LA JOLLA PHARMACEUTICAL CO
Form 10-K
March 04, 2019
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

x 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

o 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: 1-36282

LA JOLLA PHARMACEUTICAL COMPANY
(Exact name of registrant as specified in its charter)

California	33-0361285
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

4550 Towne Centre Court, San Diego, CA 92121
(Address of principal executive offices, including Zip Code)

Registrant's telephone number, including area code: (858) 207-4264
Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common Stock, Par Value $0.0001 per share	The Nasdaq Capital Market

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

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

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

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 the filing requirements for the past 90 days. Yes x No o

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes x No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405) 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 the Form 10-K or any amendment to this Form 10-K. x

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an 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	o	Accelerated filer	x
Non-accelerated filer	o	Smaller reporting company	x
		Emerging growth company	o

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

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

The aggregate market value of voting and non-voting common stock held by non-affiliates of the Company as of June 29, 2018 was approximately $603.7 million, based on the closing price on the Nasdaq Capital Market reported for such date. Shares of common stock held by each officer and director and by each person who is known to own 10% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates of the Company. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of February 20, 2019, there were 27,076,171 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information required to be disclosed in Part III of this report is incorporated by reference from the registrant's definitive Proxy Statement for the 2019 Annual Meeting of Shareholders, which proxy statement is expected to be filed no later than 120 days after the end of the fiscal year covered by this report.

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as “intends,” “believes,” “anticipates,” “indicates,” “plans,” “expects,” “suggests,” “may,” “should,” “potential,” “designed to,” “will” and si references. In addition, any statements that refer to expectations, intentions, projections or other characterizations of future events or circumstances are forward-looking statements. These statements relate to future events or the Company’s anticipated future results of operations. These statements are only predictions and involve known and unknown risks, uncertainties and other factors, which may cause actual results to be materially different from these forward-looking statements. The Company cautions readers not to place undue reliance on any such forward-looking statements, which speak only as of the date they were made. Certain of these risks, uncertainties, and other factors are described in greater detail in the Company’s filings with the U.S. Securities and Exchange Commission (SEC), all of which are available free of charge on the SEC’s website www.sec.gov. Actual results may differ materially from those expressed or implied in such statements. These risks include, but are not limited to, risks relating to: our ability to successfully commercialize GIAPREZA™ (angiotensin II); the timing for commencement of preclinical studies and clinical studies; the anticipated timing for completion of such studies and trials, and the anticipated timing for regulatory actions; the success of future development activities for our product candidates; potential indications for which our product candidates may be developed; and the expected duration over which the Company’s cash balances will fund its operations.

Important factors that could cause our actual results and financial condition to differ materially from those indicated in the forward-looking statements include, among others:

- our ability to successfully commercialize, market and achieve market acceptance of GIAPREZA™ (angiotensin II), formerly known as LJPC-501, and other product candidates, including our positioning relative to competing products;
- our ability to grow net sales of GIAPREZA;
- our ability to meet the demand for GIAPREZA in a timely manner;
- the timing and prospects for approval of GIAPREZA by the European Medicines Agency (EMA) or other regulatory authorities;
- potential market sizes for our products, including the market for the treatment of septic or other distributive shock;
- the anticipated treatment of data by the FDA, EMA or other regulatory authorities of La Jolla’s product candidates;
- the cost of producing and selling GIAPREZA;
- unforeseen safety issues from the administration of product and product candidates in patients;
- the timing, costs, conduct and outcome of preclinical studies and clinical studies;
- the expectation for future clinical and regulatory milestones, such as NDA submission and expected timing for commencement and completion of clinical studies;
- the risk that our clinical studies with our product candidates may not be successful in evaluating their safety and tolerability or providing evidence of efficacy;
- the successful and timely completion of clinical studies;
- our plans and timing with respect to seeking regulatory approvals and uncertainties regarding the regulatory process;
- the availability of funds and resources to pursue our research and development projects, including clinical studies with our product candidates;
- uncertainties associated with obtaining and enforcing patents and the availability of regulatory exclusivity;
- the uncertainty of obtaining raw materials or finished products supplies from third parties (some of which may be single sourced) and other related supply and manufacturing difficulties, interruptions and delays;
- our estimates for future performance including but not limited to net sales and net cash used in operating activities for the full-year 2019;
- our ability to hire and retain our key employees;

- our estimates regarding our capital requirements and our needs for, and ability to obtain, additional financing;

- the expected duration over which the Company's cash balances will fund its operations; and
- those risk factors identified in this Annual Report on Form 10-K under the heading "Risk Factors" and in other filings the Company periodically makes with the SEC.

Forward-looking statements contained in this Annual Report on Form 10-K speak as of the date hereof, and we do not undertake to update any of these forward-looking statements to reflect a change in our views or events or circumstances that occur after the date of this Annual Report on Form 10-K. In addition, please see the "Risk Factors" section of this Annual Report on Form 10-K. These risk factors may be updated from time to time by our future filings under the Exchange Act.

PART I

In this Annual Report on Form 10-K, all references to “we,” “our,” “us,” “La Jolla” and “the Company” refer to La Jolla Pharmaceutical Company, a California corporation, and our subsidiaries, including La Jolla Pharma, LLC, on a consolidated basis.

Item 1. Business.

Overview

La Jolla Pharmaceutical Company is a biopharmaceutical company focused on the discovery, development and commercialization of innovative therapies intended to significantly improve outcomes in patients suffering from life-threatening diseases. GIAPREZA™ (angiotensin II), formerly known as LJPC-501, was approved by the U.S. Food and Drug Administration (FDA) on December 21, 2017 as a vasoconstrictor indicated to increase blood pressure in adults with septic or other distributive shock. LJPC-0118 is La Jolla’s investigational product for the treatment of severe malaria. LJPC-401 (synthetic human hepcidin), a clinical-stage investigational product, is being developed for the potential treatment of conditions characterized by iron overload, such as hereditary hemochromatosis, beta thalassemia, sickle cell disease, myelodysplastic syndrome and polycythemia vera.

GIAPREZA™ (angiotensin II)

GIAPREZA™ (angiotensin II), injection for intravenous infusion, was approved by the FDA on December 21, 2017 as a vasoconstrictor indicated to increase blood pressure in adults with septic or other distributive shock. Angiotensin II is a major bioactive component of the renin-angiotensin-aldosterone system (RAAS). The RAAS is one of three central regulators of blood pressure. In March 2018, we announced the commercial availability of GIAPREZA. GIAPREZA is available in 1 mL single-dose vials, each containing 2.5 mg of angiotensin II (as a sterile liquid) through authorized specialty distributors and select wholesalers.

Over 1 million Americans are affected by shock on an annual basis, with 1 in 3 patients being treated for shock in the intensive care unit. Distributive shock is the most common type of shock in the inpatient setting with approximately 800,000 distributive shock cases in the U.S. each year. Of these cases, an estimated 90% are septic shock patients. Approximately 300,000 do not achieve adequate blood pressure response with standard-of-care vasopressor therapy (catecholamines and vasopressin). The inability to achieve or maintain adequate blood pressure results in inadequate blood flow to the body’s organs and tissue and is associated with a mortality rate exceeding most acute conditions requiring hospitalization. In the European Union (EU), the annual incidence of sepsis in adults is estimated to be more than 500,000, with more than 170,000 progressing to septic shock.

The GIAPREZA clinical development program included a Phase 3 study of GIAPREZA in adult patients with septic or other distributive shock who remained hypotensive despite fluid and vasopressor therapy, known as the ATHOS-3 (Angiotensin II for the Treatment of High-Output Shock) Phase 3 study. In ATHOS-3, patients were randomized in a 1:1 fashion to receive either: (i) GIAPREZA plus standard-of-care vasopressors; or (ii) placebo plus standard-of-care vasopressors. ATHOS-3 completed enrollment of 344 patients in the fourth quarter of 2016. In February 2017, we reported positive topline results from ATHOS-3, and, in May 2017, the results of ATHOS-3 were published by The New England Journal of Medicine.

The analysis of the primary efficacy endpoint, defined as the percentage of patients achieving a pre-specified target blood pressure response, was highly statistically significant: 23% of the 158 placebo-treated patients had a blood pressure response compared to 70% of the 163 GIAPREZA-treated patients ($p<0.00001$). In addition, there was a

consistent trend toward longer survival over the 28-day study period: 22% reduction in mortality risk through day 28 [hazard ratio=0.78 (0.57-1.07), p=0.12] for GIAPREZA-treated patients.

In this critically ill patient population: 92% of placebo-treated patients compared to 87% of GIAPREZA-treated patients experienced at least one adverse event, and 22% of placebo-treated patients compared to 14% of GIAPREZA-treated patients discontinued treatment due to an adverse event.

Additional analyses from the ATHOS-3 trial have been published:

- In September 2017, an analysis was presented during the 30th European Society of Intensive Care Medicine Annual Congress, entitled “Baseline angiotensin levels and ACE effects in patients with vasodilatory shock treated with

angiotensin II." The pre-specified analysis showed that a relatively low angiotensin II state (as measured by the ratio of angiotensin I to angiotensin II) predicted increased mortality in patients with vasodilatory shock, suggesting that a low angiotensin II state is a negative prognostic indicator of outcomes. Furthermore, the analysis showed a statistically significant treatment effect of GIAPREZA compared to placebo on mortality in these patients with a relatively low angiotensin II state (relative risk reduction of 36%; HR=0.64; 95% CI: 0.41-1.00; p=0.047).

In February 2018, an abstract was presented at the Society of Critical Care Medicine's (SCCM) 47th Critical Care Congress, entitled "Effect of Disease Severity on Survival in Patients Receiving Angiotensin II for Vasodilatory Shock." The abstract, which was published in the January Supplement of Critical Care Medicine, includes results from a pre-specified analysis from the ATHOS-3 Phase 3 study of GIAPREZA in patients with high severity of illness, defined as an APACHE II (Acute Physiology and Chronic Health Evaluation II) score > 30 or baseline MAP < 65 mmHg, despite treatment with high-dose vasopressors. The authors presented data showing a lower 28-day mortality rate in patients with baseline APACHE II scores > 30 in the GIAPREZA group versus the placebo group: 28-day mortality was 51.8% (n = 58) for the GIAPREZA group compared to 70.8% (n = 65) for the placebo group (hazard ratio=0.62 [95% CI: 0.39, 0.98; p=0.037]). In patients with a baseline MAP < 65 mmHg, a trend towards improved 28-day mortality was seen in the GIAPREZA group compared to the placebo group: 28-day mortality was 54.2% (n = 52) for the GIAPREZA group compared to 70.4% (n = 50) for the placebo group (hazard ratio=0.66 [95% CI: 0.40, 1.09; p=0.10]).

- In March 2018, an analysis was presented at the 23rd International Conference on Advances in Critical Care Nephrology AKI & CRRT 2018, entitled "Outcomes in Patients with Acute Kidney Injury Receiving Angiotensin II for Vasodilatory Shock." The manuscript of this analysis, entitled "Outcomes in patients with vasodilatory shock and renal replacement therapy treated with intravenous angiotensin II," was published online in Critical Care Medicine. The presentation and manuscript detail the outcomes of patients with acute kidney injury (AKI) and vasodilatory shock enrolled in the ATHOS-3 study of GIAPREZA. In this post-hoc analysis, the data from 105 AKI patients (GIAPREZA n=45; placebo n=60) requiring renal replacement therapy (RRT) at study drug initiation were analyzed. Survival through day 28 was 53% (95% CI: 38%-67%) for the GIAPREZA group compared to 30% (95% CI: 19%-41%) for the placebo group (p = 0.012). By day 7, 38% (95% CI: 25%-54%) of patients treated with GIAPREZA discontinued RRT compared to 15% (95% CI: 8%-27%) of patients treated with placebo (p = 0.007). Mean arterial pressure (MAP) response at hour 3 was achieved in 53% (95% CI: 38%-68%) of patients treated with GIAPREZA compared to 22% (95% CI: 12%-34%) of patients treated with placebo (p = 0.001).

In June 2018, we announced that the Marketing Authorization Application (MAA) for GIAPREZA was validated by the EMA. Validation of the MAA confirms that the submission is complete and starts the EMA's centralized review process. This followed our announcement in September 2017, in which we reported that the EMA's Committee for Medicinal Products for Human Use (CHMP) issued favorable Scientific Advice regarding the EU regulatory pathway for GIAPREZA. We expect a decision on the GIAPREZA MAA by the EMA in June 2019. If approved, GIAPREZA could be available for marketing in the EU in early 2020.

LJPC-0118

LJPC-0118 is an investigational product for the treatment of severe malaria. The active pharmaceutical ingredient in LJPC-0118 was demonstrated to be superior to quinine in reducing mortality in patients with severe falciparum malaria infection in two randomized, controlled, clinical studies. Severe malaria is a serious and sometimes fatal disease caused by a parasite that commonly infects a certain type of mosquito, which feeds on humans. Symptoms include, but are not limited to: fever, chills, sweating, hypoglycemia and shock. Severe malaria is often complicated by central nervous system infections that may lead to delirium, which may progress to coma. Infections usually occur a few weeks after being bitten. In 2017, an estimated 219 million cases of malaria occurred worldwide, with an estimated 200 million of these cases occurring in the World Health Organization (WHO) African Region, and in 2013, the global annual incidence of severe malaria was estimated to be 2 million cases. In 2017, an estimated 435,000

people died from malaria worldwide.

We plan to file an NDA for LJPC-0118 with the FDA in the fourth quarter of 2019.

LJPC-401

LJPC-401, a clinical-stage investigational product, is our proprietary formulation of synthetic human hepcidin. Hepcidin, an endogenous peptide hormone, is the body's naturally occurring regulator of iron absorption and distribution. In healthy individuals, hepcidin prevents excessive iron accumulation in vital organs, such as the liver and heart, where it can cause significant damage and even result in death. We are developing LJPC-401 for the potential treatment of iron overload, which occurs as a result of primary iron overload diseases such as hereditary hemochromatosis (HH), or secondary iron

overload diseases such as beta thalassemia (BT), sickle cell disease (SCD), myelodysplastic syndrome (MDS) and polycythemia vera.

