity securities (including other ownership interests, such as partnerships, unincorporated joint ventures, and limited liability companies) to be measured at fair value with changes in the fair value recognized through net income. Under the previous guidance, changes in the fair value of equity securities were recognized through other comprehensive income. Effective January 1, 2018, the Company

adopted the requirements of ASU No. 2016-01. The adoption did not have an effect on the Consolidated Financial Statements on the adoption date and no adjustment to prior year Consolidated Financial Statements was required.

In August 2016, the FASB issued ASU No. 2016-15, *Classification of Certain Cash Receipts and Cash Payments*. The new standard provides for specific guidance how certain transactions are classified in the statement of cash flows. Effective January 1, 2018, the Company adopted the requirements of ASU No. 2016-15. The adoption did not have an effect on the Consolidated Financial Statements on the adoption date and no adjustment to prior year Consolidated Financial Statements was required.

In October 2016, the FASB issued ASU No. 2016-16, *Intra-Entity Transfers of Assets Other Than Inventory*, which requires companies to account for the income tax effects of intercompany sales and transfers of assets other than inventory in the period in which the transfer occurs. Effective January 1, 2018, the Company adopted the requirements of ASU No. 2016-16. The adoption did not have an effect on the Consolidated Financial Statements on the adoption date and no adjustment to prior year Consolidated Financial Statements was required.

In November 2016, the FASB issued ASU No. 2016-18, *Restricted Cash*, which requires entities to show the changes in total of cash, cash equivalents, restricted cash and restricted cash equivalents in the statement of cash flows. Effective January 1, 2018, the Company adopted the requirements of ASU No. 2016-18. The adoption did not have an effect on the Consolidated Financial Statements on the adoption date and no adjustment to prior year Consolidated Financial Statements was required.

### ***Recently Issued Accounting Pronouncements***

In February 2016, the FASB issued ASU No. 2016-02, *Leases*, which outlines a comprehensive lease accounting model that supersedes the current lease guidance and requires lessees to recognize lease liabilities and corresponding right-of-use assets for all leases with lease terms greater than 12 months. The guidance also changes the definition of a lease and expands the disclosure requirements of lease arrangements. The new standard is to be applied using either a modified retrospective approach, or an optional transition method that allows an entity to apply the new standard at the adoption date with a cumulative effect adjustment to the opening balance of retained earnings in the period of adoption and will be effective for the Company starting with the first quarter of 2019, with early adoption permitted. Effective the first quarter of 2019, the Company will adopt the standard, using a modified retrospective approach. The Company does not expect the adoption will have a material impact on its consolidated statement of earnings. However, the new standard will require the Company to establish liabilities and corresponding right-of-use assets on its Consolidated Balance Sheet for operating leases that exist as of the January 1, 2019 adoption date.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses: Measurement of Credit Losses on Financial Instruments*. The new guidance amends the impairment model to utilize an expected loss methodology in place of the currently used incurred loss methodology, which will result in more timely recognition of losses. ASU No. 2016-13 has an effective date of the fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. The Company is currently evaluating ASU No. 2016-13 and assessing the impact, if any, it may have to the Company's Consolidated Financial Statements.

In January 2017, the FASB issued ASU 2017-04, *Intangibles-Goodwill and Other: Simplifying the Test for Goodwill Impairment*, to simplify the subsequent measurement of goodwill by eliminating step two from the goodwill impairment test. Under the amendments, an entity will recognize an impairment charge for the amount by which the carrying value exceeds the fair value. The amendments are effective for fiscal years and interim periods within those years beginning after December 15, 2019 on a prospective basis and early adoption is permitted. The Company is currently evaluating the impact of this guidance on the Company's Consolidated Financial Statements.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement*. The new guidance modifies disclosure requirements related to fair value measurement. The amendments in this ASU are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Implementation on a prospective or retrospective basis varies by specific disclosure requirement. Early adoption is permitted. The standard also allows for early adoption of any removed or modified disclosures upon issuance of this ASU while delaying adoption of the additional disclosures until their effective date.

In August 2018, the FASB issued ASU No. 2018-15, *Intangibles-Goodwill and Other-Internal-Use Software: Customer's Accounting for Implementation costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*. The new guidance reduces complexity for the accounting for costs of implementing a cloud computing service arrangement and aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal use software license). The new guidance will become effective for the Company on January 1, 2020. Early

adoption is permitted. Implementation should be applied either retrospectively or prospectively to all implementation costs incurred after the date of adoption. The Company is currently evaluating the impact the adoption of this guidance will have on its Consolidated Financial Statements.

### 3. Revenue from Contracts with Customers

#### *Disaggregation of Revenue*

The Company disaggregates its revenue from contracts with customers by segment and geographic location as the Company believes it best depicts how the nature, amount, timing and uncertainty of its revenue and cash flows are affected by economic factors. In the following table, revenue is disaggregated by segment and primary geographical market for the year ended December 31, 2018:

<i>(in thousands)</i>	Year Ended December 31, 2018	
	Medical Devices	Pharmaceutical
<b>Primary geographical markets:</b>		
North America .....	\$ 7,425	\$ 41,900
Europe .....	2,451	25,259
Asia.....	7,136	13,637
Other.....	377	—
Total revenue from contracts with customers <sup>1</sup> .....	<u>\$ 17,389</u>	<u>\$ 80,796</u>

<sup>1</sup> The table above does not include lease revenue from the Company's Medical Devices segment of \$7.3 million.

#### *Contract Balances*

The following table provides information about receivables, contract assets and contract liabilities from contracts with customers:

<i>(in thousands)</i>	December 31, 2018	January 1, 2018
Receivables, current and non-current, net.....	\$ 20,655	\$ 30,771
Contract assets .....	\$ 2,595	\$ —
Contract liabilities.....	\$ 8,938	\$ 10,084

**Receivables, Net**—Receivables, net, include amounts billed and currently due from customers. The amounts due are stated at their net estimated realizable value. The Company maintains an allowance for doubtful accounts to provide for the estimated amount of receivables that will not be collected. The allowance is based upon an assessment of customer creditworthiness, historical payment experience, the age of outstanding receivables and collateral to the extent applicable.

**Contract Assets**—The Company's contract assets represent revenue recognized for performance obligations completed before an unconditional right to payment exists, and therefore invoicing or associated reporting from the customer regarding the computation of the net product sales has not yet occurred. The Company classifies contract assets in prepaid and other current assets in the Company's consolidated balance sheet based on the timing of when it expects to receive payment.

<i>(in thousands)</i>	Medical Devices	Pharmaceutical	Total
Contract assets at January 1, 2018.....	\$ —	\$ —	\$ —
Contract assets recognized.....	—	2,595	2,595
Contract assets at December 31, 2018.....	<u>\$ —</u>	<u>\$ 2,595</u>	<u>\$ 2,595</u>

**Contract Liabilities**—The Company's contract liabilities consist of deferred revenue for products sold to customers for which the performance obligation has not been satisfied by the Company. The Company classifies deferred revenue as current or noncurrent based on the timing of when it expects to recognize revenue. The noncurrent portion of deferred revenue is included in other long-term liabilities in the Company's condensed consolidated balance sheets.

<i>(in thousands)</i>	<b>Medical Devices</b>	<b>Pharmaceutical</b>	<b>Total</b>
Contract liabilities at January 1, 2018 .....	\$ 1,391	\$ 8,693	\$ 10,084
Additions.....	834	7,771	8,605
Amounts recognized into revenue .....	(1,058)	(8,693)	(9,751)
Contract liabilities at December 31, 2018 .....	<u>\$ 1,167</u>	<u>\$ 7,771</u>	<u>\$ 8,938</u>

#### *Transaction Price Allocated to Remaining Performance Obligations*

The following table includes estimated revenue expected to be recognized in the future related to performance obligations that are unsatisfied (or partially unsatisfied) at the end of the reporting period.

<i>(in thousands)</i>	<b>Twelve months ended</b>		
	<b>December 31, 2019</b>	<b>Thereafter</b>	<b>Total</b>
Pharmaceutical product sales.....	\$ 1,000	\$ —	\$ 1,000
Medical device sales .....	\$ 3,419	\$ 2,627	\$ 6,046

The Company does not disclose the transaction price allocated to remaining performance obligations for (i) contracts with original expected lengths of one year or less or (ii) contracts for which the Company recognizes revenue at the amount to which it has the right to invoice for the products delivered or services performed.

#### **4. Net (Loss) Income per Share**

##### **Net (Loss) Income per Basic and Diluted Share**

*(in thousands, except per share amounts)*

	<b>Year Ended December 31,</b>		
	<b>2018</b>	<b>2017</b>	<b>2016</b>
<b>Numerator</b>			
(Loss) income attributable to the PDL's shareholders used to compute net (loss) income per basic and diluted share.....	<u>\$ (68,859)</u>	<u>\$ 110,748</u>	<u>\$ 63,606</u>
<b>Denominator</b>			
Total weighted-average shares used to compute net (loss) income attributable to PDL's shareholders, per basic share.....	145,669	155,394	163,805
Restricted stock outstanding .....	—	863	387
Shares used to compute net (loss) income attributable to PDL's shareholders, per diluted share .....	<u>145,669</u>	<u>156,257</u>	<u>164,192</u>
<b>Net (loss) income attributable to PDL's shareholders, per share - basic...</b>	\$ (0.47)	\$ 0.71	\$ 0.39
<b>Net (loss) income attributable to PDL's shareholders, per share - diluted.....</b>	\$ (0.47)	\$ 0.71	\$ 0.39

The computation of basic earnings per share ("EPS") is based on the weighted-average number of the Company's common shares outstanding. The computation of diluted EPS is based on the weighted-average number of the Company's common shares outstanding and dilutive potential common shares, which may be issued pursuant to outstanding stock options and restricted stock awards using the treasury stock method, and the 4.0% Convertible Senior Notes due February 1, 2018 (the "February 2018 Notes") that were repaid on February 1, 2018 and the 2.75% Convertible Senior Notes due December 1, 2021 (the "December 2021 Notes"), in each case, for the period that the notes were outstanding, including, if applicable, the effect of adding back interest expense and the underlying shares using the if converted method.

#### *December 2021 Notes Capped Call Potential Dilution*

In November 2016, the Company issued \$150.0 million in aggregate principal of the December 2021 Notes, which provide in certain situations for the conversion of the outstanding principal amount of the December 2021 Notes into shares of the Company's common stock at a predefined conversion rate. For additional information on the conversion rates on the Company's



convertible debt, see Note 16, *Term Loan and Convertible Senior Notes*. In conjunction with the issuance of the December 2021 Notes, the Company entered into a capped call transaction, with a hedge counterparty. The capped call transaction is expected generally to reduce the potential dilution, and/or offset, to an extent, the cash payments the Company may choose to make in excess of the principal amount, upon conversion of the December 2021 Notes. The Company has excluded the capped call transaction from the net (loss) income per diluted share computation as such securities would have an anti-dilutive effect and those securities should be considered separately rather than in the aggregate in determining whether their effect on net (loss) income per diluted share would be dilutive or anti-dilutive. For additional information regarding the capped call transaction related to the Company's December 2021 Notes; see Note 16, *Term Loan and Convertible Senior Notes*.

#### *Anti-Dilutive Effect of Stock Options and Restricted Stock Awards*

For the years ended December 31, 2018 and 2017, the Company excluded approximately 3,892,000 and 502,000 shares underlying outstanding stock options, respectively, calculated on a weighted-average basis, from the Company's net (loss) income per diluted share calculations because their effect was anti-dilutive. There were no outstanding options for the year ended December 31, 2016. For the years ended December 31, 2018, 2017 and 2016, the Company excluded approximately 1,139,000, 1,830,000, and 1,107,000 shares, respectively, underlying restricted stock awards, calculated on a weighted-average basis, from the Company's net (loss) income per diluted share calculations because their effect was anti-dilutive.

## 5. Fair Value Measurements

### *Assets/Liabilities Measured and Recorded at Fair Value on a Recurring Basis*

The following table presents the fair value of the Company's financial instruments measured at fair value on a recurring basis by level within the valuation hierarchy, as discussed in Note 2, *Summary of Significant Accounting Policies*:

<i>(in thousands)</i>	December 31, 2018				December 31, 2017			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Financial assets:								
Money market funds .....	\$ 226,719	\$ —	\$ —	\$ 226,719	\$ 417,563	\$ —	\$ —	\$ 417,563
Corporate securities .....	—	—	—	—	4,848	—	—	4,848
Warrants .....	—	62	—	62	—	29	—	29
Royalty rights - at fair value .....	—	—	376,510	376,510	—	—	349,223	349,223
Total .....	<u>\$ 226,719</u>	<u>\$ 62</u>	<u>\$ 376,510</u>	<u>\$ 603,291</u>	<u>\$ 422,411</u>	<u>\$ 29</u>	<u>\$ 349,223</u>	<u>\$ 771,663</u>
Financial liabilities:								
Contingent consideration, current .....	\$ —	\$ —	\$ 1,071	\$ 1,071	\$ —	\$ —	\$ —	\$ —
Contingent consideration, non-current .....	—	—	—	—	—	—	42,000	42,000
Total .....	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 1,071</u>	<u>\$ 1,071</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 42,000</u>	<u>\$ 42,000</u>

<sup>1</sup> Contingent consideration, current is classified as "Accrued liabilities" on the Consolidated Balance Sheet. See Note 14, *Accrued Liabilities*, for details.

There have been no transfers between levels during the periods presented in the table above. The Company recognizes transfers between levels on the date of the event or change in circumstances that caused the transfer.

### *Corporate Securities*

Corporate securities consisted primarily of U.S. corporate equity holdings. The fair value of corporate securities was estimated using market quoted prices.

## ***Warrants***

Warrants consist primarily of purchased call options to buy U.S. corporate equity holdings and derivative assets acquired as part of note receivable investments. The fair value of the warrants is estimated using recently quoted market prices of the underlying equity security and the Black-Scholes option pricing model.

## ***Royalty Rights - At Fair Value***

### *Depomed Royalty Agreement*

On October 18, 2013, the Company entered into the Royalty Purchase and Sale Agreement (the “Depomed Royalty Agreement”) with Depomed, Inc. and Depo DR Sub, LLC (together, “Depomed”), whereby the Company acquired the rights to receive royalties and milestones payable on sales of five Type 2 diabetes products licensed by Depomed in exchange for a \$240.5 million cash payment. Total consideration was \$241.3 million, which was comprised of the \$240.5 million cash payment to Depomed and \$0.8 million in transaction costs.

The rights acquired include Depomed’s royalty and milestone payments accruing from and after October 1, 2013: (a) from Santarus, Inc. (“Santarus”), which was subsequently acquired by Salix Pharmaceuticals, Inc. (“Salix”), which itself was acquired by Valeant Pharmaceuticals International, Inc. (“Valeant”), which, in July 2018, changed its name to Bausch Health Companies Inc. (hereafter referred to as “Bausch Health”) with respect to sales of Glumetza (metformin HCL extended-release tablets) in the United States; (b) from Merck & Co., Inc. with respect to sales of Janumet<sup>®</sup> XR (sitagliptin and metformin HCL extended-release tablets); (c) from Janssen Pharmaceutica N.V. with respect to potential future development milestones and sales of its approved fixed-dose combination of Invokana<sup>®</sup> (canagliflozin, a sodium glucose cotransporter 2 (SGLT2) inhibitor) and extended-release metformin tablets, marketed as Invokamet XR<sup>®</sup>; (d) from Boehringer Ingelheim and Eli Lilly and Company with respect to potential future development milestones and sales of the investigational fixed-dose combinations of drugs and extended-release metformin subject to Depomed’s license agreement with Boehringer Ingelheim, including its approved products, Jentaduetto XR<sup>®</sup> and Synjardy XR<sup>®</sup>; and (e) from LG Life Sciences and Bausch Health for sales of extended-release metformin tablets in Korea and Canada, respectively.

On August 2, 2018, PDL Investment Holding, LLC (“PDLIH”), a wholly-owned subsidiary of the Company and assignee from the Company under the Depomed Royalty Agreement, entered into an amendment to the Depomed Royalty Agreement with Depomed. Pursuant to the amendment, PDLIH purchased all of Depomed’s remaining interests in royalty and milestone payments payable on sales of Type 2 diabetes products licensed by Depomed for \$20.0 million. Prior to the amendment, the Depomed Royalty Agreement provided that the Company would have received all royalty and milestone payments due under license agreements between Depomed and its licensees until the Company received payments equal to two times the cash payment it made to Depomed, or approximately \$481.0 million, after which all net payments received by Depomed would have been shared equally between the Company and Depomed. Following the amendment, the Depomed Royalty Agreement provides that the Company will receive all royalty and milestone payments due under the license agreements between Depomed and its licensees. The Company has elected to continue to elect the fair value option and carry the financial asset at fair value.

The Depomed Royalty Agreement terminates on the third anniversary following the date upon which the later of the following occurs: (a) October 25, 2021, or (b) at such time as no royalty payments remain payable under any license agreement and each of the license agreements has expired by its terms.

As of December 31, 2017, the Company determined that its royalty purchase interest in Depo DR Sub, LLC represented a variable interest in a variable interest entity. However, the Company did not have the power to direct the activities of Depo DR Sub, LLC that most significantly impact Depo DR Sub, LLC’s economic performance and was not the primary beneficiary of Depo DR Sub, LLC; therefore, Depo DR Sub, LLC was not subject to consolidation by the Company.

As of December 31, 2018, in conjunction with the amendment described above, the Company was provided the power to direct the activities of Depo DR Sub, LLC and is the primary beneficiary of Depo DR Sub, LLC; therefore, Depo DR Sub, LLC is subject to consolidation by the Company. As of December 31, 2018, Depo DR Sub, LLC did not have any assets or liabilities of value for consolidation with the Company.

The financial asset acquired represents a single unit of accounting. The fair value of the financial asset acquired was determined by using a discounted cash flow analysis related to the expected future cash flows to be generated by each licensed product. This financial asset is classified as a Level 3 asset within the fair value hierarchy, as the Company’s valuation utilized significant unobservable inputs, including estimates as to the probability and timing of future commercialization for products not yet

approved by regulatory agencies outside of the United States. The discounted cash flows are based upon expected royalties from sales of licensed products over approximately a nine-year period. The discount rates utilized range from 10% to 24%. Significant judgment is required in selecting appropriate discount rates. At December 31, 2018, an evaluation was performed to assess those rates and general market conditions potentially affecting the fair market value of the financial asset. Should these discount rates increase or decrease by 2.5%, the fair value of the asset could decrease by \$22.9 million or increase by \$27.2 million, respectively. A third-party expert was engaged to assist management develop its original estimate of the expected future cash flows, which was updated after the acquisition of Depomed's reversionary interest in August 2018. The estimated fair value of the asset is subject to variation should those cash flows vary significantly from those estimates. The Company periodically assesses the expected future cash flows and to the extent such payments are greater or less than its initial estimates, or the timing of such payments is materially different than the original estimates, the Company will adjust the estimated fair value of the asset. Should the expected royalties increase or decrease by 2.5%, the fair value of the asset could increase or decrease by \$6.6 million, respectively.

When the Company acquired the Depomed royalty rights, Glumetza was marketed by Santarus. In January 2014, Salix acquired Santarus and assumed responsibility for commercializing Glumetza, which was generally perceived to be a positive development because of Salix's larger sales force and track record in the successful commercialization of therapies. In late 2014, Salix made a number of disclosures relating to an excess of supply at the distribution level of Glumetza and other drugs that it commercialized and the practices leading to this excess of supply which were under review by Salix's audit committee in relation to the related accounting practices. Because of these disclosures and the Company's lack of direct access to information as to the levels of inventory of Glumetza in the distribution channels, the Company commenced a review of all public statements by Salix, publicly available historical third-party prescription data, analyst reports and other relevant data sources. The Company also engaged a third-party expert to specifically assess estimated inventory levels of Glumetza in the distribution channel and to ascertain the potential effects those inventory levels may have on expected future cash flows. Salix was acquired by Valeant in early April 2015. In mid-2015, Valeant implemented two price increases on Glumetza. At year-end 2015, a third-party expert was engaged by the Company to assess the impact of the Glumetza price adjustments and near-term market entrance of generic equivalents to the expected future cash flows. Based on the analysis performed, management revised the underlying assumptions used in the discounted cash flow analysis at year-end 2015. In February 2013 a generic equivalent to Glumetza was approved by the U.S. Food and Drug Administration ("FDA") and in August 2016, two additional generic equivalents to Glumetza were approved to enter the U.S. market. In February 2016, Lupin Pharmaceuticals, Inc., in August 2017, Teva Pharmaceutical Industries Ltd., and in July 2018, Sun Pharmaceutical, Inc. ("Sun") each launched a generic equivalent approved product.

In May 2017, the Company received notification that a subsidiary of Valeant had launched an authorized generic equivalent product in February 2017, and the Company received royalties on such authorized generic equivalent product under the same terms as the branded Glumetza product, retroactive to February 2017.