HH is a disease characterized by a genetic deficiency in hepcidin. HH is the most common genetic disease in Caucasians and causes liver cirrhosis, liver cancer, heart disease and/or failure, diabetes, arthritis and joint pain. There are no FDA approved therapies for HH and the current standard treatment for HH is a blood removal procedure known as phlebotomy. Each phlebotomy procedure, which is usually conducted at a hospital, medical office or blood center, typically involves the removal of approximately one pint of blood. The required frequency of procedures varies by patient but often ranges from one to two times per week for an initial period after diagnosis and once every one to three months for life. Since most of the body's iron is stored in red blood cells, chronic removal of blood can effectively lower iron levels if a phlebotomy regimen is adhered to. However, phlebotomy procedures may cause and may be associated with pain, bruising and scarring at the venous puncture site, joint pain, fatigue and dizziness during and following the procedure and disruption of daily activities. Furthermore, phlebotomy is not appropriate in patients with poor venous access, anemia or heart disease.

BT, SCD and MDS are genetic diseases of blood cells that can cause life-threatening anemia and usually require frequent and life-long blood transfusions. These blood transfusions cause excessive iron accumulation in the body, which is toxic to vital organs, such as the liver and heart. In addition, the underlying anemia causes excessive iron accumulation independent of blood transfusions.

In 2015, the EMA Committee for Orphan Medicinal Products (COMP) designated LJPC-401 as an orphan medicinal product for the treatment of beta thalassemia intermedia and major. In 2016, the EMA COMP designated LJPC-401 as an orphan medicinal product for the treatment of SCD.

In September 2016, we reported positive results from a Phase 1 study of LJPC-401 in patients at risk of iron overload suffering from HH, thalassemia and SCD. In this study, single, escalating doses of LJPC-401 were associated with a dose-dependent, statistically significant reduction in serum iron. LJPC-401 was well-tolerated with no dose-limiting toxicities. Injection-site reactions were the most commonly reported adverse event and were all mild or moderate in severity, self-limiting and fully resolved.

In June 2018, two presentations on LJPC-401 were given at the 23rd Congress of the European Hematology Association (EHA). The first was an oral presentation, entitled "A Phase 1, Open-Label Study to Determine the Safety, Tolerability, and Pharmacokinetics of Escalating Doses of LJPC-401 (Synthetic Human Hepcidin) in Patients with Iron Overload." The second was a poster presentation, entitled "A Phase 1, Placebo-Controlled Study to Determine the Safety, Tolerability, and Pharmacokinetics of Escalating Subcutaneous Doses of LJPC-401 (Synthetic Human Hepcidin) in Healthy Adults."

LJPC-401 is currently the subject of two clinical studies, LJ401-HH01 in patients with HH and LJ401-BT01 in patients with BT.

LJ401-HH01

In December 2017, we announced the initiation of LJ401-HH01, a Phase 2 clinical study of LJPC 401 in patients with HH. LJ401-HH01 is a multinational, multicenter, randomized, Phase 2 study that is designed to evaluate the safety and efficacy of LJPC-401 as a treatment for HH. The primary efficacy endpoint of the study is the change in transferrin saturation, a standard measurement of iron levels in the body and one of the two key measurements used to detect iron overload, from baseline to end of treatment. Secondary efficacy endpoints include: (i) the change in serum ferritin, the other key measurement used to detect iron overload, from baseline to end of treatment; and (ii) the requirement for and frequency of phlebotomy procedures used during the study.

We expect to disclose the topline results of LJ401-HH01 in the second half of 2019.

LJ401-BT01

In September 2016, we announced that we reached agreement with the EMA on the design of a pivotal study of LJPC-401 for the treatment of BT patients suffering from iron overload, a major unmet need in an orphan patient population. In December 2017, we announced the initiation of LJ401-BT01, a pivotal, multinational, multicenter, randomized, controlled study that is designed to evaluate the safety and efficacy of LJPC-401 as a treatment for BT patients who, despite chelation therapy, have cardiac iron levels above normal. The primary efficacy endpoint of this study is the change in iron content in the

heart after 6 months, as measured by cardiac magnetic resonance imaging (MRI). If this study is successful, we would anticipate filing an MAA for LJPC-401 in the EU.

We expect to disclose the topline results of LJ401-BT01 in mid-2020.

Manufacturing

We do not currently own or operate manufacturing facilities for the production of commercial or clinical quantities of GIAPREZA or any of our product candidates. We rely on a small number of third-party manufacturers to produce our compounds and expect to continue to do so to meet our commercial needs and the requirements of our product candidates.

We have not had long-term agreements with any third parties and will likely continue to not have long-term arrangements as they relate to our commercial product and clinical and preclinical product candidates. In all of our manufacturing and processing agreements, we require that third-party contract manufacturers produce active pharmaceutical ingredients (API) and finished products in accordance with the FDA's current Good Manufacturing Practices (cGMP) and all other applicable laws and regulations. We maintain confidentiality agreements with potential and existing manufacturers in order to protect our proprietary rights related to our product and product candidates.

With regard to GIAPREZA, we have utilized third parties to manufacture the API, formulate, fill and finish, and perform the analytical release testing of the drug product. We have also completed our commercial scale-up of manufacturing process development and the validation of commercial production runs. The commercial success of GIAPREZA will depend in part on the ability of our contract manufacturers to produce cGMP-compliant API and drug product in commercial quantities and at competitive costs. Further, some of the critical materials and components used in manufacturing GIAPREZA are sourced from single suppliers. An interruption in the supply of key materials could significantly delay our sales or increase our expenses.

We plan to continue to scale up manufacturing through multiple third-party manufacturers as required, with the objectives of realizing important economies of scale and security of supply. These scale-up activities will take time to implement, require additional capital investment, process development, validation and FDA review.

Patents and Proprietary Technologies

Patents and other proprietary rights are important to our business. As part of our strategy to protect our current product and product candidates and to provide a foundation for future products, we have filed a number of patent applications and have licensed rights from third parties for other patent applications related to our product candidates.

As of December 31, 2018, we owned or had the rights to 49 issued patents (21 U.S. and 28 foreign) and 100 pending applications (22 U.S. and 78 foreign). These patents and patent applications owned or licensed by us cover GIAPREZA, LJPC-401 and other product candidates.

	United States			Foreign		
Description	Issued	Pending	Expiration	Issued	Pending	Expiration
GIAPREZA	5	12	2029 - 2038	—	49	2034 - 2037
LJPC-401	3	3	2022 - 2038	7	18	2022 - 2037
Other	13	7	2022 - 2038	21	11	2022 - 2037

In addition to those above, we plan to file additional patent applications that, if issued, would provide further protection for GIAPREZA and LJPC-401. Although we believe the bases for these patents and patent applications are sound, they are untested, and there is no assurance that they will not be successfully challenged. There can be no

assurance that any patent previously issued will be of commercial value, that any patent applications will result in issued patents of commercial value, or that our technology will not be held to infringe patents held by others.

Material Contracts

In December 2014, we entered into a patent license agreement with the George Washington University (GW), which the parties amended and restated on March 1, 2016. Pursuant to the amended and restated license agreement, GW exclusively licensed to us certain intellectual property rights relating to GIAPREZA, including the exclusive rights to certain issued patents

and patent applications covering GIAPREZA. Under the license agreement, we are obligated to use commercially reasonable efforts to develop, commercialize, market and sell GIAPREZA. We have paid a one-time license initiation fee, annual maintenance fees, an amendment fee, additional payments following the achievement of certain development and regulatory milestones, and royalty payments. We may be obligated to make additional milestone payments of up to $0.5 million in the aggregate. Following the commencement of commercial sales of GIAPREZA, we paid tiered royalties in the low- to mid-single digits on products covered by the licensed rights. The patents and patent applications covered by the GW license agreement are expected to expire between 2029 and 2038, and the obligation to pay royalties under this agreement extends through the last-to-expire patent covering GIAPREZA.

On May 10, 2018, the Company closed a $125.0 million royalty financing agreement (the Royalty Agreement) with HealthCare Royalty Partners (HCR). Under the terms of the Royalty Agreement, the Company received $125.0 million in exchange for tiered royalty payments on worldwide net product sales of GIAPREZA. HCR is entitled to receive quarterly royalties on worldwide net product sales of GIAPREZA beginning April 1, 2018. Quarterly payments to HCR under the Royalty Agreement start at a maximum royalty rate, with step-downs based on the achievement of annual net product sales thresholds. Through December 31, 2021, the royalty rate will be a maximum of 10%. Starting January 1, 2022, the maximum royalty rate may increase by 4% if an agreed-upon, cumulative sales threshold has not been met, and, starting January 1, 2024, the maximum royalty rate may increase by an additional 4% if a different agreed-upon, cumulative sales threshold has not been met. The Royalty Agreement is subject to maximum aggregate royalty payments to HCR of 180% of the $125.0 million to be received by the Company, at which time the payment obligations under the Royalty Agreement would expire. In the event of certain material breaches of the Royalty Agreement, HCR would have the right to terminate the Royalty Agreement and demand payment by La Jolla Pharma, LLC of an amount equal to either $125.0 million, minus aggregate royalties paid to HCR, or $225.0 million, minus aggregate royalties paid to HCR, depending on the type of breach. The Royalty Agreement was entered into by the Company’s wholly-owned subsidiary, La Jolla Pharma, LLC, and HCR has no recourse under the Royalty Agreement against La Jolla Pharmaceutical Company or any assets other than GIAPREZA.

Sales and Marketing

Our U.S.-based sales and marketing team consisted of 46 employees as of February 20, 2019. The sales and marketing infrastructure includes marketing, commercial insights, commercial operations and sales training. La Jolla has deployed a hospital market access team, clinical nurse educator team and specialized hospital sales team to focus on a targeted group of hospitals and hospital systems that treat high rates of distributive shock. These teams work to educate critical care physicians, intensive care unit nurses and hospital pharmacists, with the goal that they understand the clinical value of, and adopt, GIAPREZA as part of their clinical pathway for the management of distributive shock.

Customers

GIAPREZA is distributed in the U.S. through a limited number of specialty distributors and select wholesalers who order from us on an as-needed basis and that subsequently resell GIAPREZA to hospitals. Due to the relatively short lead-time required to fill orders for our product, backlog is not material to our business. We have engaged a third-party logistics service provider to act as our logistics and supply-chain manager for the commercial distribution of GIAPREZA.

Competition

The biotechnology and pharmaceutical industries are subject to rapid technological change. Competition from domestic and foreign biotechnology companies, large pharmaceutical and specialty pharmaceutical companies,

generic drug companies and other institutions, is intense and expected to increase. A number of companies are pursuing the development of pharmaceuticals in our targeted areas. However, we are not currently aware of any other angiotensin II drug product in development. We believe that the key competitive factors that will affect the commercial success of GIAPREZA, as well as future product candidates that we may develop, are: efficacy, safety and tolerability profiles; convenience in dosing; and price.

GIAPREZA competes primarily against catecholamines (a generic class of drugs, including dopamine and norepinephrine) and vasopressins, including Vasostrict®, which is marketed by Par Pharmaceuticals. Generic drugs such as catecholamines are significantly less expensive than GIAPREZA, which may limit GIAPREZA's adoption (irrespective of efficacy, safety and tolerability profile). With respect to the competition with Vasostrict, Par Pharmaceuticals is a significantly larger company than La Jolla and has greater resources and experience in successfully commercializing drugs. Additionally, the price of Vasostrict will impact the adoption of GIAPREZA in the hospital setting. If we are unable to successfully compete with these products, our commercial prospects for GIAPREZA will be limited.

Government Regulation

Pharmaceutical Regulation

Pharmaceutical products in the U.S., including GIAPREZA, are subject to extensive government regulation. Likewise, if we seek to market and distribute products abroad, they would also be subject to extensive foreign government regulation.

In the U.S., the FDA regulates pharmaceutical products. FDA regulations govern the testing, research and development activities, manufacturing, quality, storage, advertising, promotion, labeling, sale and distribution of pharmaceutical products. Accordingly, there is a rigorous process for the approval of new drugs and ongoing oversight of marketed products. We are also subject to foreign regulatory requirements governing clinical studies and drug products if products are tested or marketed abroad. The approval process outside the U.S. varies from jurisdiction to jurisdiction and the time required may be longer or shorter than that required for FDA approval.

See Item 1A. Risk Factors of this Annual Report on Form 10-K for a discussion of the factors that could adversely impact our development of commercial products and industry regulation.

Regulation in the U.S.

The FDA testing and approval process requires substantial time, effort and money. We cannot assure you that any of our product candidates will ever obtain approval. The FDA approval process for new drugs includes, without limitation:

- preclinical studies;
- submission in the U.S. of an IND for clinical studies conducted in the U.S.;
- adequate and well-controlled human clinical studies to establish safety and efficacy of the product;
- review and approval of an NDA in the U.S.; and
- inspection of the facilities used in the manufacturing of the drug to assess compliance with the FDA's current cGMP regulations.

The FDA monitors the progress of clinical studies conducted in the U.S. under an IND and may, at its discretion, re-evaluate, alter, suspend or terminate testing based on the data accumulated to that point and the FDA's benefit-risk assessment with regard to the patients enrolled in the trial. The FDA may also withdraw approval for an IND for that drug if deemed warranted. Furthermore, even after regulatory approval is obtained, under certain circumstances, such as later discovery of previously unknown problems, the FDA can withdraw approval or subject the drug to additional restrictions.

Preclinical Testing

The testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all. Preclinical studies include laboratory evaluation of the product, as well as animal studies to assess the potential safety and effectiveness of the product. Most of these studies must be performed according to Good Laboratory Practices (GLP), a system of management controls to assure the quality and reliability of data from nonclinical laboratory studies that are intended to support applications for research or marketing permits for FDA-regulated products.

An IND is the request for authorization from the FDA to administer an investigational new drug product to humans. The IND includes information regarding the preclinical studies, the investigational product's chemistry and manufacturing, supporting data and literature, and the clinical investigational plan and protocol(s). Thirty days after an IND is received by the FDA, the IND becomes effective and the proposed clinical trial may begin, unless FDA raises

an objection. If concerns or questions are raised, an IND sponsor and the FDA must resolve any outstanding concerns before clinical studies can proceed.