In February 2016, at the Company's request and pursuant to the Depomed Royalty Agreement, Depomed exercised its audit right with respect to Glumetza royalties. The independent auditor engaged to perform the royalty audit completed it in July 2017, and based upon the results of the audit, Depomed, on behalf of the Company, filed a lawsuit on September 7, 2017, against Valeant and one of its subsidiaries, claiming damages for unpaid royalties, fees and interest. Valeant (now Bausch Health), Depomed and the Company entered into a settlement agreement on October 27, 2017 whereby the parties agreed to dismiss the litigation, with prejudice, and Valeant agreed to pay to Depomed \$13.0 million. The full amount of the settlement payment was transferred to the Company under the terms of the Depomed Royalty Agreement in November 2017. In October 2018, PDL submitted notice of its intent to exercise its audit right under the Depomed Royalty Agreement with respect to the period beginning January 1, 2016 and ending December 31, 2018.

At December 31, 2018, management re-evaluated, with assistance of a third-party expert, the market share data, the gross-to-net revenue adjustment assumptions and Glumetza demand data. These data and assumptions are based on available but limited information. At December 31, 2018, management updated the expected future cash flows based on the current period demand and supply data of Glumetza and the authorized generic equivalent product launched by Bausch Health.

As of December 31, 2018, the Company's discounted cash flow analysis reflects its expectations as to the amount and timing of future cash flows up to the valuation date, including future cash flows for the authorized generic equivalent product. The Company continues to monitor whether the generic competition further affects sales of Glumetza and thus royalties on such sales paid to the Company, and the impact of the launched authorized generic equivalent. Due to the uncertainty around Bausch Health's marketing and pricing strategy, as well as Sun's recently launched generic product and limited historical demand data after generic market entrance, the Company may need to further evaluate future cash flows in the event of more rapid reduction or increase in market share of Glumetza and its authorized generic equivalent product and/or a further erosion in net pricing.

On May 31, 2016, the Company obtained a notification indicating that the FDA approved Jentaduet XR for use in patients with Type 2 diabetes. In June 2016, the Company received a \$6.0 million FDA approval milestone pursuant to the terms of the Depomed Royalty Agreement. The product approval was earlier than initially expected. Based on the FDA approval and anticipated timing of the product launch, the Company adjusted the timing of future cash flows and discount rate used in the discounted cash flow model at June 30, 2016. At year-end 2017, management re-evaluated, with assistance of a third-party expert, the cash flow assumptions for Jentaduet XR and revised the discounted cash flow model. As of December 31, 2018, the Company's discounted cash flow analysis reflects its expectations as to the amount and timing of future cash flows up to the valuation date.

On September 21, 2016, the Company obtained a notification indicating that the FDA approved Invokamet XR for use in patients with Type 2 diabetes. The product approval triggered a \$5.0 million approval milestone payment to the Company pursuant to the terms of the Depomed Royalty Agreement. Based on the FDA approval and timing of the product launch, the Company adjusted the timing of future cash flows and discount rate used in the discounted cash flow model at December 31, 2017.

On December 13, 2016, the Company obtained a notification indicating that the FDA approved Synjardy XR for use in patients with Type 2 diabetes. The product approval triggered a \$6.0 million approval milestone payment to the Company pursuant to the terms of the Depomed Royalty Agreement. Based on the FDA approval and the April 2017 launch of Synjardy XR by Boehringer Ingelheim, the Company adjusted the timing of future cash flows and discount rate used in the discounted cash flow model at December 31, 2017.

In August 2018, Depomed, Inc. was renamed Assertio Therapeutics, Inc.

As of December 31, 2018, the fair value of the asset acquired as reported in the Company's Consolidated Balance Sheet was \$264.4 million and the maximum loss exposure was \$264.4 million.

#### *Viscogliosi Brothers Royalty Agreement*

On June 26, 2014, the Company entered into a Royalty Purchase and Sale Agreement (the "VB Royalty Agreement") with VB, whereby VB conveyed to the Company the right to receive royalties payable on sales of a spinal implant that has received pre-market approval from the FDA held by VB and commercialized by Paradigm Spine, LLC ("Paradigm Spine"), in exchange for a \$15.5 million cash payment, less fees.

The royalty rights acquired include royalties accruing from and after April 1, 2014. Under the terms of the VB Royalty Agreement, the Company receives all royalty payments due to VB pursuant to certain technology transfer agreements between VB and Paradigm Spine until the Company has received payments equal to 2.3 times the cash payment made to VB, after which all rights to receive royalties will be returned to VB. VB's ability to repurchase the royalty right for a specified amount expired on June 26, 2018.

The fair value of the royalty rights at December 31, 2018, was determined by using a discounted cash flow analysis related to the expected future cash flows to be received. This asset is classified as a Level 3 asset, as the Company's valuation utilized significant unobservable inputs, including estimates as to the probability and timing of future sales of the licensed product. The discounted cash flow was based upon expected royalties from sales of licensed product over approximately a ten-year period. The discount rate utilized was 15.0%. Significant judgment is required in selecting the appropriate discount rate. Should this discount rate increase or decrease by 2.5%, the fair value of this asset could decrease by \$1.4 million or increase by \$1.6 million, respectively. Should the expected royalties increase or decrease by 2.5%, the fair value of the asset could increase or decrease by \$0.4 million, respectively. A third-party expert is engaged to assist management with the development of its estimate of the expected future cash flows, when deemed necessary. The fair value of the asset is subject to variation should those cash flows vary significantly from the Company's estimates. At each reporting period, an evaluation is performed to assess those estimates, discount rate utilized and general market conditions affecting fair market value.

As of December 31, 2018, the fair value of the asset acquired as reported in the Company's Consolidated Balance Sheet was \$14.1 million and the maximum loss exposure was \$14.1 million.

#### *University of Michigan Royalty Agreement*

On November 6, 2014, the Company acquired a portion of all royalty payments of U-M worldwide royalty interest in Cerdelga<sup>®</sup> (eliglustat) for \$65.6 million pursuant to the Royalty Purchase and Sale Agreement with U-M (the "U-M Royalty Agreement"). Under the terms of the U-M Royalty Agreement, the Company receives 75% of all royalty payments due under U-M's license

agreement with Genzyme Corporation, a Sanofi company (“Genzyme”) until expiration of the licensed patents, excluding any patent term extension. Cerdelga, an oral therapy for adult patients with Gaucher disease type 1, was developed by Genzyme. Cerdelga was approved in the United States in August 2014, in the European Union in January 2015, and in Japan in March 2015. In addition, marketing applications for Cerdelga are under review by other regulatory authorities. While marketing applications have been approved in the United States, the European Union and Japan, national pricing and reimbursement decisions are delayed in some countries. A third-party expert is engaged by the Company to assist management with the development of its estimate of the expected future cash flows, when deemed necessary. Based on the analysis performed, management revised the underlying assumptions used in the discounted cash flow analysis. As of December 31, 2018, the Company’s discounted cash flow analysis reflects its expectations as to the amount and timing of future cash flows.

The fair value of the royalty right at December 31, 2018, was determined by using a discounted cash flow analysis related to the expected future cash flows to be received. This asset is classified as a Level 3 asset, as the Company’s valuation utilized significant unobservable inputs, including estimates as to the probability and timing of future sales of the licensed product. The discounted cash flow was based upon expected royalties from sales of licensed product over approximately a four-year period. The discount rate utilized was approximately 12.8%. Significant judgment is required in selecting the appropriate discount rate. Should this discount rate increase or decrease by 2.5%, the fair value of this asset could decrease by \$1.1 million or increase by \$1.2 million, respectively. Should the expected royalties increase or decrease by 2.5%, the fair value of the asset could increase or decrease by \$0.6 million, respectively. A third-party expert is engaged to assist management with the development of its estimate of the expected future cash flows, when deemed necessary. The fair value of the asset is subject to variation should those cash flows vary significantly from the Company’s estimates. An evaluation of those estimates, discount rate utilized and general market conditions affecting fair market value is performed in each reporting period.

As of December 31, 2018, the fair value of the asset acquired as reported in the Company’s Consolidated Balance Sheet was \$25.6 million and the maximum loss exposure was \$25.6 million.

#### *ARIAD Royalty Agreement*

On July 28, 2015, the Company entered into the revenue interest assignment agreement (the “ARIAD Royalty Agreement”) with ARIAD, whereby the Company acquired the rights to receive royalties from ARIAD’s net revenues generated by the sale, distribution or other use of Iclusig<sup>®</sup> (ponatinib), a cancer medicine for the treatment of adult patients with chronic myeloid leukemia, in exchange for up to \$200.0 million in cash payments. The purchase price of \$100.0 million was payable in two tranches of \$50.0 million each, with the first tranche having been funded on July 28, 2015 and the second tranche having been funded on July 28, 2016. Upon the occurrence of certain events, including a change of control of ARIAD, the Company had the right to require ARIAD to repurchase the royalty rights for a specified amount. The Company elected the fair value option to account for the hybrid instrument in its entirety. Any embedded derivative shall not be separated from the host contract. The asset acquired pursuant to the ARIAD Royalty Agreement represents a single unit of accounting.

In February 2017, Takeda Pharmaceutical Company Limited (“Takeda”) acquired ARIAD and the Company exercised its put option on the same day, which resulted in an obligation by Takeda to pay the Company a 1.2x multiple of the \$100.0 million funded by the Company under the ARIAD Royalty Agreement, less royalty payments already received by the Company.

On March 30, 2017, Takeda fulfilled its obligations under the put option and paid the Company the repurchase price of \$108.2 million for the royalty rights under the ARIAD Royalty Agreement.

#### *AcelRx Royalty Agreement*

On September 18, 2015, the Company entered into a royalty interest assignment agreement (the “AcelRx Royalty Agreement”) with ARPI LLC, a wholly-owned subsidiary of AcelRx, whereby the Company acquired the rights to receive a portion of the royalties and certain milestone payments on sales of Zalviso<sup>®</sup> (sufentanil sublingual tablet system) in the European Union, Switzerland and Australia by AcelRx’s commercial partner, Grünenthal, in exchange for a \$65.0 million cash payment. Under the terms of the AcelRx Royalty Agreement, the Company receives 75% of all royalty payments and 80% of the first four commercial milestone payments due under AcelRx’s license agreement with Grünenthal until the earlier to occur of (i) receipt by the Company of payments equal to three times the cash payments made to AcelRx and (ii) the expiration of the licensed patents. Zalviso received marketing approval by the European Commission in September 2015. Grünenthal launched Zalviso in the second quarter of 2016 and the Company started to receive royalties in the third quarter of 2016.

As of December 31, 2018 and 2017, the Company determined that its royalty rights under the AcelRx Royalty Agreement represented a variable interest in a variable interest entity. However, the Company does not have the power to direct the activities

of ARPI LLC that most significantly impact ARPI LLC's economic performance and is not the primary beneficiary of ARPI LLC; therefore, ARPI LLC is not subject to consolidation by the Company.

The fair value of the royalty right at December 31, 2018, was determined by using a discounted cash flow analysis related to the expected future cash flows to be received. This asset is classified as a Level 3 asset, as the Company's valuation utilized significant unobservable inputs, including estimates as to the probability and timing of future sales of the licensed product. The discounted cash flow was based upon expected royalties from sales of licensed product over approximately a fourteen-year period. The discount rate utilized was approximately 13.4%. Significant judgment is required in selecting the appropriate discount rate. Should this discount rate increase or decrease by 2.5%, the fair value of this asset could decrease by \$9.9 million or increase by \$12.2 million, respectively. Should the expected royalties increase or decrease by 2.5%, the fair value of the asset could increase or decrease by \$1.8 million, respectively. A third-party expert is engaged to assist management with the development of its estimate of the expected future cash flows, when deemed necessary. The fair value of the asset is subject to variation should those cash flows vary significantly from the Company's estimates. At December 31, 2018, management performed an evaluation of those estimates, discount rate utilized and general market conditions to determine the fair market value of the asset, and such an evaluation is performed for each reporting period. As of December 31, 2018, the Company's discounted cash flow analysis reflects its expectations as to the amount and timing of future cash flows up to the valuation date.

As of December 31, 2018, the fair value of the asset acquired as reported in the Company's Consolidated Balance Sheet was \$70.4 million and the maximum loss exposure was \$70.4 million.

#### *Kybella Royalty Agreement*

On July 8, 2016, the Company entered into a royalty purchase and sales agreement with an individual, whereby the Company acquired that individual's rights to receive certain royalties on sales of KYBELLA<sup>®</sup> by Allergan plc in exchange for a \$9.5 million cash payment and up to \$1.0 million in future milestone payments based upon product sales targets. The Company started to receive royalty payments during the third quarter of 2016.

The fair value of the royalty right at December 31, 2018, was determined by using a discounted cash flow analysis related to the expected future cash flows to be received. This asset is classified as a Level 3 asset, as the Company's valuation utilized significant unobservable inputs, including estimates as to the probability and timing of future sales of the licensed product. The discounted cash flow was based upon expected royalties from sales of a licensed product over approximately a seven-year period. The discount rate utilized was approximately 14.4%. Significant judgment is required in selecting the appropriate discount rate. Should this discount rate increase or decrease by 2.5%, the fair value of this asset could decrease or increase by \$0.2 million, respectively. Should the expected royalties increase or decrease by 2.5%, the fair value of the asset could increase or decrease by \$0.1 million, respectively. A third-party expert is engaged to assist management with the development of its estimate of the expected future cash flows, when deemed necessary. The fair value of the asset is subject to variation should those cash flows vary significantly from the Company's estimates. An evaluation of those estimates, discount rate utilized and general market conditions affecting fair market value is performed in each reporting period.

As of December 31, 2018, the fair value of the asset acquired as reported in the Company's Consolidated Balance Sheet was \$2.1 million and the maximum loss exposure was \$2.1 million.

The following tables summarize the changes in Level 3 Royalty Right Assets and the gains and losses included in earnings for the year ended December 31, 2018:

**Fair Value Measurements Using Significant Unobservable Inputs (Level 3) - Royalty Rights Assets**

<i>(in thousands)</i>	<b>Royalty Rights - At Fair Value</b>
Fair value as of December 31, 2017.....	\$ 349,223
Financial instruments purchased.....	20,000
Total net change in fair value for the period	
Change in fair value of royalty rights - at fair value.....	\$ 85,256
Proceeds from royalty rights - at fair value.....	\$ (77,969)
Total net change in fair value for the period.....	7,287
Fair value as of December 31, 2018.....	<u>\$ 376,510</u>

**Fair Value Measurements Using Significant Unobservable Inputs (Level 3) - Royalty Rights Assets**

<i>(in thousands)</i>	<b>Fair Value as of December 31, 2017</b>	<b>Purchase of Royalty Assets</b>	<b>Royalty Rights - Change in Fair Value</b>	<b>Fair Value as of December 31, 2018</b>
Assertio.....	\$ 232,038	\$ 20,000	\$ 12,333	\$ 264,371
VB.....	14,380	—	(272)	14,108
U-M.....	26,769	—	(1,174)	25,595
AcelRx.....	72,894	—	(2,514)	70,380
Avinger.....	396	—	(396)	—
KYBELLA.....	2,746	—	(690)	2,056
	<u>\$ 349,223</u>	<u>\$ 20,000</u>	<u>\$ 7,287</u>	<u>\$ 376,510</u>

The following table summarizes the changes in Level 3 Liabilities and the gains and losses included in earnings for the year ended December 31, 2018:

**Fair Value Measurements Using Significant Unobservable Inputs (Level 3) - Liabilities**

<i>(in thousands)</i>	<b>Contingent Consideration</b>
Fair value as of December 31, 2017.....	\$ (42,000)
Financial instruments purchased.....	(1,560)
Total net change in fair value for the period.....	41,631
Settlement of financial instrument.....	858
Fair value as of December 31, 2018.....	<u>\$ (1,071)</u>

The fair value of the contingent consideration was determined using an income approach derived from the revenue estimates and a probability assessment with respect to the likelihood of (a) achieving predetermined levels of net sales or (b) the launch of a generic version of aliskiren by a third party that would trigger the milestone payments to Novartis under the Noden Purchase Agreement. The key assumptions in determining the fair value are the discount rate and the probability assigned to the potential milestones being achieved. The fair value of the contingent consideration is remeasured each reporting period, with changes in fair value recorded in the Consolidated Statements of Operations. The significant decline in fair value of the contingent consideration during the year ending December 31, 2018 is due primarily to the increased probability of a third-party generic entry prior to the milestone date under the Noden Purchase Agreement and the change in fair value and partial settlement of the

contingent and conversion consideration acquired as part of the assets acquired by LENSAR from Precision Eye Services (“PES”), as described in Note 12, *Asset Acquisition*.

Gains and losses from changes in Level 3 assets included in earnings for each period are presented in “Royalty rights - change in fair value” and gains and losses from changes in Level 3 liabilities included in earnings for each period are presented in “Change in fair value of anniversary payment and contingent consideration” as follows:

<i>(in thousands)</i>	<b>Year Ended December 31,</b>	
	<b>2018</b>	<b>2017</b>
Total change in fair value for the period included in earnings for royalty right assets held at the end of the reporting period .....	\$ 85,256	\$ 162,327
Total change in fair value for the period included in earnings for liabilities held at the end of the reporting period .....	\$ 41,631	\$ (349)

*Assets/Liabilities Measured and Recorded at Fair Value on a Nonrecurring Basis*

The Company remeasures the fair value of certain assets and liabilities upon the occurrence of certain events. Such assets consist of long-lived assets, including property and equipment and intangible assets and the 1.7 million shares of Alphaeon Class A common stock, received in connection with the LENSAR credit agreement.

During the three months ended June 30, 2018, the Company recorded an impairment charge of \$152.3 million for the Noden intangible assets related to the increased probability of a generic version of aliskiren being launched in the United States. As a result of this impairment charge, which was based on the estimated fair value of the assets, the remaining carrying value of these intangible assets was determined to be \$40.1 million. The fair value calculation included level 3 inputs. For additional information on the impairment charge, see Note 13, *Intangible Assets*.

The Company’s carrying value of the investment in Alphaeon as of both December 31, 2018 and December 31, 2017 is \$6.6 million based on an estimated per share value of \$3.84, which was established by a valuation performed when the shares were acquired. The value of our investment in Alphaeon is not readily determinable as Alphaeon’s shares are not publicly traded. The Company evaluates the fair value of this investment by performing a qualitative assessment each reporting period. If the results of this qualitative assessment indicate that the fair value is less than the carrying value, the investment is written down to its fair value. There have been no such write downs since the Company acquired these shares. This investment is included in other long-term assets. For additional information on the Alphaeon investment, see Note 9, *Notes and Other Long-Term Receivables*.

*Assets/Liabilities Not Subject to Fair Value Recognition*

The following tables present the fair value of assets and liabilities not subject to fair value recognition by level within the valuation hierarchy:

<i>(in thousands)</i>	<b>December 31, 2018</b>			<b>December 31, 2017</b>		
	<b>Carrying Value</b>	<b>Fair Value Level 2</b>	<b>Fair Value Level 3</b>	<b>Carrying Value</b>	<b>Fair Value Level 2</b>	<b>Fair Value Level 3</b>
<b>Assets:</b>						
Wellstat Diagnostics note receivable .....	\$ 50,191	\$ —	\$ 57,322	\$ 50,191	\$ —	\$ 51,308
Hyperion note receivable .....	1,200	—	1,200	1,200	—	1,200
CareView note receivable .....	11,458	—	11,458	19,346	—	18,750
Total .....	<u>\$ 62,849</u>	<u>\$ —</u>	<u>\$ 69,980</u>	<u>\$ 70,737</u>	<u>\$ —</u>	<u>\$ 71,258</u>
<b>Liabilities:</b>						
February 2018 Notes .....	\$ —	\$ —	\$ —	\$ 126,066	\$ 126,131	\$ —
December 2021 Notes .....	124,644	151,356	—	117,415	148,028	—
Total .....	<u>\$ 124,644</u>	<u>\$ 151,356</u>	<u>\$ —</u>	<u>\$ 243,481</u>	<u>\$ 274,159</u>	<u>\$ —</u>



During the year ended December 31, 2018 we recorded an impairment loss of \$8.2 million to the CareView note receivable. There were no impairment losses on notes receivable in the years ended December 31, 2017 and 2016.

As of December 31, 2018 and 2017, the estimated fair values of the Hyperion Catalysis International, Inc. (“Hyperion”) note receivable and CareView note receivable, were determined using one or more discounted cash flow models, incorporating expected principal and interest payments. In addition, during the year ended December 31, 2018, the fair value of the CareView note receivable also considered the recoverability of the note receivable balance utilizing third-party revenue multiples for small cap healthcare technology companies. As of December 31, 2018 and 2017, the estimated fair value of the Wellstat Diagnostics note receivable were determined by using an asset approach and discounted cash flow model related to the underlying collateral and adjusted to consider estimated costs to sell the assets.

The Company engages a third-party valuation expert when deemed necessary to assist in evaluating its investments and the related inputs needed to estimate the fair value of certain investments. The Company determined its notes receivable assets are Level 3 assets as the Company’s valuations utilized significant unobservable inputs, including estimates of future revenues, discount rates, expectations about settlement, terminal values, required yield and the value of underlying collateral. To provide support for the estimated fair value measurements, the Company considered forward-looking performance related to the investment and current measures associated with high yield indices, and reviewed the terms and yields of notes placed by specialty finance and venture firms both across industries and in similar sectors.