Clinical Studies

Clinical trials involve the administration of the product candidate that is the subject of the trial to volunteers or patients under the supervision of a qualified principal investigator and in accordance with a clinical trial protocol, which sets forth details, such as the study objectives and the safety and effectiveness criteria to be evaluated. Each clinical trial must be reviewed and approved by an independent institutional review board (IRB) in the U.S. or ethics committee in the European Union (EU) at each institution at which the study will be conducted. The IRB or ethics committee will consider, among other things, ethical factors, safety of human subjects and the possible liability of the institution arising from the conduct of the

proposed clinical trial. In addition, clinical studies in the U.S. must be performed according to current good clinical practices (cGCPs), which are enumerated in FDA regulations and are intended to protect the rights of patients and to define the roles of trial sponsors, administrators and monitors. Some studies include oversight by an independent group of experts, known as a data safety monitoring board, which provides authorization for whether a study may move forward based on certain data from the study and may stop the clinical trial if it determines that there is an unacceptable safety risk for subjects or on other grounds.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

Clinical trials in the U.S. typically are conducted in sequential phases: Phases 1, 2, 3 and 4. The phases may overlap. The FDA may require that we suspend clinical studies at any time on various grounds, including if the FDA makes a finding that the subjects participating in the trial are being exposed to an unacceptable health risk.

In Phase 1 clinical studies, the investigational product is usually tested on a small number of healthy volunteers to determine safety, any adverse effects, proper dosage, absorption, metabolism, distribution, excretion and other drug effects. Phase 1b clinical studies may also evaluate efficacy with respect to trial participants.

In Phase 2 clinical studies, the investigational product is usually tested on a limited number of patients (generally up to several hundred) to preliminarily evaluate the efficacy of the drug for specific, targeted indications, determine dosage tolerance and optimal dosage, and identify possible adverse effects and safety risks. Multiple Phase 2 clinical studies may be conducted to obtain information prior to beginning Phase 3 clinical studies and support proof of concept.

In Phase 3 clinical studies, the investigational product is administered to an expanded patient population to support efficacy claims, provide evidence of clinical efficacy and to further test for safety, generally at multiple clinical sites.

In Phase 4 clinical studies or other post-approval commitments, additional studies and patient follow-up are conducted to gain experience from the treatment of patients in the intended therapeutic indication. FDA may require a commitment to conduct post-approval Phase 4 studies as a condition of approval. Additional studies and follow-up may be conducted to document a clinical benefit where drugs are approved under accelerated approval regulations and based on surrogate endpoints. In clinical studies, surrogate endpoints are alternative measurements of the symptoms of a disease or condition that are substituted for measurements of observable clinical symptoms. Failure to timely conduct Phase 4 clinical studies and follow-up could result in withdrawal of approval for products approved under accelerated approval regulations.

We cannot assure you that any of our current or future clinical studies will result in approval to market our product candidates.

Clinical Data Review and Approval in the U.S.

The data from the clinical studies, together with preclinical data and other supporting information that establishes a product candidate's safety, are submitted to the FDA in the form of an NDA, or NDA supplement (for approval of a new indication if the product candidate is already approved for another indication). Under applicable laws and FDA

regulations, FDA reviews the NDA within 60 days of receipt of the NDA to determine whether the application will be accepted for filing based on FDA's threshold determination that the NDA is sufficiently complete to permit substantive review. If deemed complete, the FDA will "file" the NDA, thereby triggering substantive review of the application. The FDA can refuse to file any NDA that it deems incomplete or not properly reviewable. Along with the preclinical and clinical data, the FDA will evaluate the proposed product labeling and other information in the cGMP. In addition, the FDA may convene a scientific advisory committee, comprised of clinicians and other experts, to review and provide a non-binding recommendation as to whether the application should be approved.

The FDA has established internal substantive review goals of 10 months for most NDAs. The FDA also has special programs, including Fast Track, Breakthrough Therapy, priority review, and accelerated approval, which are intended to expedite or simplify the process for reviewing drugs, and/or provide for approval based on surrogate endpoints. Generally, drugs that may be eligible for these programs are those for serious or life-threatening conditions, those with the potential to address unmet medical needs, and those that offer meaningful benefits over existing treatments. For example, Fast Track designation is designed to facilitate the development, and expedite the review of drugs that are intended to treat serious diseases

and address an unmet medical need. Breakthrough Therapy designation may be granted for a drug that is intended to treat a serious condition and if preliminary evidence indicates that the drug may demonstrate substantial clinical improvement over available therapies. Both Fast Track and Breakthrough Therapy designations may be requested at the time of IND submission, and the FDA will respond within 60 calendar days of receipt of the request. Priority review, which is requested at the time of an NDA submission, is designed to give drugs that offer major advances in treatment or provide a treatment where no adequate therapy exists, an initial review within six months as compared to a standard review time of 10 months. Although Fast Track, Breakthrough Therapy, and priority review do not affect the standards for approval, the FDA will attempt to facilitate early and frequent meetings with sponsors of Fast Track and Breakthrough Therapy drugs, and the FDA aims to expedite review of drugs granted priority review. Accelerated approval provides an earlier approval of drugs to treat serious diseases and that address an unmet medical need based on a surrogate or intermediate endpoint that is reasonably likely to predict clinical benefit. Under these special programs, the FDA is not legally required to complete its review within an expedited time period, and performance goals may change over time. Furthermore, the FDA may later decide that a drug no longer qualifies for review under one or more of these programs.

The 21st Century Cures Act of 2016 amended section 506 of the U.S. Federal Food, Drug, and Cosmetic Act to provide for the expedited development and review of regenerative medicine therapies, which are defined as cell therapies, therapeutic tissue engineering products, human cell and tissue products, or any combination product using such therapies or products, except for those regulated solely under Section 361 of the Public Health Service Act and part 1271 of Title 21, Code of Federal Regulations. A regenerative medicine therapy is eligible for “regenerative medicine advanced therapy” (RMAT) designation if it is intended to treat, modify, reverse or cure a serious condition, and the preliminary clinical evidence indicates that the regenerative medicine therapy has the potential to address unmet medical needs for such condition. RMAT designation gives the applicant the benefits of fast track and Breakthrough Therapy designations, including early interactions with the FDA to discuss potential surrogate or intermediate endpoints to support accelerated approval, and FDA may grant priority review. In a guidance document, dated February 2019, the FDA stated that the preliminary clinical evidence required to support the RMAT designation should be generated on the product intended for clinical development but that the types of evidence required would be determined on a case-by-case basis, but could include evidence such as data from historical controls, studies conducted outside the United States, and retrospective studies.

If the FDA approves the NDA, it will issue an approval letter authorizing the commercial marketing of the drug with prescribing information for specific indications. As a condition of NDA approval, the FDA may require a risk evaluation and mitigation strategy (REMS) to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing. In many cases, the outcome of the review, even if generally favorable, is not an actual approval, but a “complete response” that generally outlines the deficiencies in the submission, which may require substantial additional testing, or information, in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA’s satisfaction in a resubmission of the NDA, the FDA will issue an approval letter.

Satisfaction of FDA requirements or similar requirements of state, local, and foreign regulatory agencies typically take several years and requires the expenditure of substantial financial resources. Information generated in this process is susceptible to varying interpretations that could delay, limit or prevent regulatory approval at any stage of the process. Accordingly, the actual time and expense required to bring a product to market may vary substantially. We cannot assure you that we will submit applications for required authorizations to manufacture and/or market potential products or that any such application will be reviewed and approved by the appropriate regulatory authorities in a timely manner, if at all. Data obtained from clinical activities is not always conclusive and may be susceptible to

varying interpretations, which could delay, limit or prevent regulatory approval. Success in early stage clinical studies does not ensure success in later stage clinical studies. Even if a product candidate receives regulatory approval, the approval may be significantly limited to specific disease states, patient populations and dosages, or have conditions placed on it that restrict the commercial applications, advertising, promotion or distribution of these products.

Once issued, the FDA may withdraw product approval or request product recalls if ongoing regulatory standards are not met or if safety problems occur after the product reaches the market. In addition, the FDA may require testing and surveillance programs to monitor the safety or effectiveness of approved products which have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs. The FDA may also request or require additional Phase 4 clinical studies after a product is approved. The results of Phase 4 clinical studies can confirm the effectiveness of a product candidate and can provide important safety information to augment the FDA's voluntary adverse drug reaction reporting system.

Any products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including record-keeping requirements and reporting of adverse experiences with the drug. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements on us and our third-party manufacturers. We cannot be certain that we, or our present or future suppliers, will be able to comply with the cGMP regulations and other FDA regulatory requirements.

In addition, both before and after approval is sought, we are required to comply with a number of FDA requirements. For example, we are required to report certain adverse reactions and production problems, if any, to the FDA, and to comply with certain limitations and other requirements concerning advertising and promotion for our products. In addition, quality control and manufacturing procedures must continue to conform to cGMP after approval, and the FDA periodically inspects manufacturing facilities to assess compliance with continuing cGMP. In addition, discovery of problems, such as safety problems, may result in changes in labeling or restrictions on a product manufacturer or NDA holder, including removal of the product from the market.

The FDA closely regulates the marketing and promotion of drugs and drugs may only be marketed in a manner consistent with their FDA-approved labeling. Approval may be subject to post-marketing surveillance and other record-keeping and reporting obligations, and involve ongoing requirements. Product approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems occur following initial marketing.

The failure to comply with FDA’s requirements can result in adverse publicity, warning letters, corrective advertising, restrictions on marketing or manufacturing, refusals to review pending product applications, refusals to permit the import or export of products, seizures, injunctions, and civil and criminal penalties.

Clinical Trial Conduct and Product Approval Regulation in Non-U.S. Jurisdictions

In addition to regulations in the U.S., we may be subject to a variety of foreign regulations governing clinical studies and commercial sales and distribution of our products. Our clinical studies conducted in the EU must be done under a clinical trial application (CTA), which must be supported by an Investigational Medicinal Product Dossier (IMPD), and the oversight of an ethics committee. If we market our products in foreign countries, we also will be subject to foreign regulatory requirements governing marketing approval for pharmaceutical products. The requirements governing the conduct of clinical studies, product approval, pricing and reimbursement vary widely from country to country. Whether or not FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries must be obtained before manufacturing or marketing the product in those countries. The approval process varies from country to country and the time required for such approvals may differ substantially from that required for FDA approval. This foreign regulatory approval process involves all of the risks associated with FDA marketing approval discussed above. There is no assurance that any future FDA approval of any of our product candidates will result in similar foreign approvals or vice versa. The process for clinical studies in the EU is similar, and trials are heavily scrutinized by the designated ethics committee. In addition, foreign regulations may include applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or other transfers of value to healthcare professionals and entities.

Section 505(b)(2) Applications

Some of our product candidates may be eligible for submission of applications for approval under the FDA's Section 505(b)(2) approval process, which provides an alternate path to FDA approval for new or improved formulations or new uses of previously approved products. Section 505(b)(2) was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, and allows approval of NDAs that rely, at least in part, on studies that were not conducted by or for the applicant and to which the applicant has not obtained a right of reference. Such studies can be provided by published literature, or the FDA can rely on previous findings of safety and efficacy for a previously approved drug. If the 505(b)(2) applicant can establish that reliance on the FDA's previous approval is scientifically appropriate, it may eliminate the need to conduct certain preclinical studies or clinical studies of the new product. Section 505(b)(2) applications may be submitted for drug products that represent a modification (e.g., a new indication or new dosage form) of an eligible approved drug. In such cases, the additional information in 505(b)(2) applications necessary to support the change from the previously approved drug is frequently provided by new studies submitted by the applicant. Because a Section 505(b)(2) application relies in part on previous studies or previous FDA findings of safety and effectiveness, preparing 505(b)(2) applications is generally less costly and time-consuming than preparing an NDA based entirely on new data and information from a full set of clinical studies. The FDA may approve the new product candidate for all, or some, of the label indications for which the referenced product has been approved, as well as for any new indication sought by the

Section 505(b)(2) applicant. The law governing Section 505(b)(2) or FDA's current policies may change in such a way as to adversely affect our applications for approval that seek to utilize the Section 505(b)(2) approach. Such changes could result in additional costs associated with additional studies or clinical studies and delays.

The FDA provides that reviews and/or approvals of applications submitted under Section 505(b)(2) will be delayed in various circumstances. For example, the holder of the NDA for the listed drug may be entitled to a period of market exclusivity during which the FDA will not approve, and may not even review, a Section 505(b)(2) application from other sponsors. If the listed drug is claimed by one or more patents that the NDA holder has listed with the FDA, the Section 505(b)(2) applicant must submit a certification with respect to each such patent. If the 505(b)(2) applicant certifies that a listed patent is invalid, unenforceable or not infringed by the product that is the subject of the Section 505(b)(2) application, it must notify the patent holder and the NDA holder. If, within 45 days of providing this notice, the NDA holder sues the 505(b)(2) applicant for patent infringement, the FDA will not approve the Section 505(b)(2) application until the earlier of 30 months, a court decision favorable to the Section 505(b)(2) applicant, settlement of the lawsuit or expiration of the patent. The regulations governing marketing exclusivity and patent protection are complex, and it is often unclear how they will be applied in particular circumstances.

Drug Enforcement Agency Regulation

Our research and development processes involve the controlled use of hazardous materials, including chemicals. Some of these hazardous materials are considered to be controlled substances and subject to regulation by the U.S. Drug Enforcement Agency (DEA). Controlled substances are those drugs that appear on 1 of 5 schedules promulgated and administered by the DEA under the Controlled Substances Act (CSA). The CSA governs, among other things, the distribution, recordkeeping, handling, security and disposal of controlled substances. We must be registered by the DEA in order to engage in these activities, and are subject to periodic and ongoing inspections by the DEA and similar state drug enforcement authorities to assess ongoing compliance with the DEA's regulations. Any failure to comply with these regulations could lead to a variety of sanctions, including the revocation, or a denial of renewal, of the DEA registration, injunctions or civil or criminal penalties.