The CareView note receivable is secured by substantially all assets of, and equity interests in, CareView. The Wellstat Diagnostics note receivable is secured by substantially all assets of Wellstat Diagnostics and is supported by a guaranty from the Wellstat Diagnostics Guarantors (as defined in Note 9, *Notes and Other Long-Term Receivables*).

On December 31, 2018, the carrying value of one of the Company’s notes receivable assets differed from its estimated fair value. This is the result of inputs used in estimating the fair value of the collateral, including appraisals, projected cash flows of collateral assets and discount rates used when performing a discounted cash flow analysis.

The fair values of the Company’s convertible senior notes were determined using quoted market pricing.

The following table represents significant unobservable inputs used in determining the estimated fair value of impaired notes receivable investments:

Asset	Valuation Technique	Unobservable Input	December 31, 2018	December 31, 2017
<b><u>Wellstat Diagnostics</u></b>				
<i>Wellstat Guarantors intellectual property</i> .....	<i>Income Approach</i>	Discount rate.....	12%	12%
		Royalty amount .....	\$21 million	\$21 million
<i>Settlement Amount</i> .....	<i>Income Approach</i>	Discount rate.....	15%	15%
		Settlement amount.....	\$34 million	\$32 million
<i>Real Estate Property</i> .....	<i>Market Approach</i>	Annual appreciation rate.....	4%	4%
		Estimated realtor fee.....	6%	6%
		Estimated disposal date .....	9/30/2019	6/30/2019
<b><u>CareView</u></b>				
<i>Note receivable cash flows</i> .....	<i>Income Approach</i>	Discount rate.....	30.0%	17.5%

## 6. Cash, Cash Equivalents and Short-term Investments

As of December 31, 2018, the Company had invested its excess cash balances primarily in cash and money market funds, and as of December 31, 2017, the Company had invested its excess cash balances primarily in cash, money market funds and a corporate equity security. The Company's securities are classified as available-for-sale and are carried at estimated fair value, with unrealized gains and losses reported in "Accumulated other comprehensive income" in stockholders' equity, net of estimated taxes. For fair value information, see Note 5, *Fair Value Measurements*. To date, the Company has not experienced credit losses on investments in these instruments, and it does not require collateral for its investment activities.

The following tables summarize the Company's cash and available-for-sale securities' amortized cost, gross unrealized gains and fair value by significant investment category reported as cash and cash equivalents, or short-term investments as of December 31, 2018 and 2017:

<i>(in thousands)</i>	Amortized Cost	Unrealized Gains	Estimated Fair Value	Reported as:	
				Cash and Cash Equivalents	Short-Term Investments
<b>December 31, 2018</b>					
Cash.....	\$ 167,871	\$ —	\$ 167,871	\$ 167,871	\$ —
Money market funds.....	226,719	—	226,719	226,719	—
Total.....	<u>\$ 394,590</u>	<u>\$ —</u>	<u>\$ 394,590</u>	<u>\$ 394,590</u>	<u>\$ —</u>
<b>December 31, 2017</b>					
Cash.....	\$ 109,703	\$ —	\$ 109,703	\$ 109,703	\$ —
Money market funds.....	417,563	—	417,563	417,563	—
Corporate securities.....	3,353	1,495	4,848	—	4,848
Total.....	<u>\$ 530,619</u>	<u>\$ 1,495</u>	<u>\$ 532,114</u>	<u>\$ 527,266</u>	<u>\$ 4,848</u>

The Company recognized approximately \$0.8 million, \$0.1 million and \$0.9 million, respectively, of gains on sales of available-for-sale securities in the years ended December 31, 2018, 2017 and 2016.

The unrealized gains on investments included in "Other comprehensive (loss) income, net of tax," was approximately zero and \$1.2 million as of December 31, 2018 and 2017, respectively.

## 7. Concentration of Credit Risk

### *Product Line Concentration*

The percentage of total revenue recognized, which individually accounted for 10% or more of the Company's total revenues in one or more of the periods presented below, was as follows:

<i>(in thousands)</i>	Year Ended December 31,		
	2018	2017	2016
Genentech.....	—%	—%	43%
Biogen.....	2%	11%	24%
Assertio.....	42%	52%	13%
LENSAR.....	12%	5%	—%
Noden.....	41%	22%	13%

Total revenues by geographic area are based on the country of domicile of the counterparty to the agreement are as follows:

<i>(in thousands)</i>	Year Ended December 31,		
	2018	2017	2016
United States.....	\$ 148,622	\$ 291,448	\$ 157,327
Europe.....	27,709	16,144	82,534
Rest of World.....	21,779	12,468	4,440
Total revenues.....	<u>\$ 198,110</u>	<u>\$ 320,060</u>	<u>\$ 244,301</u>

The following tables presents total receivables which individually account for 10% or more of the Company's total receivables balance:

<i>(in thousands)</i>	December 31,	
	2018	2017
Cardinal Health.....	\$ 2,732	\$ 3,847
McKesson.....	\$ 2,352	\$ —
AmerisourceBergen.....	\$ 4,330	\$ 2,982

## 8. Foreign Currency Hedging

The Company designated the foreign currency exchange contracts it used to hedge its royalty revenues based on underlying Euro-denominated sales as cash flow hedges. All outstanding Euro forward contracts as of December 31, 2015 settled during the first quarter of 2016. There were no Euro forward contracts outstanding as of December 31, 2018 or December 31, 2017.

The effect of the Company's derivative instruments in its Consolidated Statements of Operations and its Consolidated Statements of Comprehensive Income were as follows:

<i>(in thousands)</i>	Year Ended December 31,		
	2018	2017	2016
Net gain (loss) recognized in Other Comprehensive Income, net of tax <sup>(1)</sup> .....	\$ —	\$ —	\$ —
Gain (loss) reclassified from accumulated Other Comprehensive Income into "Queen et al. royalty revenue," net of tax <sup>(2)</sup> .....	\$ —	\$ —	\$ 1,821

(1) Net change in the fair value of the effective portion of cash flow hedges classified in Other Comprehensive Income

(2) Effective portion classified as royalty revenue

## 9. Notes and Other Long-Term Receivables

Notes and other long-term receivables included the following significant agreements:

### *Wellstat Diagnostics Note Receivable and Credit Agreement and Related Litigation*

On November 2, 2012, the Company and Wellstat Diagnostics entered into a \$40.0 million credit agreement pursuant to which the Company was to accrue quarterly interest payments at the rate of 5% per annum (payable in cash or in kind). In addition, the Company was to receive quarterly royalty payments based on a low double-digit royalty rate of Wellstat Diagnostics' net revenues, generated by the sale, distribution or other use of Wellstat Diagnostics' products, if any, commencing upon the commercialization of its products. A portion of the proceeds of the \$40.0 million credit agreement were used to repay certain notes receivable which Wellstat Diagnostics entered into in March 2012.

In January 2013, the Company was informed that, as of December 31, 2012, Wellstat Diagnostics had used funds contrary to the terms of the credit agreement and breached Sections 2.1.2 and 7 of the credit agreement. The Company sent Wellstat Diagnostics a notice of default on January 22, 2013, and accelerated the amounts owed under the credit agreement. In connection with the notice of default, the Company exercised one of its available remedies and transferred approximately \$8.1 million of available cash from a bank account of Wellstat Diagnostics to the Company and applied the funds to amounts due under the credit agreement. On February 28, 2013, the parties entered into a forbearance agreement whereby the Company agreed to refrain from

exercising additional remedies for 120 days. During such forbearance period, the Company provided approximately \$1.3 million to Wellstat Diagnostics to fund ongoing operations of the business. During the year ended December 31, 2013, approximately \$8.7 million was advanced pursuant to the forbearance agreement.

On August 15, 2013, the Company entered into an amended and restated credit agreement with Wellstat Diagnostics. The Company determined that the new agreement should be accounted for as a modification of the existing agreement.

Except as otherwise described herein, the material terms of the amended and restated credit agreement are substantially the same as those of the original credit agreement, including quarterly interest payments at the rate of 5% per annum (payable in cash or in kind). In addition, the Company was to continue to receive quarterly royalty payments based on a low double-digit royalty rate of Wellstat Diagnostics' net revenues. However, pursuant to the amended and restated credit agreement: (i) the principal amount was reset to approximately \$44.1 million, which was comprised of approximately \$33.7 million original loan principal and interest, \$1.3 million term loan principal and interest and \$9.1 million forbearance principal and interest; (ii) the specified internal rates of return increased; (iii) the default interest rate was increased; (iv) Wellstat Diagnostics' obligation to provide certain financial information increased in frequency to monthly; (v) internal financial controls were strengthened by requiring Wellstat Diagnostics to maintain an independent, third-party financial professional with control over fund disbursements; (vi) the Company waived the existing events of default; and (vii) the owners and affiliates of Wellstat Diagnostics were required to contribute additional capital to Wellstat Diagnostics upon the sale of an affiliate entity. The amended and restated credit agreement had an ultimate maturity date of December 31, 2021 (but has subsequently been accelerated as described below).

In June 2014, the Company received information from Wellstat Diagnostics showing that it was generally unable to pay its debts as they became due, constituting an event of default under the amended and restated credit agreement.

On August 5, 2014, the Company delivered a notice of default (the "Wellstat Diagnostics Borrower Notice") to Wellstat Diagnostics, which accelerated all obligations under the amended and restated credit agreement and demanded immediate payment in full in an amount equal to approximately \$53.9 million, (which amount, in accordance with the terms of the amended and restated credit agreement, included an amount that, together with interest and royalty payments already made to the Company, would generate a specified internal rate of return to the Company), plus accruing fees, costs and interest, and demanded that Wellstat Diagnostics protect and preserve all collateral securing its obligations.

On August 7, 2014, the Company delivered a notice (the "Wellstat Diagnostics Guarantor Notice") to each of the guarantors of Wellstat Diagnostics' obligations to the Company (collectively, the "Wellstat Diagnostics Guarantors") under the credit agreement, which included a demand that the guarantors remit payment to the Company in the amount of the outstanding obligations. The guarantors include certain affiliates and related companies of Wellstat Diagnostics, including Wellstat Therapeutics and Wellstat Diagnostics' stockholders.

On September 24, 2014, the Company filed an ex-parte petition for appointment of receiver with the Circuit Court of Montgomery County, Maryland (the "Wellstat Diagnostics Petition"), which was granted on the same day. Wellstat Diagnostics remained in operation during the period of the receivership with incremental additional funding from the Company. On May 24, 2017, Wellstat Diagnostics transferred substantially all of its assets to the Company pursuant to a credit bid. The credit bid reduced the outstanding balance of the loan by an immaterial amount.

On September 4, 2015, the Company filed in the Supreme Court of New York a motion for summary judgment in lieu of complaint which requested that the court enter judgment against certain of the Wellstat Diagnostics Guarantors for the total amount due on the Wellstat Diagnostics debt, plus all costs and expenses including lawyers' fees incurred by the Company in enforcement of the related guarantees. On September 23, 2015, the Company filed in the same court an ex parte application for a temporary restraining order and order of attachment of the Wellstat Diagnostics Guarantor defendants' assets. Although the court denied the Company's request for a temporary restraining order at a hearing on September 24, 2015, it ordered that assets of the Wellstat Diagnostics Guarantor defendants should be held in *status quo ante* and only used in the normal course of business.

On July 29, 2016, the Supreme Court of New York granted the Company's motion for summary judgment and held that the Wellstat Diagnostics Guarantor defendants are liable for all "Obligations" owed by Wellstat Diagnostics to the Company.

After appeal by the Wellstat Diagnostics Guarantor defendants on February 14, 2017, the Appellate Division of the Supreme Court of New York reversed on procedural grounds a portion of the Memorandum of Decision granting the Company summary judgment in lieu of complaint, but affirmed the portion of the Memorandum of Decision denying the Wellstat Diagnostics Guarantor defendants' motion for summary judgment in which they sought a determination that the guarantees had been released. As a result, the litigation has been remanded to the Supreme Court of New York to proceed on the Company's claims as a plenary

action. On June 21, 2017, the Supreme Court of New York ordered the Company to file a Complaint, which was filed by the Company on July 20, 2017. The Wellstat Diagnostics Guarantors filed their answer on August 9, 2017, including counterclaims against the Company alleging breach of contract breach of fiduciary duty, and tortious interference with prospective economic advantage. This case is currently pending and in the pre-trial phase.

On October 14, 2016, the Company sent a notice of default and reference to foreclosure proceedings to certain of the Wellstat Diagnostics Guarantors which are not defendants in the New York action, but which are owners of real estate assets over which a deed of trust in favor of the Company securing the guarantee of the loan to Wellstat Diagnostics had been executed. On March 2, 2017, the Company sent a second notice to foreclose on the real estate assets, and noticed the sale for March 29, 2017. The sale was taken off the calendar by the trustee under the deed of trust and has not been re-scheduled yet. On March 6, 2017, the Company sent a letter to the Wellstat Diagnostics Guarantors seeking information in preparation for a UCC Article 9 sale of some or all of the intellectual property-related collateral of the Wellstat Diagnostics Guarantors. The Wellstat Diagnostics Guarantors did not respond to the Company's letter, but on March 17, 2017, filed an order to show cause with the Supreme Court of New York to enjoin the Company's sale of the real estate or enforcing its security interests in the Wellstat Diagnostics Guarantors' intellectual property during the pendency of any action involving the guarantees at issue. On February 6, 2018, the Supreme Court of New York issued an order from the bench which enjoins the Wellstat Diagnostics Guarantors from selling, encumbering, removing, transferring or altering the collateral pending the outcome of the proceedings before it. The Supreme Court of New York also issued an order precluding the Company from foreclosing on certain of the Wellstat Diagnostics Guarantors' collateral pending the outcome of the proceedings before it. In September of 2018, discovery in the New York action was completed. Summary judgment motions were filed by Wellstat and the Company in 2018, and accompanying briefing was completed in January 2019. The court has ordered a hearing on the summary judgment motions for March 26, 2019.

In an unrelated litigation, Wellstat Therapeutics filed a lawsuit against BTG International, Inc. for breach of contract (the "BTG Litigation"). In September 2017, the Delaware Chancery Court found in favor of Wellstat Therapeutics and awarded a judgment of \$55.8 million in damages, plus interest. In October 2017, the Company filed a motion with the Supreme Court of New York requesting a pre-judgment attachment of the award. In June 2018, the Delaware Supreme Court largely affirmed the September 2017 decision of the Delaware Chancery Court, including the \$55.8 million awarded in judgment. In August of 2018, in a letter to the Company's counsel, Wellstat Guarantors' counsel confirmed that the Wellstat Guarantors are preserving the BTG Litigation judgment award proceeds consistent with the New York Court's prior directions.

On October 22, 2015, certain of the Wellstat Diagnostics Guarantors filed a separate complaint against the Company in the Supreme Court of New York seeking a declaratory judgment that certain contractual arrangements entered into between the parties subsequent to Wellstat Diagnostics' default, and which relate to a split of proceeds in the event that the Wellstat Diagnostics Guarantors voluntarily monetize any assets that are the Company's collateral, is of no force or effect. This case has been joined for all purposes, including discovery and trial, and consolidated with the pending case filed by the Company.

Effective April 1, 2014, and as a result of the event of default, the Company determined the loan to be impaired and it ceased to accrue interest revenue. At that time and as of December 31, 2018, it has been determined that an allowance on the carrying value of the note was not necessary, as the Company believes the value of the collateral securing Wellstat Diagnostics' obligations exceeds the carrying value of the asset and is sufficient to enable the Company to recover the current carrying value of \$50.2 million. The Company continues to closely monitor the timing and expected recovery of amounts due, including litigation and other matters related to Wellstat Diagnostics Guarantors' assets. There can be no assurance that an allowance on the carrying value of the notes receivable investment will not be necessary in a future period depending on future developments.

#### *Hyperion Agreement*

On January 27, 2012, the Company and Hyperion (which is also a Wellstat Diagnostics Guarantor) entered into an agreement whereby Hyperion sold to the Company the royalty streams accruing from January 1, 2012 through December 31, 2013 due from Showa Denko K.K. ("SDK") related to a certain patent license agreement between Hyperion and SDK dated December 31, 2008. In exchange for the lump sum payment to Hyperion of \$2.3 million, in addition to any royalties from SDK, the Company was to receive two equal payments of \$1.2 million on March 5, 2013 and March 5, 2014. The first payment of \$1.2 million was paid on March 5, 2013, but the second payment that was due on March 5, 2014 has not been made by Hyperion. Effective as of such date and as a result of the event of default, the Company ceased to accrue interest revenue. As of December 31, 2018, the estimated fair value of the collateral was determined to be in excess of the carrying value. There can be no assurance of realizing value from such collateral in the event of the Company's foreclosure on the collateral.

### *Avinger Credit and Royalty Agreement*

On April 18, 2013, the Company entered into a credit agreement with Avinger, Inc. (the “Avinger Credit and Royalty Agreement”). Under the terms of the Avinger Credit and Royalty Agreement, the Company received a low, single-digit royalty on Avinger’s net revenues until April 2018. Commencing in October 2015, after Avinger repaid \$21.4 million pursuant to its note payable to the Company prior to its maturity date, the royalty on Avinger’s net revenues was reduced by 50%, subject to certain minimum payments from the prepayment date until April 18, 2018. The Company accounted for the royalty rights in accordance with the fair value option. As of April 18, 2018, there were no further obligations owed to the Company.

### *LENSAR Credit Agreement*

On October 1, 2013, the Company entered into a credit agreement with LENSAR, pursuant to which the Company made available to LENSAR up to \$60.0 million to be used by LENSAR in connection with the commercialization of its currently marketed LENSAR™ Laser System. Of the \$60.0 million available to LENSAR, an initial \$40.0 million, net of fees, was funded by the Company at the close of the transaction. The remaining \$20.0 million was never funded. Outstanding borrowings under the loans bore interest at the rate of 15.5% per annum, payable quarterly in arrears.

On May 12, 2015, the Company entered into a forbearance agreement with LENSAR, pursuant to which the Company agreed to refrain from exercising certain remedies available to it resulting from the failure of LENSAR to comply with a liquidity covenant and make interest payments due under the credit agreement. Under the forbearance agreement, the Company agreed to provide LENSAR with up to an aggregate of \$8.5 million in weekly increments through the period ended September 30, 2015 plus employee retention amounts of approximately \$0.5 million in the form of additional loans, subject to LENSAR meeting certain milestones related to LENSAR obtaining additional capital to fund or to sell the business and repay outstanding amounts under the credit agreement. In exchange for the forbearance, LENSAR agreed to additional reporting covenants, the engagement of a chief restructuring officer and an increase on the interest rate to 18.5%, applicable to all outstanding amounts under the credit agreement.

On September 30, 2015, the Company agreed to extend the forbearance agreement until October 9, 2015 and provide for up to an additional \$0.8 million in funding while LENSAR negotiated a potential sale of its assets. On October 9, 2015, the forbearance agreement expired, but the Company agreed to fund LENSAR’s operations while LENSAR continued to negotiate a potential sale of its assets.

On November 15, 2015, LENSAR, LLC (“LENSAR/Alphaeon”), a wholly-owned subsidiary of Alphaeon Corporation (“Alphaeon”), and LENSAR entered into the Asset Purchase Agreement whereby LENSAR/Alphaeon agreed to acquire certain assets of LENSAR and assumed certain liabilities of LENSAR. The acquisition was consummated on December 15, 2015.

In connection with the closing of the acquisition, LENSAR/Alphaeon entered into an amended and restated credit agreement with the Company, assuming \$42.0 million in loans as part of the borrowings under the Company’s prior credit agreement with LENSAR. In addition, Alphaeon issued 1.7 million shares of its Class A common stock to the Company which were valued at \$6.6 million at the time the shares were received. For additional information on this investment in Alphaeon, see Note 5, *Fair Value Measurements*.

In December 2016, LENSAR, re-acquired the assets from LENSAR/Alphaeon and the Company entered into a second amended and restated credit agreement with LENSAR whereby LENSAR assumed all obligations under the amended and restated credit agreement with LENSAR/Alphaeon. Also in December, LENSAR filed for a voluntary petition under Chapter 11 of the U.S. Bankruptcy Code (“Chapter 11 case”) with the support of the Company. In January 2017, the Company agreed to provide debtor-in-possession financing of up to \$2.8 million in new advances to LENSAR so that it could continue to operate its business during the Chapter 11 case. LENSAR filed a Chapter 11 plan of reorganization with the Company’s support under which LENSAR would issue all of its equity interests to the Company in exchange for the cancellation of the Company’s claims as a secured creditor in the Chapter 11 case, other than with respect to the debtor-in-possession financing, and would thereby become an operating wholly-owned subsidiary of the Company. On April 26, 2017, the bankruptcy court approved the plan of reorganization.

Pursuant to the plan of reorganization, LENSAR emerged from bankruptcy on May 11, 2017 as a wholly-owned subsidiary of the Company, and the Company started to consolidate LENSAR’s financial statements under the voting interest model beginning May 11, 2017.

For additional information on LENSAR please refer to Note 13, *Intangible Assets*, Note 23, *Business Combinations* and Note 24, *Segment Information*.