Third-Party Payor Coverage and Reimbursement

Commercial success of GIAPREZA, and any of our other product candidates that are approved or commercialized for any indication will depend, in part, on the availability of coverage and reimbursement from third-party payors at the federal, state and private levels. Government payor programs, including Medicare and Medicaid, private healthcare insurance companies and managed care plans have attempted to control costs by limiting coverage and the amount of reimbursement for particular procedures or drug treatments. The U.S. Congress and state legislatures, from time to time, propose and adopt initiatives aimed at cost containment. Ongoing federal and state government initiatives directed at lowering the total cost of healthcare will likely continue to focus on healthcare reform, the cost of prescription pharmaceuticals and on the reform of the Medicare and Medicaid payment systems.

Examples of how limits on drug coverage and reimbursement in the U.S. may cause reduced payments for drugs in the future include:

- changing Medicare reimbursement methodologies;
- fluctuating decisions on which drugs to include in formularies;
- revising drug rebate calculations under the Medicaid program or requiring that new or additional rebates be provided to Medicare, Medicaid, other federal or state healthcare programs; and
- reforming drug importation laws.

Some third-party payors also require pre-approval of coverage for new drug therapies before they will reimburse healthcare providers that use such therapies. While we cannot predict whether any proposed cost-containment

measures will be adopted or otherwise implemented in the future, the announcement or adoption of these proposals could have a material adverse effect on our ability to obtain adequate prices for our product candidates and to operate profitably.

Reimbursement systems in international markets vary significantly by country and, within some countries, by region. Reimbursement approvals must be obtained on a country-by-country basis. In many foreign markets, including markets in which we hope to sell our products, the pricing of prescription pharmaceuticals is subject to government pricing control. In these markets, once marketing approval is received, pricing negotiations could take significant additional time. As in the U.S., the lack of satisfactory reimbursement or inadequate government pricing of any of our products would limit widespread use and lower potential product revenues.

Anti-Kickback, Fraud and Abuse and False Claims Regulation

On commercial launch of a product in the U.S., we will be subject to healthcare fraud and abuse regulation and enforcement by both the federal government and the states in which we conduct our business. Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Arrangements with third-party payors and customers may expose us to applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain marketing approval.

Regulations under applicable federal and state healthcare laws and regulations include the federal healthcare programs' Anti-Kickback Law, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral or purchase of any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. Remuneration has been broadly defined to include anything of value, including cash, improper discounts, and free or reduced-price items and services. Many states have similar laws that apply to their state healthcare programs as well as private payors. In addition, the False Claims Act (FCA) imposes liability on persons who, among other things, present or cause to be presented false or fraudulent claims for payment by a federal healthcare program. The FCA has been used to prosecute persons submitting claims for payment that are inaccurate or fraudulent, that are for services not provided as claimed, or for services that are not medically necessary. Actions under the FCA may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Violations of the FCA can result in significant monetary penalties and treble damages. The federal government is using the FCA, and the accompanying threat of significant liability, in its investigation and prosecution of pharmaceutical and biotechnology companies throughout the country, for example, in connection with the promotion of products for unapproved uses and other sales and marketing practices.

The risk of being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Moreover, recent healthcare reform legislation has strengthened many of these laws. For example, the Patient Protection and Affordable Care Act (PPACA), among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes to clarify that a person or entity does not need to have actual knowledge of this statute or specific intent to violate it. In addition, PPACA provides 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 false claims statutes.

The continuing interpretation and application of these laws could have a material adverse impact on our business and our ability to compete should we commence marketing a product.

Federal and State Sunshine Laws

We must comply with federal "sunshine" laws that require transparency regarding financial arrangements with healthcare providers. This would include the reporting and disclosure requirements imposed by the PPACA on drug manufacturers regarding any "payment or transfer of value" made or distributed to physicians and teaching hospitals. Failure to submit required information can result in civil monetary penalties. A number of states have laws that require the implementation of commercial compliance programs, impose restrictions on drug manufacturer marketing practices, and/or require pharmaceutical companies to track and report payments, gifts and other benefits provided to physicians and other healthcare professionals and entities.

Foreign Corrupt Practices Act

We are subject to the Foreign Corrupt Practices Act of 1997 (FCPA). The FCPA and other similar anti-bribery laws in other jurisdictions, such as the U.K. Bribery Act, generally prohibit companies and their intermediaries from providing money or anything of value to officials of foreign governments, foreign political parties, or international organizations with the intent to obtain or retain business or seek a business advantage. Recently, there has been a substantial increase in anti-bribery law enforcement activity by U.S. regulators, with more frequent and aggressive investigations and enforcement proceedings by both the Department of Justice and the SEC. A determination that our operations or activities are not, or were not, in compliance with U.S. or foreign laws or regulations could result in the imposition of substantial fines, interruptions of business, loss of supplier, vendor or other third-party relationships, termination of necessary licenses and permits, and other legal or equitable sanctions. Other internal or government investigations or legal or regulatory proceedings, including lawsuits brought by private litigants, may also follow as a consequence.

Patient Privacy and Data Security

We are required to comply, as applicable, with numerous federal and state laws, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, and to govern the collection, use and disclosure of personal information. Other countries also have, or are developing, laws governing the collection, use and transmission of personal information. In addition, most healthcare providers who may prescribe products we may sell in the future and from whom we may obtain patient health information are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended by the Health Information Technology and Clinical Health Act (HITECH), and its implementing regulations. We are not a HIPAA covered entity, do not currently intend to become one, and we do not operate as a business associate to any covered entities. Therefore, these privacy and security requirements do not apply to us. However, we could be subject to civil and criminal penalties if we knowingly obtain individually identifiable health information from a covered entity in a manner that is not authorized or permitted by HIPAA or for aiding and abetting the violation of HIPAA. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues with the potential to affect our business, including recently enacted laws in a majority of states requiring security breach notification. These laws could create liability for us or increase our cost of doing business, and any failure to comply could result in harm to our reputation and potential fines and penalties.

In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

In May 2018, the EU Data Protection Directive was replaced with the recently adopted European General Data Protection Regulation (GDPR) which contains new provisions specifically directed at the processing of health information, higher sanctions and extraterritoriality measures intended to bring non-EU companies under the regulation. We currently conduct clinical studies in the EU are subject to such requirements. We anticipate that over time we may expand our business operations to include additional operations in the EU. With such expansion, we would be subject to increased governmental regulation in the EU countries in which we might operate, including the GDPR.

Environmental, Health and Safety Laws

Our operations and those of our third-party manufacturers are subject to complex and increasingly stringent environmental, health and safety laws and regulations. Further, in the future, we may open manufacturing facilities that would likely be subject to environmental and health and safety authorities in the relevant jurisdictions. These authorities typically administer laws which regulate, among other matters, the emission of pollutants into the air (including the workplace), the discharge of pollutants into bodies of water, the storage, use, handling and disposal of hazardous substances, the exposure of persons to hazardous substances, and the general health, safety and welfare of employees and members of the public. Violations of these laws could subject us to strict liability, fines, or liability to third parties.

Other Laws

We are subject to a variety of financial disclosure and securities trading regulations as a public company in the U.S., including laws relating to the oversight activities of the SEC and the regulations of the Nasdaq Capital Market, on which our shares are traded. We are also subject to various laws, regulations and recommendations relating to safe working conditions, laboratory practices and the experimental use of animals.

Employees

As of February 20, 2019, we employed 169 regular, full-time employees, 96 of whom are engaged in research and clinical development activities, and 73 of whom are in sales and marketing, finance, information technology, human resources and administration. None of our employees are covered by collective bargaining agreements.

Corporate and Other Information

The Company was incorporated in Delaware in 1989 and reincorporated in California in 2012. Our principal office is located at 4550 Towne Centre Court, San Diego, CA 92121 and our telephone number is (858) 207-4264. Our common stock trades on the Nasdaq Capital Market under the symbol “LJPC.” Our website address is www.ljpc.com. Information contained on or accessible through our website is not a part of this Annual Report on Form 10-K, and the inclusion of our website address in this Annual Report on Form 10-K is an inactive textual reference only.

We file electronically with the U.S. Securities and Exchange Commission (SEC) our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934. We make available on our website at www.ljpc.com, free of charge, copies of these reports as soon as reasonably practicable after filing or furnishing these reports with the SEC. The SEC maintains a website at www.sec.gov that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC.

Item 1A. Risk Factors.

An investment in shares of our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below and the other information before deciding to invest in our common stock. The risks described below are not the only ones facing our Company. Additional risks not presently known to us or that we currently consider immaterial may also adversely affect our business. We have attempted to identify below the major factors that could cause differences between actual and planned or expected results, but we cannot assure you that we have identified all of those factors.

If any of the following risks actually happen, our business, financial condition and operating results could be materially adversely affected. In this case, the trading price of our common stock could decline, and you could lose all or part of your investment.

I. RISK FACTORS RELATING TO THE COMPANY AND THE INDUSTRY IN WHICH WE OPERATE

We are substantially dependent on the commercial success of GIAPREZA™ (angiotensin II).

The near-term success of our business is largely dependent on our ability to successfully commercialize GIAPREZA™ (angiotensin II), our only commercial product. Although members of our management team have prior experience launching new products, GIAPREZA is the first product we have launched.

Even if our sales organization performs as expected, the revenue that we may receive from sales of GIAPREZA may be less than anticipated due to factors that are outside of our control. These factors that may impact revenue include:

- the perception of physicians and other members of the healthcare community of the safety and efficacy and cost-competitiveness relative to that of competing products;
- our ability to maintain successful sales, marketing and educational programs for certain physicians and other healthcare providers;
- our ability to raise patient and physician awareness;
- the cost-effectiveness of our product;
- acceptance by institutional formulary committees;
- patient and physician satisfaction with our product;
- the size of the potential market for our product;
- our ability to obtain adequate reimbursement from government and third-party payors;
- unfavorable publicity concerning our product or similar products;
- the introduction, availability and acceptance of competing treatments;
- adverse event information relating to our product or similar classes of drugs;
- product liability litigation alleging injuries relating to the product or similar classes of drugs;
- our ability to maintain and defend our patents for GIAPREZA;
- our ability to have GIAPREZA manufactured at a commercial production level successfully and on a timely basis;
- the availability of raw materials;
- our ability to access third parties to manufacture and distribute our product on acceptable terms or at all;
- regulatory developments related to the manufacture or continued use of our product;

- any pediatric investigation plan requirements and the results thereof;

- any post-approval study requirements and the results thereof;
- the extent and effectiveness of sales and marketing and distribution support for our product;
- our competitors' activities, including decisions as to the timing of competing product launches, generic entrants, pricing and discounting; and
- any other material adverse developments with respect to the potential commercialization of our product.

Our business will be adversely affected if, due to these or other factors, our commercialization of GIAPREZA does not achieve the acceptance and demand necessary to sustain revenue growth. If we are unable to successfully commercialize GIAPREZA, our business and results of operations will suffer.

If we are unable to maintain effective sales, marketing and distribution capabilities to sell and market GIAPREZA or any other products we may develop, our product sales may be hindered.

In order to successfully commercialize GIAPREZA, we must increase our sales, marketing, distribution and other non-technical capabilities. The development of a sales organization to market GIAPREZA, or any other product we may develop, is expensive and time-consuming, and we cannot be certain that we will be able to successfully develop this capacity or that this function will execute as expected. If we are unable to establish adequate sales, marketing and distribution capabilities, we may not be able to generate product revenue and our business and results of operations will suffer.

If we fail to comply with our reporting and payment obligations under U.S. governmental pricing and contracting programs, we could be subject to additional reimbursement requirements, penalties and fines, which could have a material adverse effect on our business, financial condition, and results of operations.

The Medicare program and certain government pricing programs, including the Medicaid drug rebate program, the Public Health Services' 340B drug pricing program, and the pricing program under the Veterans Health Care Act of 1992 impact the reimbursement we may receive from sales of GIAPREZA, or any other products that are approved for marketing. Pricing and rebate calculations vary among programs. The calculations are complex and are often subject to interpretation by manufacturers, governmental or regulatory agencies, and the courts. We are required to submit a number of different pricing calculations to government agencies on a quarterly basis. Failure to comply with our reporting and payment obligations under U.S. governmental pricing and contracting programs may result in additional payments, penalties and fines due to government agencies, which may have a material adverse effect on our business, financial condition and results of operations.

We have only limited assets and will need to raise additional capital before we can expect to become profitable.

As of December 31, 2018, we had GIAPREZA sales as our sole revenue source and available cash and cash equivalents of $172.6 million. To fund future operations to the point where we are able to generate positive cash flow from GIAPREZA and our product candidates, we will need to raise significant additional capital. The amount and timing of future funding requirements will depend on many factors, including the success of our commercialization efforts for GIAPREZA, the timing and results of our ongoing development efforts, the potential expansion of our current development programs, potential new development programs and related general and administrative support. We anticipate that we will seek to fund our operations through equity, debt, royalty-based financings or other sources, such as potential collaboration agreements. We cannot provide assurance that additional financing will be available to us on favorable terms, or at all. Although we have previously been successful in obtaining financing through equity offerings, there can be no assurance that we will be able to do so in the future. If we are unable to raise additional capital to fund our clinical development, commercialization efforts, and other business activities, we could be forced to abandon one or more programs and curtail or cease our operations.

We have generated limited revenue from product sales and may never be profitable.

We have a single product approved for commercialization and have generated approximately $10.1 million in total GIAPREZA sales since the commercial launch of the product. Our ability to continue to generate revenue and achieve profitability depends on our ability, alone or with strategic collaboration partners, to successfully continue the commercialization of GIAPREZA and to complete the development of, and obtain the regulatory and marketing approvals necessary to commercialize, our product candidates in development. Our ability to generate revenue from product sales depends heavily on our success in many areas, including but not limited to:

- successfully commercializing GIAPREZA, including increasing physician awareness and adoption of the product and managing our pricing and overall commercial strategy so that hospitals are willing to purchase the product;
- successfully completing research and nonclinical and clinical development of our product candidates;

- obtaining regulatory and marketing approvals for GIAPREZA outside of the United States, as well as our ability to obtain marketing approvals for other product candidates for which we complete clinical studies;
- obtaining market acceptance of our product candidates as viable treatment options;
- addressing any competing technological and market developments;
- identifying, assessing, acquiring or developing new product candidates;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- attracting, hiring and retaining qualified personnel.

We anticipate incurring significant costs associated with continued commercializing GIAPREZA and development of our product candidates. Our expenses could increase beyond expectations if we are required by the FDA, the EMA or other regulatory agencies, domestic or foreign, to change our manufacturing processes or assays, or to perform additional clinical, nonclinical or other types of studies in addition to those that we currently anticipate. For GIAPREZA and other product candidates that may be approved, our revenue will be dependent, in part, on the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to get reimbursement at any price, and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we may be unable to generate significant revenue from sales of approved products.

Results from our clinical studies may not be sufficient to obtain regulatory approvals to market our product candidates in the U.S. or other countries on a timely basis, if at all.

Product candidates are subject to extensive government regulations related to development, clinical studies, manufacturing and commercialization. In order to sell any product that is under development, we must first receive regulatory approval. To obtain regulatory approval, we must conduct clinical studies and toxicology studies that demonstrate that our product candidates are safe and effective. The process of obtaining FDA and foreign regulatory approvals is costly, time-consuming, uncertain and subject to unanticipated delays.

Even where we have obtained regulatory approval for a product in one jurisdiction, such as FDA approval of GIAPREZA in the United States, there can be no assurance that we will be able to obtain regulatory approval for that same product in other jurisdictions. Regulatory authorities such as the FDA and EMA have substantial discretion in the approval process and may not agree that we have demonstrated that our product candidates are safe and effective. If our product candidates are ultimately not found to be safe and effective, we would be unable to obtain regulatory approval to manufacture, market and sell them. We can provide no assurances that the FDA, EMA or other foreign regulatory authorities will approve our product candidates or, if approved, what the scope of the approved indication might be.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies may not be predictive of future study results.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of nonclinical studies and early clinical studies of our product candidates may not be predictive of the results of later-stage clinical studies. Product candidates that have shown promising results in early-stage clinical studies may still suffer significant setbacks in subsequent clinical studies. For example, the safety or efficacy results generated to date in our clinical studies do not ensure that later clinical studies will demonstrate similar results. There is a high failure rate for drugs proceeding through clinical studies, and product candidates in later stages of clinical studies may fail to show the desired safety and efficacy, despite having progressed through nonclinical studies and initial clinical studies. A number of companies in the

biopharmaceutical industry have suffered significant setbacks in advanced clinical studies due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier studies. Moreover, nonclinical and clinical data are often susceptible to varying interpretations and analyses. We do not know whether any clinical studies we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain regulatory approval to market our product candidates.

Clinical trials that we may undertake may be delayed or halted.

Any clinical studies of our product candidates that we may conduct in the future may be delayed or halted for various reasons, including:

- we do not have sufficient financial resources;
- supplies of drug product are not sufficient to treat the patients in the studies;
- patients do not enroll in the studies at the rate we expect;
- the product candidates are not effective;
- patients experience negative side effects or other safety concerns are raised during treatment;
- the trials are not conducted in accordance with applicable clinical practices;
- there is political unrest at foreign clinical sites; or
- there are natural disasters at any of our clinical sites.

If any future trials are delayed or halted, we may incur significant additional expenses, and our potential approval of our product candidates may be delayed, which could have a severe negative effect on our business.

We rely on third parties to conduct our preclinical and clinical studies. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, our studies may not be completed in a timely fashion or in a manner that generates acceptable data, and we may not be able to obtain regulatory approval for or commercialize our product candidates.

We have agreements with third-party contract research organizations (CROs) to monitor and manage data for our preclinical and clinical programs. We rely heavily on these parties for execution of our preclinical and clinical studies, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with current good clinical practices (cGCPs), which are regulations and guidelines enforced by the FDA, EMA and other foreign regulatory authorities for products in clinical development. Regulatory authorities enforce these cGCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these CROs fail to comply with applicable cGCP regulations, the clinical data generated in our clinical studies may be deemed unreliable and the FDA, EMA and other foreign regulatory authorities may require us to perform additional clinical studies before approving our marketing applications. We cannot assure you that, on inspection, such regulatory authorities will determine that any of our clinical studies comply with the cGCP regulations. In addition, our clinical studies must be conducted with product produced under cGMP regulations and will require a large number of test subjects. Our or our CROs' failure to comply with these regulations may require us to repeat clinical studies, which would delay the regulatory approval process.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical and clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical studies may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, we may incur significant additional expenses, and our potential approval of our product candidates may be delayed, which could have a severe negative effect on our business.

If the third-party manufacturers on which we rely fail to produce the materials that we require on a timely basis, or to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we may face commercial supply

shortages, delays in the trials, regulatory submissions, required approvals or commercialization of our product and product candidates.

We do not manufacture GIAPREZA or any of our product candidates, nor do we plan to develop any capacity to do so. Instead, we contract with third-party manufacturers to manufacture and supply GIAPREZA and all of our product candidates. The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter

difficulties in production, which include difficulties with production costs and yields, quality control and assurance and shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. The third-party manufacturers we contract with may not perform as agreed or may terminate their agreements with us. Although we believe that we could identify and qualify alternate suppliers if necessary, the steps needed for a pharmaceutical manufacturer to implement a validated manufacturing process can be time-consuming and costly. As a result, and because we currently have only a single manufacturer for GIAPREZA, termination of this manufacturing relationship or a disruption in their manufacturing facilities could adversely affect the available commercial supply of GIAPREZA. Further, certain critical materials used in manufacturing GIAPREZA have historically been sourced from single suppliers. An interruption in the supply of a key material could also significantly impact our ability to meet the demand for GIAPREZA.

Any facilities in which our product or product candidates are manufactured or tested for their ability to meet required specifications must be inspected by and approved by the FDA and/or the EMA before a commercial product can be manufactured. Failure of such a facility to be approved could delay the commercial sale or approval of one or more of our products or product candidates.

Any of these factors could cause us to delay or suspend any future commercial sales, clinical studies, regulatory submissions, required approvals or commercialization of one or more of our products or product candidates, entail higher costs and result in our being unable to effectively commercialize products.

Our success in developing and marketing our product and product candidates depends significantly on our ability to obtain patent protection and operate without infringing on the rights of others.

We depend on patents and other intellectual property to prevent others from improperly benefiting from products or technologies that we sell, develop or acquire. Our patents and patent applications cover various technologies, product and product candidates. The patent position of biotechnology firms like ours is highly uncertain and involves complex legal and factual questions, and no consistent policy has emerged regarding the breadth of claims covered in biotechnology patents or the protection afforded by these patents. Additionally, recent U.S. Supreme Court and Federal Circuit opinions further limit the scope of patentable inventions in the life sciences space and have added increased uncertainty around the validity of certain issued patents and the successful prosecution of certain pending patent applications. We intend to continue to file patent applications as we believe is appropriate to obtain patents covering both our products and processes. There can be no assurance, however, that any additional patents will be issued, that the scope of any patent that has issued or may issue will be sufficient to protect our technology, or that any current or future issued patent will be held not invalid if subsequently challenged. There is a substantial backlog of biotechnology patent applications at the U.S. Patent and Trademark Office (USPTO), which may delay the review and issuance of any patents.

Others, including our competitors, could have patents or patent applications pending that relate to compounds or processes that overlap or compete with our intellectual property or which may affect our freedom to operate.

There can be no assurance that third-party patents will not ultimately be found to impact the sales of GIAPREZA or the advancement of our product candidates. While we intend to challenge the issuance and validity of this patent, we may not be successful. If the USPTO or any foreign counterpart issues or has issued any other patents containing competitive or conflicting claims, and if these claims are valid, the protection provided by our existing patents or any future patents that may be issued could be significantly reduced, and our ability to prevent competitors from developing products or technologies identical or similar to ours could be negatively affected. In addition, there can be no guarantee that we would be able to obtain licenses to these patents on commercially reasonable terms, if at all, or that we would be able to develop or obtain alternative technology. Our failure to obtain a license to a technology or process that may be required to develop or commercialize one or more of our product candidates may have a material

adverse effect on our business.

We do not have complete patent protection for GIAPREZA or our other product candidates, as the active pharmaceutical ingredients in GIAPREZA and our other product candidates are known compounds that are not themselves covered by composition of matter patents, and thus may only be protected by formulation or method-of-use patents (to the extent that such patents are granted and are enforceable) and/or regulatory exclusivity (to the extent available). Therefore, it is possible that a competitor could develop the same or similar technology if we fail to obtain protection of this type. We may have to incur significant expense and management time in defending or enforcing our patents. If we cannot obtain and maintain effective patent rights and/or regulatory exclusivity for our product candidates, we may not be able to compete effectively and our business and results of operations would be harmed.

Patent policy and rule changes could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

Changes in either the patent laws or interpretation of the patent laws in the U.S. and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the U.S. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. We therefore cannot be certain that we or our licensors were the first to make the inventions claimed in our owned and licensed patents or pending applications, or that we or our licensor were the first to file for patent protection of such inventions.

Assuming the other requirements for patentability are met, in the U.S. prior to March 15, 2013, the first to make the claimed invention is entitled to the patent, while outside the U.S., the first to file a patent application is entitled to the patent. After March 15, 2013, under the Leahy-Smith America Invents Act (Leahy-Smith Act), enacted on September 16, 2011, the U.S. has moved to a first-to-file system. The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications will be prosecuted and may also affect patent litigation. The effects of these changes are currently unclear as the USPTO must still implement various regulations, the courts have yet to address any of these provisions and the applicability of the act and new regulations on specific patents discussed herein have not been determined and would need to be reviewed. In general, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

If our products infringe the rights of others, we could be subject to expensive litigation or be required to obtain licenses from others to develop or market them.

Our competitors or others may have patent rights that they choose to assert against us or our licensees, suppliers, customers or potential collaborators. Moreover, we may not know about patents or patent applications that our products would infringe. For example, because patent applications do not publish for at least 18 months and can take many years to issue, there may be currently pending applications unknown to us that may later result in issued patents that our product candidates would infringe. In addition, if third parties file patent applications or obtain patents claiming technology also claimed by us or our licensors in issued patents or pending applications, we may have to participate in interference proceedings in the USPTO to determine priority of invention. If third parties file oppositions in foreign countries, we may also have to participate in opposition proceedings in foreign tribunals to defend the patentability of our foreign patent applications.

If a third party claims that we infringe its proprietary rights, any of the following may occur:

- we may become involved in time-consuming and expensive litigation, even if the claim is without merit;
- we may become liable for substantial damages for past infringement if a court decides that our technology infringes a competitor’s patent;
- a court may prohibit us from selling or licensing our product without a license from the patent holder, which may not be available on commercially acceptable terms, if at all, or which may require us to pay substantial royalties or grant cross licenses to our patents; and
- we may have to redesign our product candidates or technology so that they do not infringe patent rights of others, which may not be possible or commercially feasible.

If any of these events occur, our business and prospects will suffer and the market price of our common stock will likely decline substantially.

The patent protection and patent prosecution for GIAPREZA and certain of our product candidates is dependent on third parties.

While we normally seek and gain the right to fully prosecute the patents relating to our product and product candidates, there may be times when patents relating to our products or product candidates are controlled by our licensors, such as with GIAPREZA, where patent prosecution is controlled by our licensor, the George Washington University. If any of our licensing partners fail to appropriately prosecute and maintain patent protection for patents covering any licensed patents, our ability to develop and commercialize those product candidates may be materially adversely affected and we may not be able to prevent competitors from making, using, selling and importing competing products. In addition, even where we now have the right to control patent prosecution of patents and patent applications we have licensed from third parties, we may still be

adversely affected or prejudiced by actions or inactions of our licensors and their counsel that took place prior to us assuming control over patent prosecution.

In addition to patent protection, we will need to successfully preserve our trade secrets. If we are unable to maintain effective proprietary rights for our product candidates or any future product candidates, we may not be able to compete effectively in our markets.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our product candidate discovery and development processes that involve information or technology that is not covered by patents. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors, and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors.

Although we expect all of our employees and consultants to assign their inventions to us, and all of our employees, consultants, advisors, and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed, that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating our trade secrets.

If we fail to obtain orphan or other regulatory exclusivity for certain product candidates, we may face greater commercial competition and our revenue will be reduced.

Regulatory authorities in some jurisdictions, including the U.S. and EU may designate drugs for relatively small patient populations as orphan drugs. Our business strategy for certain of our product and product candidates includes seeking orphan drug designation. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is intended to treat a rare disease or condition, defined as a patient population of fewer than 200,000 in the U.S., or a patient population greater than 200,000 in the U.S. where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the U.S. In the EU, the EMA’s Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention, or treatment of a life-threatening or chronically debilitating condition affecting not more than 5 in 10,000 persons in the EU. If orphan drug status is granted, we may be eligible for a period of commercial exclusivity, which would afford us additional protection from generic competition, beyond that protection that may be afforded by patents. Even if a particular disease has a small patient population that we believe may be eligible for orphan status, it is possible that the FDA or EMA may not grant orphan status. If we do not obtain orphan drug exclusivity for our drug products and biologic products, particularly for any products that do not have broad patent protection, our competitors may then sell the same drug to treat the same condition sooner than if we had obtained orphan drug exclusivity and our revenue could be reduced.

Because a number of companies compete with us, many of which have greater resources than we do, and because we face rapid changes in technology in our industry, we cannot be certain that our products will be accepted in the marketplace or capture market share.

Competition from domestic and foreign biotechnology companies, large pharmaceutical companies and other institutions is intense and is expected to increase. A number of companies and institutions are pursuing the development of pharmaceuticals in our targeted areas. Many of these companies are very large and have financial, technical, sales and distribution and other resources substantially greater than ours. The greater resources of these competitors could enable them to develop or market competing products more quickly or effectively, making it extremely difficult for us to develop a share of the market for our products. These competitors also include companies that are conducting clinical studies and preclinical studies in the field of cancer therapeutics. Our competitors may develop or obtain regulatory approval for products more rapidly than we do. Also, the biotechnology and pharmaceutical industries are subject to rapid changes in technology. Our competitors may develop and market technologies and products that are more effective or less costly than those we are developing or that would render our technology and proposed products obsolete or noncompetitive.