### *Direct Flow Medical Credit Agreement*

On November 5, 2013, the Company entered into a credit agreement with Direct Flow Medical, Inc. (“Direct Flow Medical”) under which the Company agreed to provide up to \$50.0 million to Direct Flow Medical. Of the \$50.0 million available to Direct Flow Medical, the first tranche of \$35.0 million, net of fees, was funded by the Company at the close of the transaction.

On November 10, 2014, the Company and Direct Flow Medical agreed to an amendment to the credit agreement to permit Direct Flow Medical to borrow an additional \$15.0 million (in a second tranche) upon receipt by Direct Flow Medical of a specified minimum amount of proceeds from an equity offering prior to December 31, 2014. In exchange, the parties amended the credit agreement to provide for additional fees associated with certain liquidity events, such as a change of control or the consummation of an initial public offering, and granted the Company certain board of director observation rights. On November 19, 2014, upon Direct Flow Medical satisfying the amended tranche two milestone, the Company funded the \$15.0 million second tranche to Direct Flow Medical, net of fees.

Outstanding borrowings under tranche one bore interest at the rate of 15.5% per annum, payable quarterly in arrears, until the occurrence of the second tranche. Upon occurrence of the borrowing of this second tranche, the interest rate applicable to all loans under the credit agreement was decreased to 13.5% per annum, payable quarterly in arrears.

Under the terms of the credit agreement, Direct Flow Medical’s obligation to repay loan principal commenced on the twelfth interest payment date, September 30, 2016. The principal amount outstanding at commencement of repayment was required to be repaid in equal installments until final maturity of the loans. The loans were scheduled to mature on November 5, 2018. The obligations under the credit agreement were secured by a pledge of substantially all of the assets of Direct Flow Medical and any of its subsidiaries.

On December 21, 2015, Direct Flow Medical and the Company entered into a waiver to the credit agreement in anticipation of Direct Flow Medical being unable to comply with the liquidity covenant and make interest payments due under the credit agreement, which was subsequently extended on January 14, 2016, and further delayed the timing of the interest payments through the period ending September 30, 2016 while Direct Flow Medical sought additional financing to operate its business.

On January 28, 2016, the Company funded an additional \$5.0 million to Direct Flow Medical in the form of a short-term secured promissory note.

On February 26, 2016, the Company and Direct Flow Medical entered into the fourth amendment to the credit agreement that, among other things, (i) converted the \$5.0 million short-term secured promissory note into a loan under the credit agreement with substantially the same interest and payment terms as the existing loans, (ii) added a conversion feature whereby the \$5.0 million loan would convert into equity of Direct Flow Medical upon the occurrence of certain events and (iii) provided for a second \$5.0 million convertible loan tranche commitment, to be funded at the option of the Company. The commitment for the second tranche was not funded and has since expired. In addition, (i) the Company agreed to waive the liquidity covenant and delay the timing of the unpaid interest payments until September 30, 2016 and (ii) Direct Flow Medical agreed to issue to the Company a specified amount of warrants to purchase shares of convertible preferred stock on the first day of each month for the duration of the waiver period at an exercise price of \$0.01 per share.

On July 15, 2016, the Company and Direct Flow Medical entered into the fifth amendment and limited waiver to the credit agreement. The Company funded an additional \$1.5 million to Direct Flow Medical in the form of a note with substantially the same interest and payment terms as the existing loans and a conversion feature whereby the \$1.5 million loan would convert into equity of Direct Flow Medical upon the occurrence of certain events. In addition, Direct Flow Medical agreed to issue to the Company warrants to purchase shares of convertible preferred stock at an exercise price of \$0.01 per share.

On September 12, 2016, the Company and Direct Flow Medical entered into the sixth amendment and limited waiver to the credit agreement under which the Company funded an additional \$1.5 million to Direct Flow Medical in the form of a note with substantially the same interest and payment terms as the existing loans. In addition, Direct Flow Medical agreed to issue to the Company a specified amount of warrants to purchase shares of convertible preferred stock at an exercise price of \$0.01 per share.

On September 30, 2016, the Company and Direct Flow Medical entered into a waiver to the credit agreement where the parties agreed, among other things, to (i) delay payment on all overdue interest payments until October 31, 2016, (ii) waive the initial principal repayment until October 31, 2016 and (iii) continue to waive the liquidity requirements until October 31, 2016. Further,

Direct Flow Medical agreed to issue to the Company a specified amount of warrants to purchase shares of convertible preferred stock at an exercise price of \$0.01 per share.

On October 31, 2016, the Company agreed to extend the waivers described above until November 30, 2016 and on November 14, 2016, the Company advanced an additional \$1.0 million loan while Direct Flow Medical continued to seek additional financing.

On November 16, 2016, Direct Flow Medical advised the Company that its potential financing source had modified its proposal from an equity investment to a loan with a substantially smaller amount and under less favorable terms. Direct Flow Medical shut down its operations in December 2016 and in January 2017 made an assignment for the benefit of creditors. The Company then initiated foreclosure proceedings, resulting in the Company obtaining ownership of most of the Direct Flow Medical assets through the Company's wholly-owned subsidiary, DFM, LLC. The assets were held for sale and carried at the lower of carrying amount or fair value, less estimated selling costs, which was primarily based on supporting data from market participant sources, and valid offers from third parties.

At December 31, 2016, the Company completed an impairment analysis and concluded that the situation qualified as a troubled debt restructuring and recognized an impairment loss of \$51.1 million.

In January 2017, the Company started to actively market the asset held for sale. On January 23, 2017, the Company and DFM, LLC entered into an Intellectual Property Assignment Agreement with Hong Kong Haisco Pharmaceutical Co., Limited ("Haisco"), a Chinese pharmaceutical company, whereby Haisco acquired former Direct Flow Medical clinical, regulatory and commercial information and intellectual property rights exclusively in China for \$7.0 million. The Company, through DFM, LLC, also sold Haisco certain manufacturing equipment for \$450,000 and collected \$692,000 on outstanding Direct Flow Medical accounts receivable during the year ended December 31, 2017.

On January 6, 2018, DFM, LLC, a wholly-owned subsidiary of the Company, and HaisThera Advisors Co., Limited ("HaisThera") entered into a license agreement whereby DFM, LLC granted HaisThera an exclusive license to develop, manufacture and commercialize percutaneously implanting stentless aortic valves in the European Union. The consideration for the license agreement was \$500,000 upfront and up to \$2.0 million in royalty payments.

#### *Paradigm Spine Credit Agreement*

On February 14, 2014, the Company entered into the Credit Agreement (the "Paradigm Spine Credit Agreement") with Paradigm Spine, LLC ("Paradigm Spine"), under which it made available to Paradigm Spine up to \$75.0 million to be used by Paradigm Spine to refinance its existing credit facility and expand its domestic commercial operations. Of the \$75.0 million available to Paradigm Spine, an initial \$50.0 million, net of fees, was funded by the Company at the close of the transaction. The second and third tranches of up to an additional \$25.0 million in the aggregate, net of fees, are no longer available under the terms of the Paradigm Spine Credit Agreement.

On October 27, 2015, the Company and Paradigm Spine entered into an amendment to the Paradigm Spine Credit Agreement to provide additional term loan commitments of up to \$7.0 million payable in two tranches, of which the first tranche of \$4.0 million was drawn on the closing date of the amendment, net of fees. Paradigm Spine chose not to draw down the second tranche of \$3.0 million and such tranche is no longer available. Borrowings under the credit agreement bore interest at the rate of 13.0% per annum, payable quarterly in arrears.

On August 26, 2016, the Company received \$57.5 million in connection with the prepayment of the loans under the Paradigm Spine Credit Agreement, which included a repayment of the full principal amount outstanding of \$54.7 million, plus accrued interest and a prepayment fee.

#### *kaléo Note Purchase Agreement*

On April 1, 2014, the Company entered into a note purchase agreement with Accel 300, LLC ("Accel 300"), a wholly-owned subsidiary of kaléo, Inc. ("kaléo"), pursuant to which the Company acquired \$150.0 million of secured notes due 2029 (the "kaléo Note"). The kaléo Note was issued pursuant to an indenture between Accel 300 and U.S. Bank, National Association, as trustee, and was secured by 20% of net sales of its first approved product, Auvi-Q<sup>®</sup> (epinephrine auto-injection, USP) (known as Allerject<sup>®</sup> in Canada) and 10% of net sales of kaléo's second proprietary auto-injector based product, EVZIO (naloxone hydrochloride injection) (the "kaléo Revenue Interests"), and a pledge of kaléo's equity ownership in Accel 300.



On September 21, 2017, the Company entered into an agreement (the “kaléo Note Sale Agreement”) with MAM-Kangaroo Lender, LLC, a Delaware limited liability company (the “kaléo Purchaser”), pursuant to which the Company sold its entire interest in the kaléo Note.

Pursuant to the kaléo Note Sale Agreement, the kaléo Purchaser paid to the Company an amount equal to all of the then outstanding principal, a premium of 1% of such amount and accrued interest under the kaléo Note, for an aggregate cash purchase price of \$141.7 million, subject to an 18-month escrow holdback of \$1.4 million against certain potential contingencies. For a further discussion on this topic, see Note 15, *Commitments and Contingencies*.

#### *CareView Credit Agreement*

On June 26, 2015, the Company entered into a credit agreement with CareView, under which the Company made available to CareView up to \$40.0 million in loans comprised of two tranches of \$20.0 million each, subject to CareView’s attainment of specified milestones. On October 7, 2015, the Company and CareView entered into an amendment of the credit agreement to modify certain definitions related to the first and second tranche milestones and the Company funded the first tranche of \$20.0 million, net of fees, based on CareView’s attainment of the first milestone, as amended. The second \$20.0 million tranche was not funded due to CareView’s failure to achieve the related funding milestones and there is no additional funding obligation due from the Company. Outstanding borrowings under the credit agreement bear interest at the rate of 13.5% per annum and are payable quarterly in arrears.

As part of the original credit agreement, the Company received a warrant to purchase approximately 4.4 million shares of common stock of CareView at an exercise price of \$0.45 per share. The Company has accounted for the warrant as derivative asset with an offsetting credit as debt discount. At each reporting period the warrant is marked to market for changes in fair value.

In connection with the October 2015 amendment of the credit agreement, the Company and CareView also agreed to amend the warrant to purchase common stock agreement by reducing the warrant’s exercise price from \$0.45 to \$0.40 per share.

In February 2018, the Company entered into a modification agreement with CareView (the “February 2018 Modification Agreement”) whereby the Company agreed, effective December 28, 2017, to modify the credit agreement before remedies could otherwise have become available to the Company under the credit agreement in relation to certain obligations of CareView that would potentially not be met, including the requirement to make principal payments. Under the February 2018 Modification Agreement, the Company agreed that (i) a lower liquidity covenant would be applicable and (ii) principal repayment would be delayed until December 31, 2018. In exchange for agreeing to these modifications, among other things, the exercise price of the Company’s warrants to purchase 4.4 million shares of common stock of CareView was repriced from \$0.40 to \$0.03 per share and, subject to the occurrence of certain events, CareView agreed to grant the Company additional equity interests. In September 2018, the Company entered into an amendment to the February 2018 Modification Agreement with CareView whereby the Company agreed, effective as of September 28, 2018, that a lower liquidity covenant would be applicable. At December 31, 2018, the Company determined an estimated fair value of the warrant to be \$0.1 million.

As a result of the February 2018 Modification Agreement, the Company determined the loan to be impaired and it ceased to accrue interest revenue effective October 1, 2017.

In December 2018, the Company further modified the loan by agreeing that (i) a lower liquidity covenant would be applicable, (ii) the first principal payment would be deferred until January 31, 2019, and (iii) the scheduled interest payment due December 31, 2018 would be deferred until January 31, 2019. The principal repayment and interest payment were subsequently deferred until March 31, 2019 under additional amendments.

In December 2018, and in consideration of the further modification to the credit agreement, the Company completed an impairment analysis and determined that the note was impaired and recorded an impairment loss of \$8.2 million. For additional information please refer to Note 5, *Fair Value Measurements*.

## 10. Inventories

Inventories consisted of the following:

<i>(in thousands)</i>	December 31,	
	2018	2017
Raw materials.....	\$ 6,214	\$ 1,717
Work in process.....	549	1,119
Finished goods .....	12,179	6,311
Total inventories .....	<u>\$ 18,942</u>	<u>\$ 9,147</u>

As of December 31, 2018 and 2017, the Company deferred approximately \$0.5 million and \$1.3 million, respectively, of costs associated with inventory transfers made under the Company's third-party logistics provider service arrangement. These costs have been recorded as Other assets on the Company's Consolidated Balance Sheets as of December 31, 2018 and 2017. The Company will recognize the cost of product sold as inventory is transferred from its third-party logistics provider to the Company's customers.

During the year ended December 31, 2018, the Company recognized a reduction in the inventory reserve of \$1.2 million. During the years ended December 31, 2017 and 2016 the Company recognized inventory write-downs of \$2.0 million and \$0.3 million respectively, related to the "Noden Products" that the Company would not be able to sell prior to their expiration.

## 11. Property and Equipment

The following table provides details of the property and equipment, net:

<i>(in thousands)</i>	December 31,	
	2018	2017
Leasehold improvements.....	\$ 322	\$ 321
Manufacturing equipment .....	1,669	1,393
Computer and office equipment .....	9,451	10,141
Furniture and fixtures .....	162	137
Equipment under lease .....	6,529	6,700
Transportation equipment.....	67	—
Total .....	<u>18,200</u>	<u>18,692</u>
Less accumulated depreciation.....	(14,203)	(11,474)
Construction in progress.....	3,390	4
Property and equipment, net.....	<u>\$ 7,387</u>	<u>\$ 7,222</u>

Depreciation expense on property and equipment amounted to \$2.7 million, \$2.3 million and less than \$0.1 million for the years ended December 31, 2018, 2017 and 2016, respectively.

## 12. Asset Acquisition

On January 8, 2018, LENSAR entered into an Asset Purchase Agreement with PES to purchase assets used in PES' laser-assisted cataract surgery business. The assets purchased include equipment, inventory and PES' customer contracts. No workforce was transferred as part of the transaction.

The Company assessed the acquisition of PES assets under ASC 805. Under ASC 805, the Company determined that the acquired assets did not constitute a business and that the transaction would be accounted for as an asset acquisition.

The following table summarizes the fair values of the identifiable assets acquired and liabilities assumed at the acquisition date (in thousands):

Equipment and inventory .....	\$	848
Fixed assets .....		67
Intangible assets (customer relationships) .....		1,845
Total identifiable assets .....	\$	<u>2,760</u>
Consideration paid at closing, cash .....	\$	1,200
Conversion consideration .....		920
Contingent consideration .....		640
Total fair value of consideration .....	\$	<u>2,760</u>

### 13. Intangible Assets

#### *Intangible Assets, Net*

On June 8, 2018, Noden Pharma DAC (“Noden DAC”), a wholly-owned subsidiary of the Company, entered into a Settlement Agreement (the “Settlement Agreement”) with Anchen Pharmaceuticals, Inc. and its affiliates (“Anchen”) to resolve the patent litigation relating to infringement of U.S. Patent No. 8,617,595 (the “595 Patent”) based on their submission of an Abbreviated New Drug Application (“ANDA”) seeking authorization from the FDA to market a generic version of aliskiren, the active ingredient in Tekturna and Tekturna HCT. Under the Settlement Agreement, Anchen, the sole ANDA filer of which the Company is aware, agreed to not commercialize its generic version of aliskiren prior to March 1, 2019. Per the Settlement Agreement, Anchen may commercialize their formulation of aliskiren, but is not permitted to commercialize a copy of Tekturna.

Accordingly, management evaluated the ongoing value of the Noden DAC asset group based upon the probability of Anchen’s market entry of a generic version of aliskiren in the United States and the associated cash flows and conducted a test for impairment. Due to the increased probability of a generic version of aliskiren being launched in the United States, the Company revised its estimates of future cash flows and as a result of this analysis, determined that the sum of undiscounted cash flows was not greater than the carrying value of the assets. Therefore, the Company performed a discounted cash flow analysis to estimate the fair value of the asset group in accordance with ASC Topic 360, *Impairment or Disposal of Long-lived Assets*. The cash flows used in this analysis are those expected to be generated by market participants, discounted to reflect an appropriate amount of risk, which was determined to be 21%. The Company concluded that the Noden DAC acquired product rights and customer relationship long-lived assets, with a carrying amount of \$192.5 million, were no longer recoverable and wrote them down to their estimated fair value of \$40.1 million, resulting in an impairment charge of \$152.3 million in the second quarter of 2018. This write-down is included in “Impairment of intangible assets” in the Consolidated Statement of Operations and the Consolidated Statement of Cash Flows for the year ended December 31, 2018. The remaining Noden DAC intangible asset balance, included in the Pharmaceutical segment, will be amortized on a straight-line basis over the remaining useful life of eight years.

On March 4, 2019, the Company announced the U.S. commercial launch of an authorized generic of Tekturna, with the same drug formulation as Tekturna. The Company performed an impairment assessment of the Noden asset group at this time by estimating the undiscounted future cash flows with respect to the asset against its carrying value and concluded a further impairment was not required.

Future events, such as FDA approval of a third-party generic version of aliskiren or publicly announced plans of a launch of a generic version of aliskiren, may be further indicators of impairment which may require the Company to perform additional impairment testing.

The components of intangible assets as of December 31, 2018 and 2017 were as follows:

<i>(in thousands)</i>	December 31, 2018			December 31, 2017		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Finite-lived intangible assets:						
Acquired products rights <sup>(1)</sup> ....	\$ 36,143	\$ (2,258)	\$ 33,885	\$ 216,690	\$ (32,503)	\$ 184,187
Customer relationships <sup>(1)(2)</sup> ....	8,028	(782)	7,246	26,080	(3,729)	22,351
Acquired technology <sup>(2)(3)</sup> .....	11,011	(1,203)	9,808	9,200	(409)	8,791
Acquired trademarks <sup>(2)</sup> .....	570	(190)	380	570	(76)	494
	\$ 55,752	\$ (4,433)	\$ 51,319	\$ 252,540	\$ (36,717)	\$ 215,823

<sup>(1)</sup> The Company acquired certain intangible assets as part of the Noden Transaction. They are being amortized on a straight-line basis over a weighted-average period of eight years.

<sup>(2)</sup> The Company acquired certain intangible assets as part of the LENSAR transaction. The intangible assets are being amortized on a straight-line basis over a weighted-average period of 15 years. The intangible assets for customer relationships are being amortized using a double-declining method of amortization as such method better represents the economic benefits to be obtained. For a further discussion of the LENSAR transaction, see Note 23, *Business Combinations*.

<sup>(3)</sup> The Company acquired certain intangible assets as part of the foreclosure on certain of Direct Flow Medical assets, as described further in Note 9, *Notes and Other Long-Term Receivables*. They are being amortized on a straight-line basis over a weighted-average period of 10 years.

Amortization expense for the years ended December 31, 2018, 2017 and 2016 was \$15.8 million, \$24.7 million and \$12.0 million, respectively.

Based on the intangible assets recorded at December 31, 2018, and assuming no subsequent additions to or impairment of the underlying assets, the remaining estimated amortization expense is expected to be as follows (in thousands):

Fiscal Year	Amount
2019 .....	\$ 6,275
2020 .....	6,240
2021 .....	6,209
2022 .....	6,104
2023 .....	6,040
Thereafter .....	20,451
Total remaining estimated amortization expense.....	\$ 51,319

#### 14. Accrued Liabilities

Accrued liabilities consist of the following:

<i>(in thousands)</i>	December 31,	
	2018	2017
Compensation .....	\$ 4,468	\$ 6,043
Interest .....	344	2,451
Deferred revenue .....	8,811	9,741
Refund to manufacturer .....	—	647
Accrued rebates, chargebacks and other revenue reserves .....	20,133	19,613
Dividend payable .....	15	79
Customer advances .....	1	3,198
Legal .....	623	595
Other .....	4,917	3,514
Total .....	\$ 39,312	\$ 45,881

The following table provides a summary of activity with respect to the Company's sales allowances and accruals for the year ended December 31, 2018:

<i>(in thousands)</i>	Discount and Distribution Fees	Government Rebates and Chargebacks	Assistance and Other Discounts	Product Returns	Total
Balance at January 1, 2018 .....	\$ 3,422	\$ 8,709	\$ 4,178	\$ 3,304	\$ 19,613
Allowances for current period sales .....	9,403	18,583	8,206	2,367	38,559
Allowances for prior period sales .....	—	38	—	61	99
Credits/payments for current period sales .....	(6,313)	(10,045)	(4,963)	—	(21,321)
Credits/payments for prior period sales .....	(3,418)	(8,384)	(3,964)	(1,051)	(16,817)
Balance at December 31, 2018 .....	\$ 3,094	\$ 8,901	\$ 3,457	\$ 4,681	\$ 20,133

#### 15. Commitments and Contingencies

##### *Operating Leases*

The Company currently occupies a leased facility in Incline Village, Nevada, with a lease term through May 2020, a leased facility in Dublin, Ireland, with a lease term through September 2025 with the option to terminate the lease in September 2021, and a leased facility in Orlando, Florida, with a lease term through July 2021. The Company also leases certain office equipment under operating leases. Rental expense under these arrangements totaled \$1.3 million, \$0.8 million and \$0.3 million for the years ended December 31, 2018, 2017 and 2016, respectively.

Future minimum operating lease payments for the years ended December 31, were as follows (in thousands):

Fiscal Years	Amount
2019 .....	\$ 1,140
2020 .....	1,003
2021 .....	559
2022 .....	—
2023 .....	—
Thereafter .....	—
Total .....	\$ 2,702

### ***Lease Guarantee***

In connection with the Spin-Off of Facet Biotech Corporation (“Facet”) in December 2008 (the “Spin-Off”), the Company entered into amendments to the leases for the Company’s former facilities in Redwood City, California, under which Facet was added as a co-tenant, and a Co-Tenancy Agreement, under which Facet agreed to indemnify us for all matters related to the leases attributable to the period after the Spin-Off date. In April 2010, Abbott Laboratories acquired Facet and later renamed the entity AbbVie Biotherapeutics, Inc. (“AbbVie”). If AbbVie were to default under its lease obligations, the Company could be held liable by the landlord as a co-tenant and, thus, the Company has in substance guaranteed the payments under the lease agreements for the Redwood City facilities. As of December 31, 2018, the total lease payments for the duration of the guarantee, which runs through December 2021, are approximately \$33.8 million.

The Company prepared a discounted, probability weighted cash flow analysis to calculate the estimated fair value of the lease guarantee as of the Spin-Off. The Company was required to make assumptions regarding the probability of Facet’s default on the lease payment, the likelihood of a sublease being executed and the times at which these events could occur. These assumptions are based on information that the Company received from real estate brokers and the then-current economic conditions, as well as expectations of future economic conditions. The fair value of this lease guarantee was charged to additional paid-in capital upon the Spin-Off and any future adjustments to the carrying value of the obligation will also be recorded in additional paid-in capital.

The Company has recorded a liability of \$10.7 million on its Consolidated Balance Sheets as of December 31, 2018 and 2017, related to this guarantee. In future periods, the Company may adjust this liability for any changes in the ultimate outcome of this matter that are both probable and estimable.

### ***Irrevocable Letters of Credit***

On June 30, 2016, the Company purchased a \$75.0 million certificate of deposit, which is designated as cash collateral for the \$75.0 million letter of credit issued on July 1, 2016 with respect to the first anniversary payment under the Noden Purchase Agreement. In addition, the Company provided an irrevocable and unconditional guarantee to Novartis, to pay up to \$14.0 million of the remaining amount of the first anniversary payment not covered by the letter of credit. The Company concluded that both guarantees were contingent obligations and should be accounted for in accordance with ASC 450, *Contingencies*. Further, it was concluded that both guarantees did not meet the conditions to be accrued at June 30, 2016 and December 31, 2016. On July 3, 2017, the first anniversary payment of \$89.0 million was paid pursuant to the Noden Purchase Agreement and the \$14.0 million guarantee expired. On July 31, 2017, the \$75.0 million certificate of deposit matured, and on August 1, 2017, the letter of credit terminated.

### ***Purchase Obligations***

Noden and Novartis entered into a supply agreement pursuant to which Novartis will manufacture and supply to Noden a bulk tableted form of the Noden Products, and for the additional supply of active pharmaceutical ingredient (“API”) form, for specified periods of time prior to the transfer of manufacturing responsibilities for the Noden Products to another manufacturer. The supply agreement may be terminated by either party for material breach that remains uncured for a specified time period. Noden has placed firm orders for bulk product of \$12.3 million, which will be fulfilled within the next twelve months. Under the terms of the supply agreement, Noden is committed to purchase certain minimum quantities of bulk product and API that would amount to approximately \$127.6 million over the next thirty-six months if fulfilled, of which \$54.0 million is committed over the next twelve months. While the supply agreement provides that the parties will agree to reasonable accommodations with respect to changes in firm orders, the Company expects that Noden will meet the requirements of the supply agreement, unless otherwise negotiated. The commitments in the supply agreement terminate upon transfer to another manufacturer.

In addition, at the end of the supply agreement, which is the earlier of November 30, 2020 or upon transfer to another manufacturer of API, Noden must acquire all remaining API inventory produced by Novartis. The purchase is payable within 60 days after the end of the supply period for API. The agreement does not specify minimum quantities but details pricing terms.

LENSAR entered into various supply agreements for the manufacture and supply of certain components. The supply agreements commit LENSAR to a minimum purchase obligation of approximately \$3.8 million over the next twenty-four months of which \$3.5 million is due in the next 12 months. LENSAR expects to meet these requirements. For more information about the LENSAR Transaction, see Note 23, *Business Combinations*.

### ***Escrow Receivable***

On September 21, 2017, the Company entered into the kaléo Note Sale Agreement, pursuant to which the Company sold its entire interest in the kaléo Note.

Pursuant to the kaléo Note Sale Agreement, the purchaser paid to the Company an amount equal to all of the then outstanding principal, a premium of 1% of such amount and accrued interest under the kaléo Notes, for an aggregate cash purchase price of \$141.7 million.

Pursuant to the terms of the kaléo Note Sale Agreement, \$1.4 million of the aggregate purchase price was deposited into an escrow account as a potential payment against certain contingencies, which expires on the 18-month anniversary of the closing date. Upon the expiration of escrow period, the escrow agent is required to release remaining funds to the Company.

The Company does not expect there to be any claims by the purchaser under the escrow agreement. However, in the event that such a claim is made, and if successful, the amount of such a claim up to \$1.4 million would be released from the escrow account to the purchaser, which amount would be reduced from the amount released to the Company at the end of the 18-month escrow period. As of December 31, 2018, the Company is not aware of any claims by the purchaser that would reduce the escrow receivable. For more information about the kaléo Note Sale Agreement, see Note 9, *Notes and Other Long-Term Receivables*.

### **16. Term Loan and Convertible Senior Notes**

#### ***March 2015 Term Loan***

On March 30, 2015, the Company entered into a credit agreement among the Company, the lenders party thereto and the Royal Bank of Canada, as administrative agent. The credit agreement consisted of a term loan of \$100.0 million.

The interest rates per annum applicable to amounts outstanding under the term loan were, at the Company's option, either (a) the alternate base rate (as defined in the credit agreement) plus 0.75%, or (b) the adjusted Eurodollar rate (as defined in the credit agreement) plus 1.75% per annum. As of December 31, 2015, the interest rate, based upon the adjusted Eurodollar rate, was 2.17%. Interest payments under the credit agreement were due on the interest payment dates specified in the credit agreement.

The credit agreement required amortization of the term loan in the form of scheduled principal payments on June 15, September 15 and December 15 of 2015, with the remaining outstanding balance due on February 15, 2016. This principal balance and outstanding interest were paid in full on February 12, 2016.

#### **Convertible Senior Notes**

Convertible Notes activity for the years ended December 31, 2018 and 2017:

<i>(in thousands)</i>	February 2018 Notes	December 2017 Notes	Total
<b>Balance at December 31, 2016</b> .....	\$ 121,595	\$ 110,848	\$ 232,443
Amortization.....	4,471	6,567	11,038
<b>Balance at December 31, 2017</b> .....	126,066	117,415	243,481
Payment.....	(126,447)	—	(126,447)
Amortization.....	381	7,229	7,610
<b>Balance at December 31, 2018</b> .....	<u>\$ —</u>	<u>\$ 124,644</u>	<u>\$ 124,644</u>

## **February 2018 Notes**

On February 12, 2014, the Company issued \$300.0 million in aggregate principal amount, at par, of the February 2018 Notes in an underwritten public offering, for net proceeds of \$290.2 million. The February 2018 Notes were due February 1, 2018, and the Company paid interest at 4.0% on the February 2018 Notes semiannually in arrears on February 1 and August 1 of each year, beginning August 1, 2014. A portion of the proceeds from the February 2018 Notes, net of amounts used for purchased call option transactions and provided by the warrant transactions described below, were used to redeem \$131.7 million of the Company's 2.975% Convertible Senior Notes due February 17, 2016.

In accordance with the accounting guidance for convertible debt instruments that may be settled in cash or other assets on conversion, the Company was required to separately account for the liability component of the instrument in a manner that reflected the market interest rate for a similar nonconvertible instrument at the date of issuance. As a result, the Company separated the principal balance of the February 2018 Notes between the fair value of the debt component and the fair value of the common stock conversion feature. Using an assumed borrowing rate of 7.0%, which represented the estimated market interest rate for a similar nonconvertible instrument available to the Company on the date of issuance, the Company recorded a total debt discount of \$29.7 million, allocated \$19.3 million to additional paid-in capital and allocated \$10.4 million to deferred tax liability. The discount was being amortized to interest expense over the term of the February 2018 Notes and increased interest expense during the term of the February 2018 Notes from the 4.0% cash coupon interest rate to an effective interest rate of 6.9%.

In connection with the issuance of the February 2018 Notes, the Company entered into purchased call option transactions with two hedge counterparties. The Company paid an aggregate amount of \$31.0 million for the purchased call options with terms substantially similar to the embedded conversion options in the February 2018 Notes. The purchased call options covered, subject to anti-dilution and certain other customary adjustments substantially similar to those in the February 2018 Notes, approximately 13.8 million shares of the Company's common stock. Outstanding purchased call options expired on February 1, 2018.

In addition, the Company sold to the hedge counterparties warrants exercisable, on a cashless basis, for the sale of rights to receive shares of common stock underlying the February 2018 Notes at a strike price of \$10.3610 per share, which represented a premium of approximately 30% over the last reported sale price of the Company's common stock of \$7.97 on February 6, 2014. The Company received an aggregate amount of \$11.4 million for the sale from the two counterparties.

The purchased call options and warrants were considered indexed to the Company stock, required net-share settlement and met all criteria for equity classification at inception and in subsequent periods. The purchased call options cost of \$31.0 million, less deferred taxes of \$10.8 million, and the \$11.4 million received for the warrants, were recorded as adjustments to additional paid-in capital.

On November 20, 2015, the Company's agent initiated the repurchase of \$53.6 million in aggregate principal amount of its February 2018 Notes for \$43.7 million in cash in four open market transactions. The closing of these transactions occurred on November 30, 2015. It was determined that the repurchase of the principal amount should be accounted for as a partial extinguishment of the February 2018 Notes. As a result, a gain on extinguishment of \$6.5 million was recorded at closing of the transaction. The \$6.5 million gain on extinguishment included the de-recognition of a proportional share of the original issuance discount of \$3.1 million, outstanding deferred issuance costs of \$0.9 million and agent fees of \$0.1 million. In connection with this repurchase of the February 2018 Notes, the Company unwound a corresponding portion of the purchased call options related to the notes. As a result of this unwinding, the Company received \$0.3 million in cash. The payments received have been recorded as an increase to additional paid-in-capital. In addition, the Company unwound a corresponding portion of the warrants issued in connection with the notes for \$0.2 million in cash, payable by the Company. The payments have been recorded as a decrease to additional paid-in-capital.

On November 22, 2016, the Company repurchased \$120.0 million in aggregate principal amount of its February 2018 Notes for approximately \$121.5 million in cash (including \$1.5 million of accrued interest) in open market transactions. It was determined that the repurchase of the principal amount be accounted for as an extinguishment. The extinguishment included the de-recognition of a proportional share of the original issuance discount of \$4.3 million and outstanding deferred issuance costs of \$1.3 million. In connection with the repurchase of the February 2018 Notes, the Company unwound a corresponding portion of the purchased call options. The transaction did not result in any cash payments between the parties. In addition, the Company and the counterparties agreed to unwind a corresponding portion of the warrants, which also did not result in any cash payments between the parties.



On February 1, 2018, upon maturity of the February 2018 Notes, the Company repaid a total cash amount of \$129.0 million to the custodian, The Bank of New York Mellon Trust Company, N.A., which was comprised of \$126.4 million in principal amount and \$2.6 million in accrued interest, to retire the February 2018 Notes.

The carrying value and unamortized discount of the February 2018 Notes were as follows:

<i>(in thousands)</i>	<b>December 31, 2018</b>	<b>December 31, 2017</b>
Principal amount of the February 2018 Notes .....	\$ —	\$ 126,447
Unamortized discount of liability component.....	—	(381)
Net carrying value of the February 2018 Notes .....	<u>\$ —</u>	<u>\$ 126,066</u>

Interest expense for the February 2018 Notes on the Company’s Consolidated Statements of Operations was as follows:

<i>(in thousands)</i>	<b>Year Ended December 31,</b>		
	<b>2018</b>	<b>2017</b>	<b>2016</b>
Contractual coupon interest.....	\$ 422	\$ 5,058	\$ 9,338
Amortization of debt issuance costs.....	88	1,022	2,863
Amortization of debt discount.....	293	3,449	9,870
Total.....	<u>\$ 803</u>	<u>\$ 9,529</u>	<u>\$ 22,071</u>

#### **December 2021 Notes**

On November 22, 2016, the Company issued \$150.0 million in aggregate principal amount, at par, of the December 2021 Notes in an underwritten public offering, for net proceeds of \$145.7 million. The December 2021 Notes are due December 1, 2021, and the Company pays interest at 2.75% on the December 2021 Notes semiannually in arrears on June 1 and December 1 of each year, beginning June 1, 2017. A portion of the proceeds from the December 2021 Notes, net of amounts used for the capped call transaction described below, was used to extinguish \$120.0 million of the February 2018 Notes.

Upon the occurrence of a fundamental change, as defined in the indenture entered into in connection with the December 2021 Notes (the “December 2021 Notes Indenture”), holders have the option to require the Company to repurchase their December 2021 Notes at a purchase price equal to 100% of the principal, plus accrued interest.

The December 2021 Notes are convertible under any of the following circumstances:

- During any fiscal quarter (and only during such fiscal quarter) commencing after the fiscal quarter ended March 31, 2017, if the last reported sale price of Company common stock for at least 20 trading days (whether or not consecutive), in the period of 30 consecutive trading days, ending on, and including, the last trading day of the immediately preceding fiscal quarter, exceeds 130% of the conversion price for the notes on each applicable trading day;
- During the five business-day period immediately after any five consecutive trading-day period, which the Company refers to as the measurement period, in which the trading price per \$1,000 principal amount of notes for each trading day of that measurement period was less than 98% of the product of the last reported sale price of Company common stock and the conversion rate for the notes for each such trading day; or
- Upon the occurrence of specified corporate events as described in the December 2021 Notes Indenture.

The initial conversion rate for the December 2021 Notes is 262.2951 shares of the Company’s common stock per \$1,000 principal amount of December 2021 Notes, which is equivalent to an initial conversion price of approximately \$3.81 per share of common stock, subject to adjustments upon the occurrence of certain specified events as set forth in the December 2021 Notes Indenture.

In accordance with the accounting guidance for convertible debt instruments that may be settled in cash or other assets on conversion, the Company was required to separately account for the liability component of the instrument in a manner that reflects the market interest rate for a similar nonconvertible instrument at the date of issuance. As a result, the Company separated the principal balance of the December 2021 Notes between the fair value of the debt component and the fair value of the common stock conversion feature. Using an assumed borrowing rate of 9.5%, which represented the estimated market interest rate for a similar nonconvertible instrument available to the Company on the date of issuance, the Company recorded a total debt discount of \$4.3 million, allocated \$23.8 million to additional paid-in capital and allocated \$12.8 million to deferred tax liability. The discount is being amortized to interest expense over the term of the December 2021 Notes and increases interest expense during

the term of the December 2021 Notes from the 2.75% cash coupon interest rate to an effective interest rate of 3.4%. As of December 31, 2018, the remaining discount amortization period is 2.9 years.

The carrying value and unamortized discount of the December 2021 Notes were as follows:

<i>(in thousands)</i>	<b>December 31, 2018</b>	<b>December 31, 2017</b>
Principal amount of the December 2021 Notes.....	\$ 150,000	\$ 150,000
Unamortized discount of liability component.....	(25,356)	(32,585)
Net carrying value of the December 2021 Notes.....	<u>\$ 124,644</u>	<u>\$ 117,415</u>

Interest expense for the December 2021 Notes on the Company's Consolidated Statements of Operations was as follows:

<i>(in thousands)</i>	<b>Year Ended December 31,</b>	
	<b>2018</b>	<b>2017</b>
Contractual coupon interest.....	\$ 4,125	\$ 4,125
Amortization of debt issuance costs.....	76	74
Amortization of debt discount.....	542	526
Amortization of conversion feature.....	6,611	5,967
Total.....	<u>\$ 11,354</u>	<u>\$ 10,692</u>

As of December 31, 2018 and 2017, the December 2021 Notes are not convertible. At December 31, 2018 and 2017, the if-converted value of the December 2021 Notes did not exceed the principal amount.

#### *Capped Call Transaction*

In connection with the offering of the December 2021 Notes, the Company entered into a privately-negotiated capped call transaction with an affiliate of the underwriter of such issuance. The aggregate cost of the capped call transaction was \$14.4 million. The capped call transaction is generally expected to reduce the potential dilution upon conversion of the December 2021 Notes and/or partially offset any cash payments the Company is required to make in excess of the principal amount of converted December 2021 Notes in the event that the market price per share of the Company's common stock, as measured under the terms of the capped call transaction, is greater than the strike price of the capped call transaction. This initially corresponds to the approximate \$3.81 per share conversion price of the December 2021 Notes and is subject to anti-dilution adjustments substantially similar to those applicable to the conversion rate of the December 2021 Notes. The cap price of the capped call transaction was initially \$4.88 per share, and is subject to certain adjustments under the terms of the capped call transaction. The Company will not be required to make any cash payments to the option counterparty upon the exercise of the options that are a part of the capped call transaction, but the Company will be entitled to receive from it an aggregate amount of cash and/or number of shares of the Company's common stock, based on the settlement method election chosen for the related convertible senior notes, with a value equal to the amount by which the market price per share of the Company's common stock, as measured under the terms of the capped call transaction, is greater than the strike price of the capped call transaction during the relevant valuation period under the capped call transaction, with such number of shares of the Company's common stock and/or amount of cash subject to the cap price.

The Company evaluated the capped call transaction under authoritative accounting guidance and determined that it should be accounted for as a separate transaction and classified as a net reduction to additional paid-in capital within stockholders' equity with no recurring fair value measurement recorded.

As of December 31, 2018, the future minimum principal payments under the December 2021 Notes were:

<i>(in thousands)</i>	December 2021 Notes	Total
2019.....	\$ —	\$ —
2020.....	—	—
2021.....	150,000	150,000
2022.....	—	—
2023.....	—	—
Thereafter.....	—	—
Total.....	<u>\$ 150,000</u>	<u>\$ 150,000</u>

## 17. Other Long-Term Liabilities

Other long-term liabilities consist of the following:

<i>(in thousands)</i>	December 31,	
	2018	2017
Accrued lease liability.....	\$ 10,700	\$ 10,700
Long-term incentive.....	125	1,729
Deferred tax liability.....	13,847	1,208
Uncertain tax positions.....	31,706	30,682
Dividend payable.....	4	47
Other.....	461	343
Total.....	<u>\$ 56,843</u>	<u>\$ 44,709</u>

## 18. Stock-Based Compensation

The Company grants stock-based incentive awards to attract, motivate and retain qualified employees and non-employee directors, and to align their financial interest with those of the Company's stockholders. The Company utilizes stock-based compensation in the form of restricted stock awards and options to purchase common stock, in each case pursuant to a stockholder approved equity incentive plan.

### Stock-Based Compensation Expense

The following table summarizes the Company's stock option and restricted stock award activity during the years ended December 31, 2018, 2017 and 2016:

<b>Stock-based Compensation</b>	Year Ended December 31,		
<i>(in thousands)</i>	2018	2017	2016
Employees and directors.....	\$ 4,758	\$ 3,138	\$ 3,679
Non-employees.....	—	—	63
Total.....	<u>\$ 4,758</u>	<u>\$ 3,138</u>	<u>\$ 3,742</u>

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option-pricing model. Expected volatility is based on the historical volatility of our common stock over the estimated expected life of the options. The expected term represents the period of time the options are expected to be outstanding. The expected term is based on the "simplified method" as defined by the SEC Staff Accounting Bulletin No. 110 (Topic 14.D.2). The Company uses the "simplified method" due to the lack of sufficient historical exercise data to provide a reasonable basis upon which to otherwise estimate the expected life of the options. The risk-free rate is based on yields on U.S. Treasury securities with a maturity similar to the estimated expected term of the options.

The fair value of our stock options was estimated assuming no expected dividends and the following weighted-average assumptions:

	Year Ended December 31,		
	2018	2017	2016
Range of expected term (in years).....	3.5 - 6	3.7	—
Range of risk-free interest rate .....	2.7% - 3.0%	2.0%	—%
Expected volatility.....	40%	44%	—%

### Stock-Based Incentive Plans

#### 2005 Equity Incentive Plan

The Company currently has one active stock-based incentive plan under which it may grant stock-based awards to the Company’s employees, directors and non-employees.

Under the Company’s Amended and Restated 2005 Equity Incentive Plan effective June 8, 2018 (the “2005 Equity Incentive Plan”), the Company is authorized to issue a variety of incentive awards, including stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance share and performance unit awards, deferred compensation awards and other stock-based or cash-based awards. As of December 31, 2018, awards granted under the 2005 Equity Incentive Plan consisted of stock options and restricted stock awards. There were no other grants of any other award types under the 2005 Equity Incentive Plan.