Our product and product candidates may cause undesirable side effects or have other properties that could delay or prevent their market acceptance or regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Undesirable side effects caused by our product or product candidates could cause us or regulatory authorities to interrupt, delay, or halt clinical studies and commercial sales and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. Results of our studies could reveal a high and unacceptable severity and prevalence of undesirable side effects. In such an event, our studies could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny or withdraw approval of our product or product candidates for any or all targeted indications.

The drug-related side effects could affect commercial sales, patient recruitment, the ability of enrolled patients to complete the study, or result in potential product liability claims. We carry product liability insurance in the amount of $10.0 million in the aggregate. We believe our product liability insurance coverage is sufficient in light of our clinical programs; however, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business. In addition, regardless of merit or eventual outcome, product liability claims may result in impairment of our business reputation, withdrawal of clinical trial participants, costs due to related litigation, distraction of management's attention from our primary business, initiation of investigations by regulators, substantial monetary awards to patients or other claimants, the inability to commercialize our product candidates and decreased demand for our product candidates, if approved for commercial sale.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including but not limited to:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label;
- we may be required to create a Risk Evaluation and Mitigation Strategy (REMS) plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers, and/or other elements to assure safe use;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product and could significantly harm our business, results of operations, and prospects.

Our product and product candidates are subject to regulatory scrutiny.

As an approved product, GIAPREZA is subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, pharmacovigilance, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the U.S. and requirements of comparable foreign regulatory authorities.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA, and comparable foreign regulatory authorities, requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA, biologic license application (BLA), or market authorization application (MAA). Accordingly, we and others with whom we work must continue to expend

time, money, and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory approvals that we have received or may receive for our product and product candidates are and may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical studies, and surveillance to monitor the safety and efficacy of the product candidate. We will be required to report certain adverse reactions and production problems, if any, to the FDA and comparable foreign regulatory authorities. Any new legislation addressing drug safety issues could result in delays in product development or commercialization, or increased costs to assure compliance. We will have to

comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we may not promote our products for indications or uses for which they do not have approval. The holder of an approved NDA, BLA, or MAA must submit new or supplemental applications and obtain approval for certain changes to the approved product, product labeling or manufacturing process. We could also be asked to conduct post-marketing clinical studies to verify the safety and efficacy of our products in general or in specific patient subsets. If original marketing approval were obtained via the accelerated approval pathway, we could be required to conduct a successful post-marketing clinical trial to confirm clinical benefit for our products. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue warning letters;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approval;
- suspend any of our ongoing clinical studies;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our contract manufacturers' facilities; or
- seize or detain products, or require a product recall.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our Company and our operating results will be adversely affected.

We may not be successful in our efforts to identify, license, discover, develop, or commercialize additional product candidates.

Although a substantial amount of our effort will focus on the continued clinical testing, potential approval, and commercialization of our existing product candidates, the success of our business also depends on our ability to identify, license, discover, develop or commercialize additional product candidates. Research programs to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful. Our research programs or licensing efforts may fail to yield additional product candidates for clinical development and commercialization for a number of reasons, including but not limited to the following:

- our research or business development methodology or search criteria and process may be unsuccessful in identifying potential product candidates;
- we may not be able or willing to assemble sufficient resources to acquire or discover additional product candidates;
- our product candidates may not succeed in preclinical or clinical testing;
- our potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates we develop may be covered by third parties' patents or other exclusive rights;
- the market for a product candidate may change during our program so that such a product may become unreasonable to continue to develop;

- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, or we may not be able to identify, license, discover, develop or commercialize additional product candidates, which would have a material adverse effect on our business and could potentially cause us to cease operations.

If the market opportunities for our products are smaller than we believe, our revenue may be adversely affected, and our business may suffer.

Our estimates of the potential market opportunity for each of our products include several key assumptions based on our industry knowledge, industry publications, third-party research reports and other surveys. For example, GIAPREZA was approved for use in adult patients with septic or other distributive shock. However, determining the approximate number of hypotension patients in a given market requires numerous estimates and assumptions. While we believe that our internal assumptions are reasonable, no independent source has verified such assumptions. If any of these assumptions proves to be inaccurate, then the actual market for our product candidates could be smaller than our estimates of our potential market opportunity. Moreover, hospital and third-party payors may only approve GIAPREZA for a subset of the total patient population, such as those patients who have failed a first-line or second-line therapy. In that case, the total addressable market for GIAPREZA may be smaller than we estimated. If the actual market for our products is smaller than we estimate, our product revenue may be limited and it may be more difficult for us to achieve or maintain profitability.

We are subject to federal and state healthcare fraud and abuse laws, false claims laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Our operations are subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal FCA and physician sunshine laws and regulations. These laws impact, among other things, our sales, marketing and education programs. In addition, we are subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that affect our ability to operate 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;
- 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;
- 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;
- HIPAA, as amended by the federal Health Information Technology for Economic and Clinical Health Act and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;
- the federal physician sunshine requirements under the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 (Health Care Reform Laws) require manufacturers of drugs, devices, biologics, and medical supplies to report annually to the U.S. Department of Health and Human Services 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 and applicable group purchasing organizations; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant 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 and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, our business activities could be subject to challenge under one or more of such laws. In addition, recent healthcare reform legislation has strengthened these laws. For example, the Health Care Reform Laws, among other things, amends the intent

requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. Moreover, the Health Care Reform Laws provides that 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 False Claims Act.

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

Current and future legislation and court rulings may increase the difficulty and cost needed to obtain marketing approval and the subsequent commercialization of our product candidates and affect the prices we may obtain.

In the U.S. and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, (collectively, the PPACA), currently provides the following:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices;
- extension of manufacturers' Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs;
- new requirements to report financial arrangements with physicians and teaching hospitals;
- 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.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. These changes included aggregate reductions of Medicare payments to providers of up to 2% per fiscal year. Additionally, the American Taxpayer Relief Act of 2012 reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from 3 to 5 years. Further, it is possible that additional regulatory changes, as well as the repeal (in whole or in part) of the PPACA or the striking down of the PPACA by a court, could negatively affect insurance coverage and drug prices. These new laws may result in additional reductions in Medicare and other healthcare funding.

We expect that the PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. Additionally, legislation has been introduced to repeal the PPACA. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or

prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

Recent partial shutdowns of the U.S. Government have adversely affected the ability of companies in our industry to operate. Future shutdowns could result in material delays in regulatory actions and could limit our ability to access capital markets in the normal fashion.

Commencing in December 2018, the U.S. Federal Government was partially shut down for a period of 35 days. During this time, the FDA was not reviewing or acting on IND submissions or NDA filings. As a result, companies were effectively unable to receive regulatory clearance to commence new clinical studies and were unable to have new drugs approved. Similarly, the SEC was shut down during this time, which meant that the SEC was unable to review registration statements filed under the Securities Act of 1933, as amended. While this shutdown did not directly adversely affect our operations, future shutdowns could negatively affect our ability to interact with the FDA and/or the SEC, which could negatively affect our ability to operate in the ordinary course. Any such future event could negatively affect our prospects and our stock price.

Governments outside the U.S. tend to impose strict price controls, which may adversely affect our revenues, if any.

In some countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

We rely on certain key employees, and the loss of their service could negatively impact our future success.

We have a relatively small number of employees and we rely on the services of certain key employees, including George Tidmarsh, M.D. Ph.D., who serves as our President and Chief Executive Officer, as well as other members of our senior management team. Additionally, we had a significant reduction in force in 2018, which could prompt further attrition and employee dislocation in 2019 and beyond. The loss of the services of Dr. Tidmarsh or other key employees could negatively affect our ability to execute on our business plan and development activities and could cause a decline in our stock price.

Our business and operations may be materially adversely affected in the event of computer system failures or security breaches.

Despite the implementation of security measures, our internal computer systems, and those of our third-party CROs and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, cyber-attacks, natural disasters, fire, terrorism, war and telecommunication and electrical failures. If such an event were to occur and interrupt our operations, it could result in a material disruption of our development programs. For example, the loss of data from ongoing or planned clinical studies could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, loss of trade secrets or inappropriate disclosure of confidential or proprietary information, including protected health information or personal data of employees or former employees, access to our clinical data or disruption of the manufacturing process, we could incur liability and the further development of our product candidates could be delayed. We may also be vulnerable to cyber-attacks by hackers or other malfeasance. This type of breach of our cybersecurity may compromise our confidential information or our financial information and adversely affect our business or result in legal proceedings.

We and our subsidiary have certain operational covenants in our Royalty Agreement with HealthCare Royalty Partners. If we or our subsidiary are found to have breached these covenants, our subsidiary may be required to pay a substantial sum to HealthCare Royalty Partners.

On May 10, 2018, the La Jolla Pharmaceutical Company (LJPC), through its wholly-owned subsidiary, La Jolla Pharma, LLC (the Subsidiary), closed a $125.0 million royalty financing agreement (the Royalty Agreement) with HealthCare Royalty Partners (HCR). In this transaction, LJPC contributed certain assets related to, and including, GIAPREZA to the Subsidiary (the Contributed Assets). The royalty payment obligations under the Royalty Agreement are limited to the Subsidiary, and HCR has no recourse under the Royalty Agreement against LJPC or any assets other than the Contributed Assets and LJPC’s equity interest in the Subsidiary. LJPC and the Subsidiary are required to comply with certain covenants

relating to the conduct of their business and the commercialization of GIAPREZA. In the event of certain material breaches of the Royalty Agreement, HCR would have the right to terminate the Royalty Agreement and demand payment by the Subsidiary of an amount equal to either $125.0 million, minus aggregate royalties paid to HCR, or $225.0 million, minus aggregate royalties paid to HCR, depending on the type of breach. In the event that the Subsidiary is unable to make any such payment, then HCR may be able to foreclose on the collateral that was pledged to HCR, which collateral consists of the Contributed Assets. Any such damages award or foreclosure remedy would significantly negatively affect us on a consolidated basis and could result in the Company losing its interest in the Contributed Assets.

II. RISK FACTORS RELATED SPECIFICALLY TO OUR STOCK

As of December 31, 2018, we had approximately 26.3 million shares of common stock outstanding and currently may be required to issue up to a total of approximately 14.0 million additional shares of common stock upon conversion of existing convertible preferred stock and upon exercise of outstanding stock option grants and warrants. Such an issuance would be significantly dilutive to our existing common shareholders. You will experience further dilution if we issue additional equity securities in future fundraising transactions.

As of December 31, 2018, there were approximately 3,906 shares of Series C-1[2] Convertible Preferred Stock and approximately 2,737 shares of Series F Convertible Preferred Stock issued and outstanding. In light of the conversion rate of our preferred stock (approximately 1,724 shares of common stock are issuable upon the conversion of one share of Series C-1[2] Convertible Preferred Stock, and approximately 286 shares of common stock are issuable upon the conversion of one share of Series F Convertible Preferred Stock), the presence of such a large number of convertible preferred shares may dilute the ownership of our existing shareholders and provide the preferred investors with a sizeable interest in the Company.

Assuming the conversion of all preferred stock into common stock at the current conversion rates, and the exercise of all outstanding options and warrants, we would have approximately 40.3 million shares of common stock issued and outstanding following any such conversion and exercise, although the issuance of the common stock upon the conversion of our preferred stock is limited by a 9.999% beneficial ownership cap for each preferred shareholder, which such cap may be amended or waived by each such holder with no less than 61 days' notice to the Company. With approximately 26.3 million shares of common stock issued and outstanding as of December 31, 2018, the issuance of this number of shares of common stock underlying the convertible preferred stock and outstanding stock options and warrants would represent approximately 35% dilution to our existing shareholders.

In addition, we may choose to raise additional capital due to market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our shareholders or result in downward pressure on the price of our common stock.

The price of our common stock has been, and will be, volatile and may decline.

Our stock has historically experienced significant price and volume volatility and could continue to be volatile. Market prices for securities of biotechnology and pharmaceutical companies, including ours, have historically been highly volatile, and the market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. The following factors, among others, can have a significant effect on the market price of our securities:

- significant conversions of preferred stock into common stock and sales of those shares of common stock;
- results from our preclinical studies and clinical studies;
- limited financial resources;

- announcements regarding financings, mergers or other strategic transactions;
- future sales of significant amounts of our capital stock by us or our shareholders;
- developments in patent or other proprietary rights;
- developments concerning potential agreements with collaborators; and
- general market conditions and comments by securities analysts.

The realization of any of the risks described in these “Risk Factors” could have a negative effect on the market price of our common stock. In addition, class action litigation is sometimes instituted against companies whose securities have

experienced periods of volatility in market price. Any such litigation brought against us could result in substantial costs and a diversion of management's attention and resources, which could hurt our business, operating results and financial condition.

Because we do not expect to pay dividends on our common stock in the foreseeable future, you must rely on stock appreciation for any return on your investment.

We have paid no cash dividends on our common stock to date, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. As a result, we do not expect to pay any cash dividends on our common stock in the foreseeable future, and payment of cash dividends, if any, will also depend on our financial condition, results of operations, capital requirements and other factors and will be at the discretion of our board of directors. Furthermore, we may in the future become subject to contractual restrictions on, or prohibitions against, the payment of dividends. Accordingly, the success of your investment in our common stock will likely depend entirely upon any future appreciation. There is no guarantee that our common stock will appreciate in value or even maintain the price at which you purchased your shares, and you may not realize a return on your investment in our common stock.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

Our corporate headquarters is located at 4550 Towne Centre Court, San Diego, California 92121. We lease 83,008 square feet of office and laboratory space. Our lease commenced on October 30, 2017 for a 10-year period and provides an option to extend the lease for an additional 5 years at the end of the initial term. The annual rent is subject to escalation during the term. In addition to rent, the lease requires us to pay certain taxes, insurance and operating costs relating to the leased premises. The lease contains customary default provisions, representations, warranties and covenants.

Item 3. Legal Proceedings.

We are not currently a party to any material legal proceedings.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information

Shares of our common stock are traded on the Nasdaq Capital Market, under the symbol "LJPC."