In June 2018, the Company’s stockholders approved an amendment and restatement of the 2005 Equity Incentive Plan that increased the number of shares available for grant by 15,000,000 to 26,200,000. The number of shares of common stock authorized for issuance, shares of common stock issued upon exercise of options or grant of restricted stock awards, shares of common stock subject to outstanding awards and shares available for grant under this plan as of December 31, 2018, are as follows:

Title of Plan	Total Shares of Common Stock Authorized	Total Shares of Common Stock Issued	Total Shares of Common Stock Available for Grant
2005 Equity Incentive Plan .....	26,200,000	10,416,523	15,783,477

#### Stock Options

The following table summarizes the option activity under the 2005 Equity Incentive Plan for the year ended December 31, 2018:

	Options (in thousands)	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at beginning of year .....	—	\$ —	—	\$ —
Granted .....	6,908	\$ 2.76		
Outstanding at end of year .....	6,908	\$ 2.76	9.1	\$ 1,099
Exercisable at end of year .....	1,763	\$ 2.76	9.1	\$ 259

Options to purchase common stock generally vest over a 4-year period and are generally granted for a term of 10 years.

The weighted-average grant-date fair value of options granted during the year ended December 31, 2018 was \$1.09. The total fair value of options vested during the year ended December 31, 2018 was approximately \$1.8 million. Total unrecognized compensation expense of \$5.0 million related to options will be recognized over a weighted-average period of 2.9 years.

### *Restricted Stock Awards*

Restricted stock has the same rights as other issued and outstanding shares of the Company's common stock, including, in some cases, the right to accrue dividends, which are held in escrow until the award vests. The compensation expense related to these awards is determined using the fair market value of the Company's common stock on the date of the grant, and the compensation expense is recognized ratably over the vesting period. Under the Company's restricted stock plans, restricted stock awards typically vest over one to five years and compensation expense associated with these awards is recognized on a straight-line basis over the vesting period. In addition to service requirements, vesting of restricted stock awards may be subject to the achievement of specified performance goals set by the Compensation Committee. If the performance goals are not met, no compensation expense is recognized and any previously recognized compensation expense is reversed.

The following table summarizes the restricted stock award activity under the 2005 Equity Incentive Plan for the year ended December 31, 2018:

	<b>2018</b>	
	<b>Number of shares</b>	<b>Weighted- average grant- date fair value per share</b>
	<i>(in thousands)</i>	
Unvested at beginning of year .....	2,065	\$ 2.61
Awards granted .....	1,057	\$ 2.61
Awards vested .....	(758)	\$ 2.78
Withheld related to net settlement .....	(104)	\$ 2.71
Forfeited .....	(1,537)	\$ 2.44
Unvested at end of year .....	<u>723</u>	<u>\$ 2.79</u>

The total fair value of restricted stock awards vested during the years ended December 31, 2018, 2017 and 2016 was approximately \$2.1 million, \$2.8 million and \$2.4 million, respectively.

The weighted-average grant date fair value for restricted stock awards granted under the 2005 Equity Incentive Plan for the years end December 31, 2018, 2017 and 2016 was \$2.61, \$2.15 and \$3.31, respectively.

At December 31, 2018, there was approximately \$1.1 million of total unrecognized compensation expense related to restricted stock awards granted under the 2005 Equity Incentive Plan, which is expected to be recognized over a weighted-average period of 0.8 years.

### *Inducement Award Agreements*

On September 12, 2017, the Company granted 961,000 shares of common stock in the form of a non-statutory inducement stock option grant pursuant to a non-statutory inducement stock option agreement and granted 240,200 shares of our common stock in the form of an inducement restricted stock grant pursuant to an inducement restricted stock agreement. These inducement awards were not granted under the 2005 Equity Incentive Plan.

### *Inducement Stock Option Activity*

As of December 31, 2018, all stock option awarded under the non-statutory inducement stock option agreement were outstanding and 260,271 shares were exercisable. The total fair value of options vested during the year ended December 31, 2018 was approximately \$0.4 million. Total unrecognized compensation expense of \$0.4 million related to these options will be recognized over a weighted-average period of 2.8 years.

### *Inducement Restricted Stock*

As of December 31, 2018, 160,134 shares of restricted stock awarded under the non-statutory inducement restricted stock agreement were outstanding and unvested. The total fair value of the restricted stock awards vested during the year ended December 31, 2018 was approximately \$0.3 million.

Compensation expense associated with unvested restricted stock awards is recognized on a straight-line basis over the vesting period. At December 31, 2018, there was approximately \$0.3 million of total unrecognized compensation expense related to restricted stock awards granted under the non-statutory inducement restricted stock agreement, which is expected to be recognized over a weighted-average period of 1.4 years.

## 19. Income Taxes

For financial reporting purposes, (loss) income before income taxes includes the following components:

<i>(in thousands)</i>	Years Ended December 31,		
	2018	2017	2016
United States.....	\$ 48,844	\$ 195,865	\$ 103,656
Foreign.....	(104,766)	(11,338)	5,714
Total .....	\$ (55,922)	\$ 184,527	\$ 109,370

The provision for income taxes for the years ended December 31, 2018, 2017 and 2016 consisted of the following:

<i>(in thousands)</i>	Year Ended December 31,		
	2018	2017	2016
Current income tax (benefit) expense			
Federal.....	\$ 2,169	\$ 31,338	\$ 49,582
State.....	1,029	2,843	3,103
Foreign .....	(4,107)	529	2,455
Total current .....	(909)	34,710	55,140
Deferred income tax expense (benefit)			
Federal.....	11,497	36,911	(8,476)
State.....	1,313	2,591	147
Foreign .....	1,036	(386)	(1,100)
Total deferred .....	13,846	39,116	(9,429)
Total provision .....	\$ 12,937	\$ 73,826	\$ 45,711

A reconciliation of the income tax provision computed using the U.S. statutory federal income tax rate compared to the income tax provision for income included in the Consolidated Statements of Operations is as follows:

<i>(in thousands)</i>	Year Ended December 31,		
	2018	2017	2016
Tax at U.S. statutory rate on (loss) income before income taxes.....	\$ (11,744)	\$ 64,589	\$ 38,279
Change in valuation allowance .....	11,226	1,807	(744)
State taxes .....	1,376	1,496	74
Change in uncertain tax positions.....	809	681	2,184
Foreign income .....	1,048	3,231	5,668
Foreign rate differential .....	8,936	1,356	(1,445)
Change in tax rate reform .....	—	716	—
True-ups .....	939	—	—
Other .....	347	(50)	1,695
Total.....	\$ 12,937	\$ 73,826	\$ 45,711

Deferred tax assets and liabilities are determined based on the differences between financial reporting and income tax bases of assets and liabilities, as well as net operating loss carryforwards and are measured using the enacted tax rates and laws in effect when the differences are expected to reverse. The significant components of the Company's net deferred tax assets and liabilities are as follows:

<i>(in thousands)</i>	December 31,	
	2018	2017
Deferred tax assets:		
Net operating loss carryforwards.....	\$ 11,713	\$ 6,276
Research and other tax credits.....	1,580	1,414
Intangible assets.....	2,203	1,453
Stock-based compensation.....	1,130	547
Accruals.....	2,362	4,667
Debt modifications.....	4,661	—
Capital loss carryforward.....	1,866	2,027
Other.....	6,642	5,878
Total deferred tax assets.....	32,157	22,262
Valuation allowance.....	(13,271)	(2,046)
Total deferred tax assets, net of valuation allowance.....	18,886	20,216
Deferred tax liabilities:		
Deferred gain on repurchase of convertible notes.....	—	(117)
Debt modifications.....	(2,981)	(1,197)
Intangible assets.....	(28,214)	(16,932)
Other.....	—	(427)
Unrealized gain on foreign currency hedge contracts and investments.....	—	(320)
Total deferred tax liabilities.....	(31,195)	(18,993)
Net deferred tax (liabilities) assets.....	\$ (12,309)	\$ 1,223

As of December 31, 2018 and 2017, the Company had federal net operating loss carryforwards of \$101.7 million and \$117.3 million, respectively. As of December 31, 2018 and 2017, the Company also had state net operating loss carryforwards of \$285.9 million and \$299.9 million, respectively. The federal and state net operating loss carryforwards will begin expiring in the year 2023, if not utilized. As of December 31, 2018 and 2017, the Company had \$2.2 million and \$2.2 million, respectively, of federal tax credits that will begin expiring in the year 2025, if not utilized. As of December 31, 2018 and 2017, the Company had \$19.3 million and \$19.3 million, respectively, of state tax credit carryforwards that do not expire. As of December 31, 2018, the Company had \$73.0 million of net operating loss carryforwards in Ireland that do not expire.

Utilization of the federal and state net operating loss and tax credit carryforwards may be subject to a substantial annual limitation due to the “change in ownership” provisions of the Internal Revenue Code of 1986. The annual limitation may result in the expiration of net operating losses and credits before utilization. Of the Company's \$101.7 million of federal net operating loss carryforwards as of December 31, 2018, \$30.4 million are subject to an annual limitation of \$1.8 million for each of the years ending December 31, 2018 to 2022, and \$1.3 million for the year ending December 31, 2023. As of December 31, 2018, the Company estimates that at least \$22.0 million of federal net operating loss carryforwards and none of the state net operating losses will expire unutilized. Furthermore, under the 2017 Tax Act, although the treatment of tax losses generated in taxable years ending before December 31, 2017 has not changed, tax losses generated in taxable years beginning after December 31, 2017 may only be utilized to offset 80% of taxable income annually. This change may require the Company to pay additional federal income taxes in future years if additional losses are generated post 2017.

As of December 31, 2018, the Company determined that it was more likely than not that certain deferred tax assets would not be realized in the near future and had a \$13.3 million valuation allowance against deferred tax assets. The net change in total valuation allowance for each of the years ending December 31, 2018 and 2017, was an increase of \$11.2 million and \$0.5 million, respectively. \$1.9 million of the valuation allowance at December 31, 2018, is related to capital losses that have limited carryforward utilization. The Company does not have an expectation of future capital gains against which such losses could be

utilized and as such determined that it was more likely than not that such deferred tax assets would not be realized. \$11.4 million of the valuation allowance at December 31, 2018, is related to Ireland deferred tax assets that the Company determined it was more likely than not would not be realized.

The cumulative amount of earnings of our foreign subsidiaries are expected to be permanently invested in the foreign subsidiaries. Deferred taxes have not been provided on the excess of book basis over tax basis, or the excess tax basis over book basis in the shares of our foreign subsidiaries because these basis differences are not expected to reverse in the foreseeable future and are essentially permanent in duration. Our intention is to reinvest the earnings of the foreign subsidiaries indefinitely.

The Tax Cuts and Job Act of 2017 significantly changed the existing U.S. corporate income tax laws by, among other things, lowering the corporate tax rate (from a top rate of 35% to a flat rate of 21%), implementing elements of a territorial tax system, and imposing a one-time deemed repatriation transition tax on cumulative undistributed foreign earnings, for which we have not previously paid U.S. taxes. Due to the complexities involved in accounting for the 2017 Tax Act, the SEC staff issued Staff Accounting Bulletin No. 118 ("SAB 118") to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Act. SAB 118 provided a measurement period of up to one year after the enactment date of the 2017 Tax Act to finalize the recording of the related tax impacts.

The Company's accounting for the following elements of the 2017 Tax Act is complete:

- *Change in federal corporate tax rate from a top rate of 35% to a flat rate of 21% ("Rate Adjustment")*: The December 31, 2017 provisional estimate and December 31, 2018 additional measurement-period adjustment related to the Rate Adjustment on our deferred tax assets and liabilities impacted the Company's income tax rate by less than 1% for each of the years ended December 31, 2017 and 2018.
- *Global intangible low-taxed income ("GILTI")*: The Company did not recognize any GILTI for the year ended December 31, 2017. No provisional estimate or additional measurement-period adjustments were recorded for the years ended December 31, 2017 and 2018. The Company have made a policy election with respect to its treatment of potential GILTI to account for taxes on GILTI as a current-period expense as incurred.
- *Foreign-derived intangible income ("FDII")*: The Company did not recognize any FDII benefit for the year ended December 31, 2017. No provisional estimate or additional measurement-period adjustments were recorded for the years ended December 31, 2017 and 2018.
- *Deemed repatriation transition tax ("Transition Tax")*: The December 31, 2017 provisional estimate and December 31, 2018 additional measurement-period adjustment to the Transition Tax obligation impacted the Company's income tax rate by less than 1% for each of the years ended December 31, 2017 and 2018.
- *Base-erosion and anti-abuse tax ("BEAT")*: The Company did not recognize any BEAT obligation for the year ended December 31, 2017. No provisional estimate or additional measurement-period adjustments were recorded for the years ended December 31, 2017 and 2018.

A reconciliation of the Company's unrecognized tax benefits, excluding accrued interest and penalties, for 2018, 2017 and 2016 is as follows:

<i>(in thousands)</i>	<b>December 31,</b>		
	<b>2018</b>	<b>2017</b>	<b>2016</b>
Balance at the beginning of the year .....	\$ 79,179	\$ 59,429	\$ 57,125
Increases related to tax positions from prior fiscal years .....	1,604	783	436
Increases related to tax positions taken during current fiscal year .....	—	18,967	1,868
Balance at the end of the year.....	<u>\$ 80,783</u>	<u>\$ 79,179</u>	<u>\$ 59,429</u>

The future impact of the unrecognized tax benefit of \$80.8 million, if recognized, is as follows: \$59.5 million would affect the effective tax rate and \$21.3 million would result in adjustments to deferred tax assets. The Company periodically evaluates its exposures associated with our tax filing positions. As noted below, the Company is currently under audit by the California Franchise Tax Board and the Internal Revenue Service. The timing of the audit resolution and the amount to be ultimately paid (if any) is uncertain. The outcome of these audits could result in the payment of tax amounts that differ from the amounts the Company has reserved for uncertain tax positions for the periods under audit resulting in incremental expense or a reversal of the Company's reserves in a future period. At this time, the Company does not anticipate a material change in the unrecognized tax



benefits related to the California or Internal Revenue Service audits that would affect the effective tax rate or deferred tax assets over the next 12 months.

Estimated interest and penalties associated with unrecognized tax benefits increased income tax expense in the Consolidated Statements of Operations by \$1.0 million, during each of the years ended December 31, 2018, 2017 and 2016, respectively. In general, the Company's income tax returns are subject to examination by U.S. federal, foreign, state and local tax authorities for tax years 2000 forward. Interest and penalties associated with unrecognized tax benefits accrued on the balance sheet were \$8.0 million and \$7.0 million as of December 31, 2018 and 2017, respectively. The Company is currently under income tax examination by the State of California for the tax years 2009 through 2015 and by the Internal Revenue Service for the tax year 2016.

## **20. Stockholders' Equity**

### ***Stock Repurchase Program***

On March 1, 2017, the Company announced that its board of directors authorized the repurchase through March 2018 of issued and outstanding shares of the Company's common stock having an aggregate value of up to \$30.0 million pursuant to a share repurchase program. The repurchases under the share repurchase program were made from time to time in the open market or in privately negotiated transactions and were funded from the Company's working capital. All shares of common stock repurchased under the Company's share repurchase program were retired and restored to authorized but unissued shares of common stock at June 30, 2017. The Company repurchased 13.3 million shares of its common stock under the share repurchase program during the fiscal year ended December 31, 2017 for an aggregate purchase price of \$30.0 million, or an average cost of \$2.25 per share, including trading commissions.

On September 25, 2017, the Company announced that its board of directors authorized the repurchase of issued and outstanding shares of the Company's common stock having an aggregate value of up to \$25.0 million pursuant to a share repurchase program. The repurchases under the share repurchase program were made from time to time in the open market or in privately negotiated transactions and were funded from the Company's working capital. All shares of common stock repurchased under this share repurchase program were retired and restored to authorized but unissued shares of common stock at July 5, 2018. The Company repurchased 8.7 million shares of its common stock for an aggregate purchase price of \$25.0 million, or an average cost of \$2.86 per share, including trading commissions.

On September 24, 2018, the Company announced that its board of directors authorized the repurchase of issued and outstanding shares of the Company's common stock having an aggregate value of up to \$100.0 million pursuant to a new share repurchase program. Repurchases under the new share repurchase program will be made from time to time in the open market or in privately negotiated transactions and funded from the Company's working capital. The amount and timing of such repurchases will depend upon the price and availability of shares, general market conditions and the availability of cash. Repurchases may also be made under a trading plan under Rule 10b5-1, which would permit shares to be repurchased when the Company might otherwise be precluded from doing so because of self-imposed trading blackout periods or other regulatory restrictions. All shares of common stock repurchased under the Company's new share repurchase program are expected to be retired and restored to authorized but unissued shares of common stock. As of December 31, 2018, the Company has repurchased 8.7 million shares of its common stock under this share repurchase program for an aggregate purchase price of \$25.5 million, or an average cost of \$2.94 per share, including trading commissions. As of December 31, 2018, the Company had 750,000 shares held in treasury stock at a total cost of \$2.1 million. Those shares were settled and retired on January 8, 2019. This share repurchase program may be suspended at any time without notice.

## **21. Cash Dividends**

On August 3, 2016, the Company's board of directors decided to eliminate the quarterly cash dividend payment.

On May 2, 2016, the Company's board of directors declared a quarterly dividend of \$0.05 per share of common stock to stockholders of record on June 6, 2016. On June 13, 2016, the Company paid \$8.2 million in connection with such dividend payment. Unvested restricted stock awards as of the record date are also entitled to dividends, which will only be paid when the restricted stock awards vest and are released.

On January 26, 2016, the Company's board of directors declared a quarterly dividend of \$0.05 per share of common stock to stockholders of record on March 4, 2016. On March 11, 2016, the Company paid \$8.2 million in connection with such dividend

payment. Unvested restricted stock awards as of the record date are also entitled to dividends, which will only be paid when the restricted stock awards vest and are released.

## 22. Accumulated Other Comprehensive Income

Comprehensive income is comprised of net (loss) income and other comprehensive (loss) income. The Company includes unrealized net gains (losses) on investments held in its available-for-sale securities and unrealized gains (losses) on its cash flow hedges in other comprehensive (loss) income, and presents the amounts net of tax. The Company's other comprehensive (loss) income is included in the Company's Consolidated Statements of Comprehensive (Loss) Income.

The balance of "accumulated other comprehensive (loss) income," net of tax, was as follows:

<i>(in thousands)</i>	Unrealized gains (losses) on available-for- sale securities	Unrealized gains (losses) on cash flow hedges	Total Accumulated Other Comprehensive Income
Balance at December 31, 2015.....	\$ 435	\$ 1,821	\$ 2,256
Activity for the year ended December 31, 2016 .....	(435)	(1,821)	(2,256)
Balance at December 31, 2016.....	—	—	—
Activity for the year ended December 31, 2017 .....	1,181	—	1,181
Ending Balance at December 31, 2017 .....	1,181	—	1,181
Activity for the year ended December 31, 2018 .....	(1,181)	\$ —	\$ (1,181)
Ending Balance at December 31, 2018 .....	\$ —	\$ —	\$ —

## 23. Business Combinations

### NODEN TRANSACTION

#### *Description of the Noden Transaction*

On July 1, 2016, the Noden Transaction was consummated for cash consideration of \$110.0 million that was paid to Novartis on July 1, 2016, the closing date of the acquisition. In addition, pursuant to the terms of the Noden Purchase Agreement, Noden Pharma DAC committed to pay Novartis the following amounts in cash: \$89.0 million payable on the first anniversary of the closing date, and up to an additional \$95.0 million contingent on achievement of sales targets and the date of the launch of a generic drug containing the pharmaceutical ingredient aliskiren.

On July 1, 2016, upon the consummation of the Noden Transaction, a non-controlling interest holder acquired a 6% equity interest in Noden. In May 2017, such equity interest was repurchased for \$2.2 million in cash by the Company. The Company accounted for the repurchase in accordance with ASC 810 and recognized the difference between the fair value of the consideration paid and the amount by which the non-controlling interest is adjusted for in equity attributable to the Company.

The Company determined that Noden shall be consolidated under the voting interest model as of December 31, 2018 and 2017.

On July 3, 2017, Noden made the \$89.0 million anniversary payment to Novartis pursuant to the terms of the Noden Purchase Agreement, of which \$32.0 million was funded by the Company in the form of an equity contribution. The Company may make additional equity contributions to Noden of at least \$38.0 million to fund a portion of certain milestone payments under the Noden Purchase Agreement, subject to the occurrence of such milestones.

#### *Fair Value of Consideration Transferred*

The fair value of consideration transferred totals \$244.3 million, which consists of \$216.7 million in acquired product rights, \$23.9 million in customer relationships, \$47.4 million in contingent consideration and \$87.0 million in anniversary

payments. Contingent consideration includes the future payments that the Company may pay to Novartis based on achieving certain milestones.

The contingent consideration was measured at fair value and recognized as of the acquisition date. The Company determined the acquisition date fair value of the contingent consideration obligation based on an income approach derived from the Noden Products revenue estimates and a probability assessment with respect to the likelihood of (a) achieving the level of net sales or (b) there being no generic product launch that would trigger the milestone payments. The fair value measurement is based on significant inputs not observable in the market and thus represents a Level 3 measurement as defined in fair value measurement accounting. The key assumptions in determining the fair value are the discount rate and the probability assigned to the potential milestones being achieved. At each reporting date, the Company will re-measure the contingent consideration obligation to estimated fair value. Any changes in the fair value of contingent consideration will be recognized in operating expenses until the contingent consideration arrangement is settled.

As of the effective time of the acquisition, the identifiable intangible assets are required to be measured at fair value and these assets could include assets that are not intended to be used or sold or that are intended to be used in a manner other than their highest and best use. For purposes of the valuation, it is assumed that all assets will be used in the manner that represents the highest and best use of those assets, but it is not assumed that any market synergies will be achieved. The consideration of synergies has been excluded because they are not considered to be factually supportable.

The fair value of identifiable assets is determined primarily using the “income method,” which starts with a forecast of all expected future cash flows. Some of the more significant assumptions inherent in the development of intangible asset values, from the perspective of a market participant, include, among other factors: the amount and timing of projected future cash flows (including net revenue, cost of product sales, research and development costs, sales and marketing expenses, income tax expense, capital expenditures and working capital requirements) and estimated contributory asset charges; the discount rate selected to measure the risks inherent in the future cash flows; and the assessment of the asset’s life cycle and the competitive trends impacting the asset.

The following table presents a summary of the total fair value of consideration transferred for the Noden Products acquisition:

*(in thousands)*

Consideration paid in cash at closing.....	\$ 109,938
Discounted anniversary payment.....	87,007
Fair value of contingent consideration.....	47,360
Total fair value of consideration transferred .....	<u>\$ 244,305</u>

#### ***Assets Acquired and Liabilities Assumed***

In accordance with the authoritative guidance for business combinations, the Noden Transaction was determined to be a business combination and is expected to be accounted for using the acquisition method of accounting.

The following table summarizes the fair values of the identifiable intangible assets acquired and liabilities assumed at the acquisition date:

*(in thousands)*

Acquired product rights .....	\$ 216,690
Customer relationships.....	23,880
Goodwill .....	3,735
Net intangible assets.....	<u>\$ 244,305</u>

The acquired product rights represent developed technology of products approved for sales in the market, which the Company refers to as marketed products, and have finite useful lives. During the second quarter of 2018, the Company concluded that the Noden DAC acquired product rights and customer relationship long-lived assets, with a carrying amount of \$192.5 million, were no longer recoverable and wrote them down to their estimated fair value of \$40.1 million, resulting in an impairment charge of \$152.3 million. The remaining Noden DAC intangible asset balance, included in the Pharmaceutical segment, will be amortized on a straight-line basis over the remaining useful life of eight years. They are amortized on a straight-line basis over a weighted-average remaining useful life of 8 years.

## LENSAR TRANSACTION

### *Description of the LENSAR Transaction*

In December 2016, LENSAR filed the Chapter 11 case with the support of the Company, as its largest senior secured creditor under a credit agreement, as amended, that the Company and LENSAR had entered into in 2013. For more information regarding the credit agreement between the Company and LENSAR, please see Note 9, *Notes and Other Long-Term Receivables*. In January 2017, the Company agreed to provide debtor-in-possession financing of up to \$2.8 million in new advances to LENSAR so that it could continue to operate its business during the remainder of the Chapter 11 case. As part of the Chapter 11 case, LENSAR filed a Chapter 11 plan of reorganization, with the Company's support, under which LENSAR would issue 100% of its equity securities to the Company in exchange for the cancellation of the Company's claims as a secured creditor in the Chapter 11 case. Following consummation of the Chapter 11 plan of reorganization, LENSAR would become an operating subsidiary of the Company and the Company provided LENSAR a new, senior-secured, first-priority term loan facility (the "Exit Facility").

On April 26, 2017, the bankruptcy court approved the plan of reorganization. On May 11, 2017, LENSAR and the Company consummated the plan of reorganization and LENSAR emerged from bankruptcy. Pursuant to the plan of reorganization, the Company obtained control of 100% of the outstanding voting shares of LENSAR. All assets of the LENSAR bankruptcy estate re-vested in reorganized LENSAR free and clear of all liens, claims or charges. Upon consummation of the plan of reorganization, all debt owed to the Company was eliminated other than the Exit Facility. Liabilities to other creditors, including general unsecured creditors, were satisfied through the plan of reorganization.

The Company concluded that the LENSAR transaction should be accounted for by applying the acquisition method in accordance with ASC 805 that did not involve a transfer of consideration ("combinations by contract").

### *Fair Value of Consideration Transferred*

Contemporaneously with the cancellation of the Company's notes receivable with a carrying value of \$43.9 million, the Company acquired 100% equity interests in LENSAR, at fair value, for \$31.7 million resulting in a loss on extinguishment of notes receivable of \$10.6 million. The fair value of the equity interest in LENSAR was determined primarily using the "income method," which starts with a forecast of all expected future cash flows of the acquired business. The acquisition resulted in a gain on bargain purchase because the fair value of assets acquired and liabilities assumed exceeded the total of the fair value of the equity interest in LENSAR by approximately \$9.3 million, net of loss on extinguishment of notes receivables, which was recorded in the Consolidated Statement of Operations for the year ended December 31, 2017.

### *Assets Acquired and Liabilities Assumed*

The following table summarizes the fair values of the identifiable intangible assets acquired and liabilities assumed at the acquisition date (in thousands):

<i>(in thousands)</i>	
Cash.....	\$ 1,983
Tangible assets .....	18,647
Intangible assets <sup>(1)</sup> .....	11,970
Net deferred tax assets .....	25,723
Total identifiable assets .....	<u>58,323</u>
Current liabilities .....	<u>(6,673)</u>
Total liabilities assumed.....	<u>(6,673)</u>
Net loss on derecognition of notes receivables.....	<u>(10,615)</u>
Gain on bargain purchase, net of loss on extinguishment of notes receivable .....	<u>(9,309)</u>
Total fair value of consideration .....	<u>\$ 31,726</u>

<sup>(1)</sup> As of the effective date of the transaction, identifiable intangible assets are required to be measured at fair value. The fair value measurement is based on significant inputs that are unobservable in the market and thus represents a Level 3

measurement. The Company used an income approach to estimate the preliminary fair value of the intangibles which includes technology, trademarks and customer relationships. The assumptions used to estimate the cash flows of the business included a discount rate of 16%, estimated gross margins ranging from 37-72%, income tax rate of 35%, and operating expenses consisting of direct costs based on the anticipated level of revenues. The intangible assets have a weighted-average useful life of approximately 15 years. The intangible assets for acquired technology and trademarks are being amortized over their estimated useful lives using the straight-line method of amortization. The intangible assets for customer relationship are being amortized using a double-declining method of amortization as such method better represents the economic benefits to be obtained.

### ***Pro Forma Impact of Business Combination***

The following table represents the unaudited consolidated financial information for the Company on a pro forma basis for the years ended December 31, 2018 and 2017, assuming that the LENSAR transaction had closed on January 1, 2017. The historical financial information has been adjusted to give effect to pro forma items that are directly attributable to the acquisition and are expected to have a continuing impact on the consolidated results. Additionally, the following table sets forth unaudited financial information and has been compiled from historical financial statements and other information, but is not necessarily indicative of the results that actually would have been achieved had the transactions occurred on the dates indicated or that may be achieved in the future.

<i>(in thousands, except per share amounts)</i>	<b>Year Ended December 31,</b>	
	<b>2018</b>	<b>2017</b>
Pro forma revenues .....	\$ 198,110	\$ 325,605
Pro forma net (loss) income .....	\$ (68,859)	\$ 107,193
Pro forma net (loss) income per share - basic .....	\$ (0.47)	\$ 0.69
Pro forma net (loss) income per share - diluted .....	\$ (0.47)	\$ 0.69

The unaudited pro forma consolidated results include historical revenues and expenses of assets acquired in the LENSAR Transaction with the following adjustments:

- Adjustment to recognize incremental amortization expense based on the fair value of intangibles acquired;
- Elimination of non-recurring charges directly related to the acquisition that were included in the historical results of operations for the Company; and
- Adjustment to recognize pro forma income tax based on income tax benefit on the amortization of intangible asset at the statutory tax rate of the United States, at such time, and the income tax benefit on the interest expense at the statutory tax rate of the United States, at such time.

### **24. Segment Information**

Information regarding the Company's segments for the year ended December 31, 2018 and 2017 is as follows:

<i>Revenues by segment (in thousands)</i>	<b>Year Ended December 31,</b>	
	<b>2018</b>	<b>2017</b>
Pharmaceutical .....	\$ 80,796	\$ 69,032
Medical Devices .....	24,652	15,091
Income Generating Assets .....	92,662	235,937
Total revenues .....	<u>\$ 198,110</u>	<u>\$ 320,060</u>

<i>(Loss) income by segment</i> <i>(in thousands)</i>	<b>Year Ended December 31,</b>	
	<b>2018</b>	<b>2017</b>
Pharmaceutical .....	\$ (98,368)	\$ (5,755)
Medical Devices .....	(5,086)	(9,256)
Income Generating Assets .....	34,595	125,759
Total net (loss) income.....	<u>\$ (68,859)</u>	<u>\$ 110,748</u>

<i>Long-lived assets by segment</i> <i>(in thousands)</i>	<b>Year Ended December 31,</b>	
	<b>2018</b>	<b>2017</b>
Pharmaceutical .....	\$ 3,682	\$ 822
Medical Devices.....	3,545	6,263
Income Generating Assets.....	160	137
Total long-lived assets.....	<u>\$ 7,387</u>	<u>\$ 7,222</u>

The operations for the Company’s Pharmaceutical and Medical Devices segments are primarily located in Ireland and the United States, respectively.

## 25. Legal Proceedings

### *PDL BioPharma, Inc. v Merck Sharp & Dohme, Corp.*

On January 22, 2016, the Company filed a complaint against Merck Sharp & Dohme, Corp (“Merck”) for patent infringement in the United States District Court for the District of New Jersey. In the complaint, the Company alleged that manufacture and sales of certain of Merck’s Keytruda product infringed one or more claims of the Company’s U.S. Patent No. 5,693,761 (the “761 Patent”). The Company requested judgment that Merck infringed the 761 Patent, an award of damages due to the infringement, a finding that such infringement was willful and deliberate and trebling of damages therefore, and a declaration that the case is exceptional and warrants an award of attorney’s fees and costs.

On April 21, 2017, the Company entered into a settlement agreement with Merck to resolve the patent infringement lawsuit between the parties pending in the U.S. District Court for the District of New Jersey related to Merck’s Keytruda humanized antibody product. Under the terms of the agreement, Merck paid the Company a one time, lump-sum payment of \$19.5 million, and the Company granted Merck a fully paid-up, royalty free, non-exclusive license to certain of the Company’s rights to issued patents in the United States and elsewhere, covering the humanization of antibodies (the “Queen et al. patent”) for use in connection with Keytruda as well as a covenant not to sue Merck for any royalties regarding Keytruda. In addition, the parties agreed to dismiss all claims in the relevant legal proceedings.

### *Wellstat Litigation*

On September 4, 2015, the Company filed in the Supreme Court of New York a motion for summary judgment in lieu of complaint which requested that the court enter judgment against Wellstat Diagnostics Guarantors for the total amount due on the Wellstat Diagnostics debt, plus all costs and expenses including lawyers’ fees incurred by the Company in enforcement of the related guarantees. On July 29, 2016, the court issued its Memorandum of Decision granting the Company’s motion for summary judgment and denying the Wellstat Diagnostics Guarantors’ cross-motion for summary judgment seeking a determination that they were no longer liable under the guarantees. The Supreme Court of New York held that the Wellstat Diagnostics Guarantors are liable for all “Obligations” owed by Wellstat Diagnostics to the Company. It did not set a specific dollar amount due, but ordered that a judicial hearing officer or special referee be designated to determine the amount of the Obligations owing, and awarded the Company its attorneys’ fees and costs in an amount to be determined. On July 29, 2016, the Wellstat Diagnostics Guarantors filed a notice of appeal from the Memorandum of Decision to the Appellate Division of the Supreme Court of New York. On February 14, 2017, the Appellate Division reversed the summary judgment decision of the Supreme Court in the Company’s favor, but affirmed the denial of the Wellstat Guarantors’ cross-motion for summary judgment. The Appellate Division determined that the action was inappropriate for summary judgment pursuant to New York Civil Practice Law & Rules section 3213 on procedural grounds, but specifically made no determination regarding whether the Company was entitled to a judgment on the merits. Pursuant to this decision, the action has been remanded to the Supreme Court for further proceedings on the merits.

The proceeding is conducted as a plenary proceeding, with both parties having the opportunity to take discovery and file dispositive motions in accordance with New York civil procedure.

#### ***Noden Pharma DAC v Anchen Pharmaceuticals, Inc. et al***

On June 12, 2017, Noden Pharma DAC filed a complaint against Anchen and Par Pharmaceutical (“Par”) for infringement of U.S. Patent No. 8,617,595 based on their submission of an Abbreviated New Drug Application (“ANDA”) seeking authorization from the FDA to market a generic version of Tekturna<sup>®</sup> aliskiren hemifumarate tablets, 150 mg and 300 mg, in the United States. Noden Pharma DAC’s suit triggered a 30-month stay of FDA approval of that application under the Hatch Waxman Act. Par filed a counterclaim seeking a declaratory judgment that their proposed generic version of Tekturna HCT<sup>®</sup> aliskiren hemifumarate hydrochlorothiazide tablets (150 mg eq. base/12.5 mg HCT, 150 mg eq. base/25 mg HCT, 300 mg eq. base/12.5 mg HCT, and 300 mg eq. base/25 mg HCT), described in a separate ANDA submitted by Par to FDA, alleging noninfringement of U.S. Patent No. 8,618,172 (“the ‘172 Patent”), also owned by Noden Pharma DAC. This case was litigated in the United States District Court for the District of Delaware. In March of 2018, the Parties filed a joint stipulation of dismissal of the defendants’ counterclaim seeking a declaratory judgment of non-infringement of the ‘172 Patent. In the stipulation, Anchen and Par agreed that they will not seek, or otherwise join or assist in, any post-grant review, including *inter partes* review, of the ‘172 patent or U.S. Patent No. 9,023,893. The defendants further stipulated that they will not seek marketing approval of Par’s ANDA or submit any other ANDA seeking approval to market aliskiren hemifumarate hydrochlorothiazide prior to the expiration of the ‘172 Patent in July of 2028. Both the ‘172 Patent and the ‘893 Patent are listed in the Orange Book for Tekturna HCT. On June 8, 2018, Noden and Anchen entered into a settlement agreement (the “Settlement Agreement”). Under the Settlement Agreement, the parties agreed to file a stipulation of dismissal with the court to facilitate dismissal of the litigation in its entirety, with prejudice. In the Settlement Agreement, Noden granted Anchen a non-exclusive, royalty free, fully paid up and non-transferable license to manufacture and commercialize in the United States a generic version of aliskiren which is described in Anchen’s ANDA, and Anchen agreed not to commercialize its generic version of aliskiren prior to March 1, 2019. The license grant excludes certain formulations covered by the ‘595 Patent which closely relate to the commercial formulation of Tekturna marketed by Noden. The Settlement Agreement includes a release by each party for liabilities associated with the litigation and an acknowledgment from Anchen that the ‘595 Patent claims are valid and enforceable.

#### ***Depomed, Inc. vs. Valeant Pharmaceuticals, Inc.***

On October 27, 2017, Valeant, Depomed and the Company entered into a settlement agreement (“Depomed Settlement Agreement”) to resolve all matters addressed in the lawsuit. Under the terms of the Depomed Settlement Agreement, the litigation was dismissed, with prejudice, and Valeant paid to Depomed a one-time, lump-sum payment of \$13.0 million. In addition, Depomed and the Company released Valeant and its subsidiary from any and all claims against them as a result of the audit, Valeant’s obligation to pay additional royalties under the commercialization agreement and/or the litigation; and Valeant released Depomed and the Company against any and all claims against them as a result of the audit and/or the litigation. The settlement payment was transferred to the Company under the terms of the Depomed Royalty Agreement in November of 2017.

#### ***Other Legal Proceedings***

From time to time, the Company is involved in lawsuits, arbitrations, claims, investigations and proceedings, consisting of intellectual property, commercial, employment and other matters, which arise in the ordinary course of business. The Company makes provisions for liabilities when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. Such provisions are reviewed at least quarterly and adjusted to reflect the impact of settlement negotiations, judicial and administrative rulings, advice of legal counsel, and other information and events pertaining to a particular case. Litigation is inherently unpredictable. If any unfavorable ruling were to occur in any specific period, there exists the possibility of a material adverse impact on the results of the Company’s operations of that period and on its cash flows and liquidity.

## **26. Subsequent Events**

#### ***Share Repurchase***

From January 1, 2019 to March 13, 2019, the Company repurchased approximately 10.7 million shares of its common stock at a weighted-average price of \$3.32 per share for a total of \$35.5 million. The total amounts repurchased by the Company under the \$100.0 million share repurchase program authorized by the Company’s board of directors equal approximately 19.4 million shares of its common stock for an aggregate purchase price of \$61.0 million, or an average cost of \$3.15 per share, including trading commissions.

### CareView Modification Agreement

As further discussed in Note 9, *Notes and Other Long-Term Receivables*, the first principal payment and the scheduled interest payment due December 31, 2018 that were previously deferred until January 31, 2019 were subsequently deferred until March 31, 2019 under additional amendments.

### Authorized Generic

As further discussed in Note 13, *Intangible Assets*, on March 4, 2019, the Company announced the U.S. commercial launch of an authorized generic of Tekturna, with the same drug formulation as Tekturna.

## 27. Quarterly Financial Data (Unaudited)

<i>(in thousands, except per share data)</i>	<b>Three Months Ended</b>			
	<b>December 31, 2018</b>	<b>September 30, 2018</b>	<b>June 30, 2018</b>	<b>March 31, 2018</b>
Total revenues .....	\$ 45,119	\$ 67,898	\$ 46,575	\$ 38,518
Net income (loss) attributable to PDL's stockholders....	\$ 16,279	\$ 25,556	\$ (112,296)	\$ 1,602
Net income (loss) per basic share .....	\$ 0.12	\$ 0.18	\$ (0.76)	\$ 0.01
Net income (loss) per diluted share .....	\$ 0.11	\$ 0.18	\$ (0.76)	\$ 0.01

<i>(in thousands, except per share data)</i>	<b>Three Months Ended</b>			
	<b>December 31, 2017</b>	<b>September 30, 2017</b>	<b>June 30, 2017</b>	<b>March 31, 2017</b>
Total revenues .....	\$ 68,036	\$ 62,749	\$ 143,835	\$ 45,440
Net income attributable to PDL's stockholders.....	\$ 22,336	\$ 20,732	\$ 60,439	\$ 7,241
Net income per basic share .....	\$ 0.15	\$ 0.14	\$ 0.39	\$ 0.04
Net income per diluted share .....	\$ 0.15	\$ 0.14	\$ 0.39	\$ 0.04



**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's management has evaluated, with the participation of the chief executive officer and the chief financial officer, the effectiveness of the Company's disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (Exchange Act)) as of the end of the period covered by this report. Based on this evaluation, management concluded that the Company's disclosure controls and procedures were effective as of December 31, 2018.

**Management's Report on Internal Control over Financial Reporting**

The Company's management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in the Exchange Act Rules 13a-15(f) and 15d-15(f). The Company's management, including the chief executive officer and chief financial officer, conducted an evaluation of the effectiveness of the Company's internal control over financial reporting based on the *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on the results of this evaluation, the Company's management concluded that internal control over financial reporting was effective as of December 31, 2018.

The effectiveness of the Company's internal control over financial reporting as of December 31, 2018, has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in its report included herein.

**Changes in Internal Control over Financial Reporting**

During the quarter ended December 31, 2018, there were no changes in the Company's internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

**ITEM 9B. OTHER INFORMATION**

Not applicable.

### **PART III**

Certain information required by Part III is omitted from this Annual Report on Form 10-K and is incorporated herein by reference to our definitive Proxy Statement for our 2019 Annual Meeting of Stockholders (the "Proxy Statement"), which we intend to file pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended, within 120 days after December 31, 2018.

#### **ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

The information required by this Item 10 will be contained in the Proxy Statement and is incorporated herein by reference.

#### **ITEM 11. EXECUTIVE COMPENSATION**

The information required by this Item 11 will be contained in the Proxy Statement and is incorporated herein by reference.

#### **ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

The information required by this Item 12 will be contained in the Proxy Statement and is incorporated herein by reference.

#### **ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

The information required by this Item 13 will be contained in the Proxy Statement and is incorporated herein by reference.

#### **ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES**

The information required by this Item 14 will be contained in the Proxy Statement and is incorporated herein by reference.