Holders of Record

As of February 20, 2019, we had three holders of record. Certain shares of common stock are held in “street” name, and, accordingly, the number of beneficial owners of such shares of common stock is not known or included in the foregoing number. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividends

We have never paid dividends on shares of our common stock, and we do not anticipate paying dividends in the foreseeable future.

Item 6. Selected Financial Data.

We are a smaller reporting company, as defined by Rule 12b-2 under the Securities and Exchange Act of 1934 and in Item 10(f)(1) of Regulation S-K, and are not required to provide the information under this item.

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

Introduction

Management's discussion and analysis of financial condition and results of operations is provided as a supplement to the accompanying consolidated financial statements and notes, included in Item 15 of this Annual Report on Form 10-K, to help provide an understanding of our financial condition, the changes in our financial condition and our results of operations. Our discussion is organized as follows:

- Business Overview. This section provides a general description of our business and significant events and transactions that we believe are important in understanding our financial condition and results of operations.
- Critical Accounting Policies and Estimates. This section provides a description of our significant accounting policies, including the critical accounting policies and estimates, which are summarized in Note 2 to the accompanying consolidated financial statements included in Item 15 of this Annual Report on Form 10-K.
- Results of Operations. This section provides an analysis of our results of operations presented in the accompanying consolidated statements of operations by comparing the results for the year ended December 31, 2018 to the results for the year ended December 31, 2017 and comparing the results for the year ended December 31, 2017 to the results for the year ended December 31, 2016.
- Liquidity and Capital Resources. This section provides an analysis of our historical cash flows, as well as our future capital requirements.

Business Overview

La Jolla Pharmaceutical Company is a biopharmaceutical company focused on the discovery, development and commercialization of innovative therapies intended to significantly improve outcomes in patients suffering from life-threatening diseases. GIAPREZA™ (angiotensin II), formerly known as LJPC-501, was approved by the U.S. Food and Drug Administration (FDA) on December 21, 2017 as a vasoconstrictor indicated to increase blood pressure in adults with septic or other distributive shock. LJPC-0118 is La Jolla's investigational product for the treatment of severe malaria. LJPC-401 (synthetic human hepcidin), a clinical-stage investigational product, is being developed for the potential treatment of conditions characterized by iron overload, such as hereditary hemochromatosis, beta thalassemia, sickle cell disease, myelodysplastic syndrome and polycythemia vera.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles (GAAP). The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities. We evaluate our estimates on an ongoing basis. We base our estimates on historical experience and on other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ materially from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in the notes to our consolidated financial statements included in Item 15 of this Annual Report on Form 10-K, we believe that the following critical accounting policies are most critical to understanding and evaluating our reported financial result.

Revenue Recognition

Our revenue consists of U.S. sales of GIAPREZA, which we began shipping to customers in the first quarter of 2018. We had no revenue from product sales prior to the first quarter of 2018. We sell GIAPREZA to distributors and select wholesalers in the U.S. (collectively, customers). These customers subsequently resell our products to hospitals. In addition to

distribution agreements with customers, we enter into arrangements with group purchasing organizations (GPOs) and indirect customers that provide for privately negotiated rebates, chargebacks and discounts with respect to the purchase of our products.

Revenue is recorded at the transaction price, net of estimates for variable consideration consisting of chargebacks, discounts, returns and GPO discounts, rebates and administrative fees. Variable consideration is estimated using the most-likely amount method, which is the single-most likely outcome under a contract and is typically at the stated contractual rate. Actual amounts of consideration ultimately received may differ from our estimates. If actual results vary materially from our estimates, we will adjust these estimates, which will affect revenue from product sales and earnings in the period such estimates are adjusted.

Inventory Valuation

Inventory consist of finished goods held for sale and distribution and work in process. The Company periodically analyzes inventory levels and writes down inventory as cost of product sales when inventory has become obsolete or has a cost basis in excess of its estimated net realizable value and inventory quantities are in excess of expected product sales. The determination of events requiring the establishment of inventory valuation reserves, together with the calculation of the amount of such reserves may require judgment. Assumptions utilized in our quantification of inventory reserves include, but are not limited to, estimates of future product demand, consideration of current and future market conditions, net selling price of the product, potential product obsolescence and other events related to special circumstances surrounding the product. Adverse changes in assumptions utilized in our inventory reserve calculations could result in an increase to our inventory valuation reserves and higher cost of product sales.

Accrued Expenses

As part of the process of preparing the financial statements, we are required to estimate accrued expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed by service providers and estimating the level of service performed and the associated cost incurred for services that have not yet been invoiced. The majority of service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of accrued expenses as of each balance sheet date in the financial statements based on facts and circumstances known at that time. We periodically confirm the accuracy of recorded estimates with the service providers and make adjustments if necessary. Examples of estimated accrued expenses include costs associated with conducting development and regulatory activities, including fees paid to third-party professional consultants and service providers, and costs to develop and manufacture clinical study materials.

We base our accrued expenses on our estimates of the services received and efforts expended pursuant to our contractual arrangements. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our service providers will precede the level of services provided and result in a prepayment of the expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepayment accordingly.

Share-based Compensation Expense

We generally grant share-based awards under our shareholder-approved, share-based compensation plan and are required to measure and recognize compensation expense for all share-based awards based on estimated fair value. We estimate the fair value of stock options granted using the Black-Scholes option pricing model (Black-Scholes

model), which is then amortized over the requisite service periods of the awards. These include estimates of the expected volatility of our stock price, expected life of an award, the risk-free interest rate and expected dividends. Expected volatility is based our historical volatility of our common stock. The expected life of employee stock options, is calculated using the “simplified” method. The expected life assumption for non-employee’s options is based on the contractual term of the stock option. The risk-free interest rate is based on U.S. Treasury yield for a period consistent with the expected term of the stock options in effect at the time of the grants. The dividend yield assumption is based on the expectation of no future dividend payment by us in the foreseeable future.

Interest Expense

In the second quarter of 2018, we entered into a financing arrangement and recorded a deferred royalty obligation in our consolidated financial statements at December 31, 2018. The deferred royalty obligation is repaid based on royalties from the net product sales of GIAPREZA. Interest expense and the amortization of issuance costs related to the deferred royalty

obligation are recognized over the expected repayment term using the effective interest method. The assumptions used in determining the expected repayment term of the deferred royalty obligation require us to make estimates that could impact the effective interest rate. Each reporting period, we update our estimate of accrued interest under this agreement based on actual and forecasted net product sales of GIAPREZA. Changes in interest expense resulting from changes in the effective interest rate, if any, are recorded on a prospective basis.

Recent Accounting Pronouncements

Recent accounting pronouncements are disclosed in Note 2 to the accompanying consolidated financial statements included in Item 15 of this Annual Report on form 10-K.

Results of Operations

The following table summarizes our results of operations for each of the periods below (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Net product sales	$10,056	$—	$—
Contract revenue - related party	—	—	616
Cost of product sales	(1,643)	—	—
Research and development expense	(117,302)	(84,575)	(62,288)
Selling, general and administrative expense	(85,162)	(30,852)	(16,700)
Other (expense) income, net	(5,418)	624	187
Net loss	$(199,469)	$(114,803)	$(78,185)

Net Product Sales

For the year ended December 31, 2018, GIAPREZA net product sales were $10.1 million. La Jolla launched GIAPREZA in the U.S. in March 2018.

Cost of Product Sales

For the year ended December 31, 2018, we recognized cost of product sales of $1.6 million for sales of GIAPREZA related to royalty, labeling, shipping and distribution costs and a one-time charge of $0.8 million for inventory reserves.

Prior to approval by the FDA, approximately $0.6 million of direct material costs to manufacture GIAPREZA were recorded to research and development expense in 2017. As of December 31, 2018, inventory excludes approximately $0.2 million of manufacturing costs that were recorded to research and development expense.

Research and Development Expense

The following table summarizes our research and development expense for each of the periods below (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Clinical development costs	$42,766	$34,420	$32,798
Personnel and related costs	35,574	26,735	13,570
Share-based compensation expense	21,113	11,980	5,657
Other research and development costs	17,849	11,440	10,263
Total research and development expense	$117,302	$84,575	$62,288

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Years Ended December 31, 2018 and 2017

During the year ended December 31, 2018, research and development expense increased to $117.3 million from $84.6 million for the same period in 2017. The increase was primarily due to increased personnel and related costs and share-based compensation expense in support of the advancement of GIAPREZA and the clinical development of LJPC-401 and our other product candidates.

In October 2018, we effected a Company-wide realignment to increase our efficiency and focus on achieving our corporate goals. We anticipate research and development expense will decrease in 2019 as a result of our Company-wide realignment.

Years Ended December 31, 2017 and 2016

During the year ended December 31, 2017, research and development increased to $84.6 million from $62.3 million for the same period in 2016. The increase was primarily due to increased personnel and related costs and share-based compensation expense in support of the advancement and clinical development of GIAPREZA and LJPC-401.

Selling, General and Administrative Expense

The following table summarizes our selling, general and administrative expense for each of the periods below (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Personnel and related costs	$38,355	$9,367	$4,020
Selling and marketing costs	23,933	5,033	—
Share-based compensation expense	14,038	9,815	8,889
General and administrative costs	8,836	6,637	3,791
Total selling, general and administrative expense	$85,162	$30,852	$16,700

Years Ended December 31, 2018 and 2017

During the year ended December 31, 2018, selling, general and administrative expense increased to $85.2 million from $30.9 million for the same period in 2017. The increase was due to increased personnel and related costs, share-based compensation and commercialization and promotional activities to support the product launch of GIAPREZA. We anticipate selling, general and administrative expense will decrease in 2019 as a result of our Company-wide realignment.

Years Ended December 31, 2017 and 2016

During the year ended December 31, 2017, selling, general and administrative expense increased to $30.9 million from $16.7 million for the same period in 2016. The increase was primarily due to increased personnel costs and professional and outside service costs to support our increased development and pre-commercialization activities.

Other (Expense) Income, Net

Years Ended December 31, 2018 and 2017

During the year ended December 31, 2018, other (expense) income, net increased to $5.4 million from $0.6 million for the same period in 2017. The increase was due to amounts accrued pursuant to our deferred royalty obligation

balance outstanding during the year ended December 31, 2018.

Years Ended December 31, 2017 and 2016

During the year ended December 31, 2017, other (expense) income, net increased to $0.6 million from $0.2 million for the same period in 2016. The increase was due to higher cash balance.

Liquidity and Capital Resources

Since January 2012, when the Company was effectively restarted with new assets and a new management team, through December 31, 2018, our cash used for operating activities was $340.9 million. From inception through December 31, 2018, we have incurred an accumulated deficit of $921.0 million and have financed our operations through public and private offerings of securities, a royalty financing, revenues from collaborative agreements and net product sales, equipment financings and interest income on invested cash balances. As of December 31, 2018, we had $172.6 million in cash and cash equivalents, compared to $90.9 million in cash and cash equivalents as of December 31, 2017. The Company had no debt as of December 31, 2018 and 2017. Based on our current operating plans and projections, we believe that our cash and cash equivalents as of December 31, 2018 will be sufficient to fund operations for at least one year from the date this Annual Report on Form 10-K is filed with the SEC.

Cash used for operating activities for the year ended December 31, 2018 was $152.4 million, compared to $85.1 million for the same period in 2017. The increase in cash used for operating activities was a result of the increase in our net loss, primarily offset by increases in share-based compensation, non-cash interest expense, depreciation and amortization and changes in working capital.

Cash used for investing activities for the year ended December 31, 2018, was $2.3 million compared to $9.2 million for the same period in 2017.

Cash provided by financing activities for the year ended December 31, 2018 was $236.4 million, compared to $120.2 million for the same period in 2017. The increase in cash provided by financing activities was primarily a result of $109.8 million of net proceeds from the March 2018 common stock offering and $124.3 million of net proceeds from the May 2018 royalty financing.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements that have, or are reasonably likely to have, a current or future effect on our financial condition, changes in our financial condition, expenses, results of operations, liquidity, capital expenditures or capital resources.

Contractual Obligations

Contractual obligations represent future minimum cash commitments and liabilities under agreements with third parties. See Note 11 Commitments and Contingencies in the Notes to consolidated financial statements included in Item 15 of this Annual Report on Form 10-K. The following table represents our contractual obligations as of December 31, 2018, aggregated by type (amounts in thousands):

	Payments Due by Period				
Contractual Obligations[1]	Total	Less Than 1 Year	1 - 3 Years	3 - 5 Years	More Than 5 Years
Leases	$39,286	$3,951	$8,262	$8,765	$18,308
Purchase obligations	8,277	2,759	5,518	—	—
License agreements	600	120	240	240	—
Total	$48,163	$6,830	$14,020	$9,005	$18,308

(1) Excludes future amounts payable by our wholly-owned subsidiary, La Jolla Pharma, LLC pursuant to our $125.0 million royalty financing transaction with HealthCare Royalty Partners (HCR). See Note 8 to the accompanying consolidated financial statements included in Item 15 of this Annual Report on form 10-K.

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

Our exposure to market risk for changes in interest rates relates primarily to interest earned on our cash equivalents and investments. The primary objective of our investment activities is to preserve our capital to fund operations. A secondary objective is to maximize income from our investments without assuming significant risk. Our investment policy provides for investments in low-risk, investment-grade debt instruments. As of December 31, 2018, we had cash and cash equivalents of $172.6 million. A hypothetical 10% change in interest rates during any of the periods presented would not have had a material

impact on our consolidated financial statements. To date, we have not experienced a loss of principal on any of our investments.

We face foreign exchange risk as a result of entering into transactions denominated in currencies other than U.S. dollars. Due to the uncertain timing of expected payments in foreign currencies, we do not utilize any forward exchange contracts. All foreign transactions settle on the applicable spot exchange basis at the time such payments are made. An adverse movement in foreign exchange rates could have an effect on payments made to foreign suppliers and for license agreements. A hypothetical 10% change in foreign exchange rates during any of the periods presented would not have had a material impact on our financial statements.

Item 8. Financial Statements and Supplementary Data.

The financial statements required by this item are set forth at the end of this Annual Report on Form 10-K beginning on page F-2 and are incorporated herein by reference.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

(a) Disclosure Controls and Procedures; Changes in Internal Control Over Financial Reporting

Our management, with the participation of our principal executive and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2018. Based on this evaluation, our principal executive and principal financial officer concluded that our disclosure controls and procedures were effective as of December 31, 2018.