### **PART IV**

#### **ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

**(a) The following documents are filed as part of this Annual Report on Form 10-K:**

**(1) Financial Statements - See Index to Consolidated Financial Statements at Item 8 of this Annual Report on Form 10-K.**

**(2) Financial Statement Schedules**

The financial statement schedules are omitted because the information is not applicable, not required under the instructions, or the information requested is set forth in our Consolidated Financial Statements or related notes thereto.

**(3) Exhibits required by Item 601 of Regulation S-K**

The information required by this Section (a)(3) of Item 15 is set forth on the exhibit index that precedes the Signatures page of this Annual Report on Form 10-K.

#### **ITEM 16. FORM 10-K SUMMARY**

None.

## EXHIBIT INDEX

Exhibit Number	Exhibit Title
2.1	Separation and Distribution Agreement, dated December 17, 2008, between the Company and Facet Biotech Corporation (incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed December 23, 2008)
2.2	Amendment No. 1 to Separation and Distribution Agreement, dated January 20, 2009, between the Company and Facet Biotech Corporation (incorporated by reference to Exhibit 2.2 to Annual Report on Form 10-K filed March 2, 2009)
3.1	Restated Certificate of Incorporation effective March 23, 1993 (incorporated by reference to Exhibit 3.1 to Annual Report on Form 10-K filed March 31, 1993)
3.2	Certificate of Amendment of Certificate of Incorporation effective August 21, 2001 (incorporated by reference to Exhibit 3.3 to Annual Report on Form 10-K filed March 14, 2002)
3.3	Certificate of Amendment of Certificate of Incorporation effective January 9, 2006 (incorporated by reference to Exhibit 99.1 to Current Report on Form 8-K filed January 10, 2006)
3.4	Certificate of Designation, Preferences and Rights of the Terms effective August 25, 2006 (incorporated by reference to Exhibit 3.4 to Registration Statement on Form 8-A filed September 6, 2006)
3.5	Third Amended and Restated Bylaws effective December 4, 2014 (incorporated by reference to Exhibit 99.1 to Current Report on Form 8-K filed December 9, 2014)
3.6	Certificate of Amendment of Restated Certificate of Incorporation effective May 22, 2013 (incorporated by reference to Exhibit 4.4 to Registration Statement on Form S-3 filed June 21, 2013)
4.1	Indenture between the Company and The Bank of New York Mellon Trust Company, N.A., dated February 12, 2014 (incorporated by reference to Exhibit 4.1 to Current Report on Form 8-K filed February 12, 2014)
4.2	Supplemental Indenture between the Company and The Bank of New York Mellon Trust Company, N.A., dated February 12, 2014 (incorporated by reference to Exhibit 4.1 to Current Report on Form 8-K filed February 12, 2014)
4.3	Second Supplemental Indenture between the Company and The Bank of New York Mellon Trust Company, N.A., dated February 28, 2014 (incorporated by reference to Exhibit 4.9 to Annual Report on Form 10-K filed March 3, 2014)
4.4	Indenture between the Company and the Bank of New York Mellon Trust Company, N.A., dated November 22, 2016 (incorporated by reference to Exhibit 4.1 to Current Report on Form 8-K filed November 28, 2016)
4.5	Supplemental Indenture between the Company and The Bank of New York Mellon Trust Company, N.A., dated November 22, 2016 (incorporated by reference to Exhibit 4.2 to Current Report on Form 8-K filed November 28, 2016)
10.1*	Amended and Restated 2005 Equity Incentive Plan effective June 4, 2009 (incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed July 31, 2009)
10.2*	Form of Notice of Grant of Stock Option under the 2005 Equity Incentive Plan (incorporated by reference to Exhibit 10.7 to Quarterly Report on Form 10-Q filed August 9, 2006)
10.3*	Form of Stock Option Agreement under the 2005 Equity Incentive Plan (incorporated by reference to Exhibit 10.8 to Quarterly Report on Form 10-Q filed August 9, 2006)
10.4*	Form of Notice of Grant of Restricted Stock Award under the 2005 Equity Incentive Plan (incorporated by reference to Exhibit 10.9 to Quarterly Report on Form 10-Q filed August 9, 2006)
10.5*	Form of Restricted Stock Agreement under the 2005 Equity Incentive Plan (for the officers of the Company) (incorporated by reference to Exhibit 10.10 to Quarterly Report on Form 10-Q filed August 9, 2006)
10.6*	Offer Letter between the Company and John McLaughlin, dated November 4, 2008 (incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed November 10, 2008)
10.7	Tax Sharing and Indemnification Agreement, dated December 18, 2008, between the Company and Facet Biotech Corporation (incorporated by reference to Exhibit 10.3 to Current Report on Form 8-K filed December 23, 2008)

- 10.8 Patent Licensing Master Agreement between the Company and Genentech, Inc., dated September 25, 1998 (incorporated by reference to Exhibit 10.10 to Quarterly Report on Form 10-Q filed November 16, 1998)†
- 10.9 Amendment No. 1 to Patent Licensing Master Agreement between the Company and Genentech, Inc., dated September 18, 2003 (incorporated by reference to Exhibit 10.45 to Annual Report on Form 10-K filed March 8, 2004)†
- 10.10 Amendment No. 2 to Patent Licensing Master Agreement between the Company and Genentech, Inc., dated December 18, 2003 (incorporated by reference to Exhibit 10.26 to Annual Report on Form 10-K filed March 2, 2009)
- 10.11 Amendment No. 1 to the Herceptin License Agreement between the Company and Genentech, Inc., dated December 18, 2003 (incorporated by reference to Exhibit 10.47 to Annual Report on Form 10-K filed March 8, 2004)
- 10.12 Patent License Agreement, dated July 17, 1997, between the Company and MedImmune Inc. (incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed January 24, 2011)†
- 10.13 Patent License Agreement, dated April 24, 1998, between the Company and Elan International Services Ltd. (incorporated by reference to Exhibit 10.29 to Annual Report on Form 10-K filed March 2, 2009) †
- 10.14\* Offer Letter between the Company and Christopher Stone, dated December 30, 2008 (incorporated by reference to Exhibit 10.29 to Annual Report on Form 10-K filed March 1, 2010)
- 10.15 Settlement Agreement between the Company and Genentech, Inc., dated December 18, 2003 (incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed November 9, 2010) †
- 10.16 Amended and Restated Patent Licensing Master Agreement between the Company and Genentech, Inc., dated July 27, 2009 (incorporated by reference to Exhibit 10.2 to Quarterly Report on Form 10-Q filed November 9, 2010)†
- 10.17 Amendments to Product Licenses and Settlement Agreement between the Company and Genentech, Inc. dated July 27, 2009 (incorporated by reference to Exhibit 10.3 to Quarterly Report on Form 10-Q filed November 9, 2010)
- 10.18\* Offer Letter between the Company and Danny Hart, dated January 11, 2010 (incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed April 18, 2011)
- 10.19\* Form of Executive Officer Severance Agreement (incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed May 26, 2011)
- 10.20 Lease Agreement between 932936, LLC and the Company, dated April 17, 2012 (incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed May 3, 2012)
- 10.21 Revenue Interests Purchase Agreement between the Company and AxoGen, Inc., dated October 5, 2012 (incorporated by reference to Exhibit 10.49 to Annual Report on Form 10-K filed March 1, 2013)†
- 10.22 Credit Agreement between the Company and Wellstat Diagnostics, LLC, dated November 2, 2012 (incorporated by reference to Exhibit 10.50 to Annual Report on Form 10-K filed March 1, 2013)†
- 10.23\* Offer Letter between the Company and Peter Garcia, dated March 27, 2013 (incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed April 30, 2013)
- 10.24 Credit Agreement between the Company and Avinger, Inc., dated April 18, 2013 (incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed August 8, 2013)†
- 10.25 Amended and Restated Credit Agreement between the Company and Wellstat Diagnostics, LLC, dated August 15, 2013 (incorporated by reference to Exhibit 10.2 to Quarterly Report on Form 10-Q filed November 6, 2013)†
- 10.26 Form of Credit Agreement between the Company and certain borrowers (incorporated by reference to Exhibit 10.56 to Annual Report on Form 10-K filed March 3, 2014)
- 10.27 Royalty Purchase and Sale Agreement between the Company and Depomed, Inc. and Depo DR Sub, LLC, dated October 18, 2013 (incorporated by reference to Exhibit 10.58 to Annual Report on Form 10-K filed March 3, 2014)†
- 10.28 Settlement Agreement among Genentech, Inc., F. Hoffman-la Roche Ltd. and the Company, dated January 31, 2014 (incorporated by reference to Exhibit 10.2 to Quarterly Report on Form 10-Q filed May 12, 2014)†

- 10.29 Summary of omitted Credit Agreement between PDL BioPharma, Inc. and Paradigm Spine, LLC, dated February 14, 2014 (incorporated by reference to Exhibit 10.5 to Quarterly Report on Form 10-Q filed May 12, 2014)
- 10.30 Note Purchase Agreement between the Company and Accel 300, LLC, dated April 1, 2014 (incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed August 18, 2014)
- 10.31\* 2014/18 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.2 to Quarterly Report on Form 10-Q filed August 18, 2014)
- 10.32 First Amendment to Lease Agreement between 932936, LLC and the Company, effective May 27, 2014 (incorporated by reference to Exhibit 10.3 to Quarterly Report on Form 10-Q filed August 18, 2014)
- 10.33 First Amendment to Amended and Restated Credit Agreement between the Company and Wellstat Diagnostics, LLC, dated June 19, 2014 (incorporated by reference to Exhibit 10.4 to Quarterly Report on Form 10-Q filed August 18, 2014)†
- 10.34 Second Amendment to Amended and Restated Credit Agreement between the Company and Wellstat Diagnostics, LLC, dated August 21, 2014 (incorporated by reference to Exhibit 10.64 to Annual Report on Form 10-K filed February 23, 2015)†
- 10.35 Third Amendment to Amended and Restated Credit Agreement between the Company and Wellstat Diagnostics, LLC, dated November 4, 2014 (incorporated by reference to Exhibit 10.65 to Annual Report on Form 10-K filed February 23, 2015)†
- 10.36 Schedule of Amendment to Omitted Credit Amendment between PDL BioPharma, Inc. and Direct Flow Medical (incorporated by reference to Exhibit 10.67 to Annual Report on Form 10-K filed February 23, 2015)
- 10.37 Credit Agreement among the Company, as borrower, the lenders from time to time party thereto and Royal Bank of Canada, as administrative agent, dated as of March 31, 2015 (incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed April 1, 2015)
- 10.38\* 2015/19 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.2 to Quarterly Report on Form 10-Q filed May 6, 2015)
- 10.39\* Offer Letter between the Company and Steffen Pietzke, executed May 19, 2015 (incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed June 24, 2015)
- 10.40 Second Amendment to Lease Agreement between 932936, LLC and the Company, effective May 19, 2015 (incorporated by reference to Exhibit 10.3 to Quarterly Report on Form 10-Q filed August 5, 2015)
- 10.41\* Amended and Restated 2005 Equity Incentive Plan effective May 28, 2015 (incorporated by reference to Exhibit 10.4 to Quarterly Report on Form 10-Q filed August 5, 2015)
- 10.42\* Amended and Restated 2015/19 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.2 to Quarterly Report on Form 10-Q filed November 4, 2015)
- 10.43 Revenue Interest Assignment Agreement, dated as of July 28, 2015, between ARIAD Pharmaceuticals, Inc. and the Company (incorporated by reference to Exhibit 10.3 to Quarterly Report on Form 10-Q filed November 4, 2015)†
- 10.44 Schedule of Amendments to Omitted Credit Amendments between PDL BioPharma, Inc. and LENSAR, Inc. and between PDL BioPharma, Inc. and Paradigm Spine, LLC (incorporated by reference to Exhibit 10.71 to Annual Report on Form 10-K filed February 23, 2016)
- 10.45\* 2016 Annual Bonus Plan (incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed May 4, 2016)
- 10.46\* 2016/20 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.2 to Quarterly Report on Form 10-Q filed May 4, 2016)
- 10.47 Asset Purchase Agreement between Novartis AG, Novartis Pharma AG, Speedel Holding AG and Noden Pharma DAC, dated as of May 24, 2016 (incorporated by reference to Exhibit 2.1 to Current Report on Form 8-K/A filed August 3, 2016)†
- 10.48 Schedule of Amendment to Omitted Credit Agreement between PDL BioPharma, Inc. and Direct Flow Medical, Inc. (incorporated by reference to Exhibit 10.2 to Quarterly Report on Form 10-Q filed August 4, 2016)

- 10.49 Amendment No. 1 to RIAA between ARIAD Pharmaceuticals, Inc. and PDL BioPharma, Inc., dated as of May 9, 2016 (incorporated by reference to Exhibit 10.3 to Quarterly Report on Form 10-Q filed August 4, 2016)†
- 10.50 Supply Agreement between Novartis Pharma AG and Noden Pharma DAC, dated as of May 24, 2016 (incorporated by reference to Exhibit 10.4 to Quarterly Report on Form 10-Q filed August 4, 2016)†
- 10.51 Noden Pharma DAC Investment and Stockholders' Agreement by and among Noden Pharma DAC, PDL BioPharma, Inc., Elie Farah and other Persons listed on Annex A thereto, dated as of July 1, 2016 (incorporated by reference to Exhibit 10.5 to Quarterly Report on Form 10-Q filed August 4, 2016)†
- 10.52 Schedule of Amendment to Omitted Credit Amendment between PDL BioPharma, Inc. and LENSAR, Inc. (incorporated by reference to Exhibit 10.75 to Annual Report on Form 10-K filed March 1, 2017)
- 10.53\* 2017 Annual Bonus Plan (incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed May 3, 2017)
- 10.54\* 2017/21 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.2 to Quarterly Report on Form 10-Q filed May 3, 2017)
- 10.55 Third Amendment to Lease Agreement between 932936, LLC and the Company, effective April 24, 2017 (incorporated by reference to Exhibit 10.3 to Quarterly Report on Form 10-Q filed May 3, 2017)
- 10.56\* Offer Letter between the Company and Dominique Monnet, dated August 31, 2017 (incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed September 11, 2017)
- 10.57\* Form of Nonstatutory Inducement Stock Option Grant Notice and Nonstatutory Inducement Stock Option Agreement between PDL BioPharma, Inc. and Dominique Monnet. (incorporated by reference to Exhibit 99.1 to Form S-8 Registration Statement filed September 12, 2017)
- 10.58\* Form of Inducement Restricted Stock Grant Notice and Inducement Restricted Stock Agreement between PDL BioPharma, Inc. and Dominique Monnet (incorporated by reference to Exhibit 99.2 to Form S-8 Registration Statement filed September 12, 2017)
- 10.59\* Confidential Separation Agreement and Release of All Claims between Danny Hart and the Company, dated as of October 23, 2017 (incorporated by reference to Exhibit 10.2 to Quarterly Report on Form 10-Q filed November 13, 2017)
- 10.60 Fourth Amendment to Lease Agreement between 932936, LLC and the Company, effective December 1, 2017
- 10.61\* Amended and Restated 2005 Equity Incentive Plan (incorporated by reference to Exhibit 99.1 to Form S-8 Registration Statement filed June 8, 2018)
- 10.62\* Form of Stock Option Grant Notice and Stock Option Agreement for use in connection with awards under the Amended and Restated 2005 Equity Incentive Plan (incorporated by reference to Exhibit 99.2 to Form S-8 Registration Statement filed June 8, 2018)
- 10.63\* Form of Restricted Stock Grant Notice and Restricted Stock Agreement for use in connection with awards under the Amended and Restated 2005 Equity Incentive Plan (incorporated by reference to Exhibit 99.3 to Form S-8 Registration Statement filed June 8, 2018)
- 10.64\* 2018 Annual Bonus Plan (incorporated by reference to Exhibit 10.1 to Quarterly Report on Form 10-Q filed August 9, 2018)
- 10.65 Amendment No. 1 to Royalty Purchase and Sale Agreement and Bill of Sale between PDL Investment Holding, LLC and Depomed, Inc. and Depo DR Sub, LLC, dated August 2, 2018 (incorporated by reference to Exhibit 10.2 to Quarterly Report on Form 10-Q filed August 9, 2018)
- 10.66\* Form of Director and Officer Indemnification Agreement (incorporated by reference to Exhibit 10.2 to Quarterly Report on Form 10-Q filed November 7, 2018)
- 12.1# Ratio of Earnings to Fixed Charges
- 21.1# Subsidiaries of the Registrant
- 23.1# Consent of Independent Registered Public Accounting Firm
- 31.1# Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended

31.2#	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended
32.1#+	Certifications of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 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
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Linkbase
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase

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# Filed herewith.

\* Management contract or compensatory plan or arrangement.

† Certain information in this exhibit has been omitted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request under 17 C.F.R. Sections 200.80(b)(4) and 24b-2.

+ The certifications attached as Exhibit 32.1 accompany this Annual Report on Form 10-K pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed “filed” by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

PDL BIOPHARMA, INC.

By:           /S/ DOMINIQUE MONNET            
**(Dominique Monnet)**  
**President and Chief Executive Officer**

Date: March 14, 2019

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/S/ DOMINIQUE MONNET</u> <b>(Dominique Monnet)</b>	President and Chief Executive Officer (Principal Executive Officer)	March 14, 2019
<u>/S/ PETER S. GARCIA</u> <b>(Peter S. Garcia)</b>	Vice President and Chief Financial Officer (Principal Financial Officer and Acting Principal Accounting Officer)	March 14, 2019
<u>/S/ DAVID GRYSKA</u> <b>(David Gryska)</b>	Director	March 14, 2019
<u>/S/ JOHN P. MCLAUGHLIN</u> <b>(John P. McLaughlin)</b>	Director	March 14, 2019
<u>/S/ ELIZABETH O'FARRELL</u> <b>(Elizabeth O'Farrell)</b>	Director	March 14, 2019
<u>/S/ DR. SAMUEL SAKS</u> <b>(Dr. Samuel Saks)</b>	Director	March 14, 2019
<u>/S/ PAUL W. SANDMAN</u> <b>(Paul W. Sandman)</b>	Director	March 14, 2019
<u>/S/ HAROLD E. SELICK</u> <b>(Harold E. Slick)</b>	Director	March 14, 2019
<u>/S/ SHLOMO YANAI</u> <b>(Shlomo Yanai)</b>	Director	March 14, 2019



# Corporate Directory

## Senior Leadership Team

**Dominique P. Monnet**  
President and  
Chief Executive Officer

**Peter S. Garcia**  
Vice President and  
Chief Financial Officer

**Jill M. Jene, Ph.D.**  
Vice President,  
Business Development

**Christopher L. Stone**  
Vice President and  
General Counsel

## Board of Directors

**Harold E. Selick, Ph.D.**  
Chairman, PDL BioPharma, Inc.  
Vice Chancellor  
University of California  
San Francisco (UCSF)

**David W. Gryska**  
Former Executive Vice President and  
Chief Financial Officer  
Incyte Corporation

**John P. McLaughlin**  
Former Chief Executive Officer  
PDL BioPharma, Inc.

**Dominique P. Monnet**  
President and  
Chief Executive Officer  
PDL BioPharma, Inc.

**Elizabeth G. O'Farrell**  
Former Chief Procurement Officer  
Eli Lilly and Company

**Samuel R. Saks, M.D.**  
Chief Development Officer  
Protagonist Therapeutics, Inc.

**Paul W. Sandman**  
Former General Counsel  
Boston Scientific Corporation

**Shlomo Yanai**  
Former President and  
Chief Executive Officer  
Teva Pharmaceuticals

## Corporate Headquarters

PDL BioPharma, Inc.  
932 Southwood Blvd.  
Incline Village, NV 89451

## For More Information

Tel: 775.832.8500  
Fax: 775.832.8501  
Email: [ir@pdl.com](mailto:ir@pdl.com)  
[www.PDL.com](http://www.PDL.com)

## Transfer Agent

Computershare  
Shareowner Services LLC  
P.O. Box 30170  
College Station, TX 77842-3170  
877.424.4271  
(dedicated for shareholders  
of PDL BioPharma)  
[computershare.com/investor](http://computershare.com/investor)

## Common Stock

NASDAQ Global  
Select Market®: PDLI

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This annual Report contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical facts are "forward looking statements" for purposes of these provisions, including any projections of earnings, revenues or other financial items, any statements of the plans and objectives of management for future operations, any statements regarding future economic conditions or performance, and any statement of assumptions underlying any of the foregoing in some cases, forward-looking statements can be identified by the use of terminology such as "may," "will," "intends," "plans," "believes," "anticipates," "expects," "estimates," "predicts," "potential," "continue" or "opportunity," or the negative thereof or other comparable terminology. Although we believe that the expectations presented in the forward-looking statements contained herein are reasonable, there can be no assurance that such expectations or any of the forward-looking statements will prove to be correct, and actual results could differ materially from those projected or assumed in the forward-looking statements. Our future financial condition and results of operations, as well as any forward-looking statements, are subject to inherent risks and uncertainties, including but not limited to the risk factors set forth below, and for the reasons described elsewhere in this Annual Report. All forward-looking statements and reasons why results may differ included in this Annual Report are made as of the date hereof, and we assume no obligation to update these forward-looking statements or reasons why actual results may differ.



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