During the year ended December 31, 2018, we implemented controls in connection with the newly-adopted accounts receivable, inventory, revenue recognition and interest expense policies as disclosed in Note 2 to our consolidated financial statements included in Item 15 of this Annual Report on Form 10-K.

(b) Management Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) of the Exchange Act. Our management used the Committee of Sponsoring Organizations of the Treadway Commission Internal Control - Integrated Framework (2013) (COSO framework) to evaluate the effectiveness of internal control over financial reporting. Management believes that the COSO framework is a suitable framework for its evaluation of financial reporting because it is free from bias, permits reasonably consistent qualitative and quantitative measurements of our internal control over financial reporting, is sufficiently complete so that those relevant factors that would alter a conclusion about the effectiveness of our internal control over financial reporting are not omitted and is relevant to an evaluation of internal control over financial reporting.

Management has assessed the effectiveness of our internal control over financial reporting as of December 31, 2018 and has concluded that such internal control over financial reporting was effective.

(c) Attestation report of the independent registered public accounting firm

The effectiveness of the Company's internal control over financial reporting has been audited by Squar Milner LLP, an independent registered public accounting firm, as stated in their attestation report appearing below, which expresses an unqualified opinion on the effectiveness of the Company's internal control over financial reporting as of December 31, 2018.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of La Jolla Pharmaceutical Company

Opinion on the Internal Control Over Financial Reporting

We have audited La Jolla Pharmaceutical Company's (the Company) internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission in 2013. 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 issued by the Committee of Sponsoring Organizations of the Treadway Commission in 2013.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of La Jolla Pharmaceutical Company as of December 31, 2018 and 2017, and the related consolidated statements of operations, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2018, and the related notes to the consolidated financial statements of the Company and our report dated March 4, 2019 expressed an unqualified opinion.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting in the accompanying Management Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit 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 audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

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

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

/s/ SQUAR MILNER LLP
San Diego, California
March 4, 2019

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Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officer and Corporate Governance.

The information required by this Item is expected to be in our definitive Proxy Statement for the 2019 Annual Meeting of Shareholders, which we expect to be filed with the U.S. Securities and Exchange Commission (SEC) within 120 days of the end of our fiscal year ended December 31, 2018 and is incorporated herein by reference.

We have adopted a Code of Business Conduct and Ethics that applies to all of our directors, officers and employees, including our principal executive, principal financial and principal accounting officers, or persons performing similar functions. Our Code of Business Conduct and Ethics is posted on our website located at www.ljpc.com in the Corporate Governance section under “Investor Relations.” We intend to disclose future amendments to certain provisions of the Code of Business Conduct and Ethics, and waivers of the Code of Business Conduct and Ethics granted to executive officers and directors, on the website within 4 business days following the date of the amendment or waiver.

Item 11. Executive Compensation.

The information required by this Item is expected to be in our definitive Proxy Statement for the 2019 Annual Meeting of Shareholders, which we expect to be filed with the SEC within 120 days of the end of our fiscal year ended December 31, 2018 and is incorporated herein by reference.

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

The information required by this Item is expected to be in our definitive Proxy Statement for the 2019 Annual Meeting of Shareholders, which we expect to be filed with the SEC within 120 days of the end of our fiscal year ended December 31, 2018 and is incorporated herein by reference.

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

The information required by this Item is expected to be in our definitive Proxy Statement for the 2019 Annual Meeting of Shareholders, which we expect to be filed with the SEC within 120 days of the end of our fiscal year ended December 31, 2018 and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services.

The information required by this Item is expected to be in our definitive Proxy Statement for the 2019 Annual Meeting of Shareholders, which we expect to be filed with the SEC within 120 days of the end of our fiscal year ended December 31, 2018 and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) Documents filed as part of this report.

1. The following financial statements of La Jolla Pharmaceutical Company are filed as part of this report under Item 8 — Financial Statements and Supplementary Data:

Report of Independent Registered Public Accounting Firm	F - 1
Consolidated Balance Sheets at December 31, 2018 and 2017	F - 2
Consolidated Statements of Operations for the years ended December 31, 2018, 2017 and 2016	F - 3
Consolidated Statements of Shareholders' Equity for the years ended December 31, 2018, 2017 and 2016	F - 4
Consolidated Statements of Cash Flows for the years ended December 31, 2018, 2017 and 2016	F - 5
Notes to Consolidated Financial Statements	F - 6

2. Financial Statement Schedules.

The following financial statement schedules of La Jolla Pharmaceutical Company are filed as part of this report under Item 8 — Financial Statements and Supplementary Data.

None.

3. Exhibits.

List of Exhibit required by Item 601 of Regulation S-K. See part (b) below.

(b) Exhibits:

Exhibit No.	Exhibit Description	Incorporated by Reference Form	Date Filed	Filed Herewith
3.1.1	Amended and Restated Articles of Incorporation	S-8	12/20/2013	
3.1.2	Certificate of Amendment of Articles of Incorporation	8-K	1/15/2014	
3.1.3	Certificate of Amendment to Amend and Restated Articles of Incorporation	8-A12B/A	10/17/2014	
3.2	Amended and Restated Bylaws	8-A12B/A	10/17/2014	
4.1	Certificate of Determination of Series F Convertible Preferred Stock	8-K	9/25/2013	
10.1*	Form of Indemnification Agreement	10-Q	11/17/2005	

10.7*	Employment Offer Letter by and between La Jolla Pharmaceutical Company and George F. Tidmarsh, M.D., Ph.D., dated as of January 19, 2012	8-K	1/20/2012
10.11*	La Jolla Pharmaceutical Company 2013 Equity Incentive Plan	8-K	9/25/2013
10.12*	Employment Offer Letter by and between La Jolla Pharmaceutical Company and Lakhmir Chawla, M.D., dated as of February 3, 2015	10-K	2/25/2016
10.13*	Employment Offer Letter by and between La Jolla Pharmaceutical Company and Dennis Mulroy dated as of March 12, 2015	8-K	4/10/2015
10.14*	Employment Offer Letter by and between La Jolla Pharmaceutical Company and Jennifer Anne Carver dated January 1, 2016	10-K	2/25/2016

10.15	Lease between BMR-Axiom LP and La Jolla Pharmaceutical Company, dated December 29, 2016	10-K	2/23/2017	
10.16	Amended and Restated Patent License Agreement by and between La Jolla Pharmaceutical Company and the George Washington University dated March 1, 2016†	10-K	2/22/2018	
10.17	Revenue Interest Agreement, dated May 10, 2018, among La Jolla Pharma, LLC, HealthCare Royalty Partners III, L.P., HCRP Overflow Fund, L.P. and HCR Molag Fund, L.P.	8-K	5/14/2018	
21.1	Subsidiaries of La Jolla Pharmaceutical Company			X
23.1	Consent of Independent Registered Public Accounting Firm Squar Milner LLP			X
24.1	Power of Attorney (included on the signature page of this Form 10-K)			X
31.1	Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002			X
31.2	Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002			X
32.1	Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002			X
101.INS	XBRL Instance Document			X
101.SCH	XBRL Taxonomy Extension Schema Document			X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document			X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document			X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document			X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document			X

* This exhibit is a management contract or compensatory plan or arrangement.

† Confidential treatment has been requested with respect to certain portions of the exhibit, which portions have been omitted and filed separately with the Securities and Exchange Commission.

Item 16. Form 10-K Summary.

None.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

La Jolla Pharmaceutical Company

Date: March 4, 2019 /s/ George Tidmarsh
George Tidmarsh, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENT, that each person whose signature appears below constitutes and appoints each of George Tidmarsh, M.D., Ph.D. and Dennis Mulroy as his or her true and lawful attorney-in-fact and agent, with full power of substitution for him or her, and in his or her name in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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.

Signature	Title	Date
/s/ George Tidmarsh George Tidmarsh, M.D., Ph.D.	Director, President, Chief Executive Officer and Secretary (Principal Executive Officer)	March 4, 2019
/s/ Dennis Mulroy Dennis Mulroy	Chief Financial Officer (Principal Financial and Accounting Officer)	March 4, 2019
/s/ Kevin Tang Kevin Tang	Chairman of the Board and Director	March 4, 2019

/s/ Laura Douglass Laura Douglass	Director	March 4, 2019
/s/ Craig Johnson Craig Johnson	Director	March 4, 2019
/s/ Robert Rosen Robert Rosen	Director	March 4, 2019

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of La Jolla Pharmaceutical Company

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of La Jolla Pharmaceutical Company (the Company) as of December 31, 2018 and 2017, the related consolidated statements of operations, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2018, and the related notes to the consolidated financial statements (collectively the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 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.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission in 2013, and our report dated March 4, 2019 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ SQUAR MILNER LLP

We have served as the Company's auditor since 2012.

San Diego, California

March 4, 2019

LA JOLLA PHARMACEUTICAL COMPANY
Consolidated Balance Sheets
(in thousands, except share and par value amounts)

	December 31, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 172,604	$ 90,915
Accounts receivable, net	1,381	—
Inventory, net	2,020	—
Prepaid expenses and other current assets	5,111	3,147
Total current assets	181,116	94,062
Property and equipment, net	22,267	24,568
Restricted cash	909	909
Total assets	$ 204,292	$ 119,539
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 8,572	$ 11,484
Accrued expenses	12,988	703
Accrued payroll and related expenses	7,509	4,995
Deferred rent, current portion	1,370	1,370
Total current liabilities	30,439	18,552
Deferred rent, less current portion	13,609	12,785
Deferred royalty obligation, net	124,323	—
Total liabilities	168,371	31,337
Commitments and contingencies (Note 11)		
Shareholders' equity:		
Common Stock, $0.0001 par value; 100,000,000 shares authorized, 26,259,254 and 22,167,529 shares issued and outstanding at December 31, 2018 and December 31, 2017, respectively	3	2
Series C-1[2] Convertible Preferred Stock, $0.0001 par value; 11,000 shares authorized, 3,906 shares issued and outstanding at December 31, 2018 and December 31, 2017, and a liquidation preference of $3,906 at December 31, 2018 and 2017	3,906	3,906
Series F Convertible Preferred Stock, $0.0001 par value; 10,000 shares authorized, 2,737 shares issued and outstanding at December 31, 2018 and December 31, 2017, and a liquidation preference of $2,737 at December 31, 2018 and 2017	2,737	2,737
Additional paid-in capital	950,258	803,071
Accumulated deficit	(920,983)	(721,514)
Total shareholders' equity	35,921	88,202
Total liabilities and shareholders' equity	$ 204,292	$ 119,539

See accompanying notes to the consolidated financial statements.

LA JOLLA PHARMACEUTICAL COMPANY
Consolidated Statements of Operations
(in thousands, except per share amounts)

	Year Ended December 31,		
	2018	2017	2016
Revenue			
Net product sales	$10,056	$—	$—
Contract revenue - related party	—	—	616
Total revenue	10,056	—	616
Operating expenses			
Cost of product sales	1,643	—	—
Research and development	117,302	84,575	62,288
Selling, general and administrative	85,162	30,852	16,700
Total operating expenses	204,107	115,427	78,988
Loss from operations	(194,051)	(115,427)	(78,372)
Other (expense) income			
Interest expense	(7,303)	—	—
Interest income	1,885	624	187
Total other (expense) income, net	(5,418)	624	187
Net loss	(199,469)	(114,803)	(78,185)
Net loss per share, basic and diluted	$(7.85)	$(5.41)	$(4.54)
Weighted-average common shares outstanding, basic and diluted	25,422	21,215	17,228

See accompanying notes to the consolidated financial statements.

La Jolla Pharmaceutical Company

Consolidated Statements of Shareholders' Equity
For the Years Ended December 31, 2018, 2017 and 2016
(in thousands)

	Series C-1[2] Convertible Preferred Stock		Series F Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at December 31, 2015	4	$ 3,906	3	$ 2,737	18,244	$ 2	$ 646,408	$ (528,526)	$ 124,527
Share-based compensation expense	—	—	—	—	—	—	14,349	—	14,349
Third party share-based compensation expense	—	—	—	—	—	—	197	—	197
Exercise of stock options for common stock	—	—	—	—	17	—	149	—	149
Net loss	—	—	—	—	—	—	—	(78,185)	(78,185)
Balance at December 31, 2016	4	3,906	3	2,737	18,261	2	661,103	(606,711)	61,037
Issuance of common stock for March 2017 financing	—	—	—	—	3,731	—	117,480	—	117,480
Share-based compensation expense	—	—	—	—	—	—	20,776	—	20,776
Third party share-based compensation expense	—	—	—	—	—	—	1,019	—	1,019
Exercise of stock options for common stock	—	—	—	—	175	—	2,693	—	2,693
Net loss	—	—	—	—	—	—	—	(114,803)	(114,803)
Balance at December 31, 2017	4	3,906	3	2,737	22,167	2	803,071	(721,514)	88,202
Issuance of common stock for March 2018 financing	—	—	—	—	3,910	1	109,808	—	109,809
Share-based compensation expense	—	—	—	—	—	—	34,748	—	34,748
Third party share-based compensation expense	—	—	—	—	—	—	332	—	332
Exercise of stock options for common stock	—	—	—	—	150	—	1,908	—	1,908
Issuance of common stock under ESPP	—	—	—	—	32	—	391	—	391
Net loss	—	—	—	—	—	—	—	(199,469)	(199,469)
Balance at December 31, 2018	4	$ 3,906	3	$ 2,737	26,259	$ 3	$ 950,258	$ (920,983)	$ 35,921

See accompanying notes to the consolidated financial statements.

LA JOLLA PHARMACEUTICAL COMPANY
Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,		
	2018	2017	2016
Operating activities			
Net loss	$(199,469)	$(114,803)	$(78,185)
Adjustments to reconcile net loss to net cash used for operating activities:			
Share-based compensation expense	35,151	21,795	14,546
Depreciation expense	4,405	1,268	730
Loss on disposal of equipment	236	199	75
Non-cash interest expense	6,797	—	—
Changes in operating assets and liabilities:			
Accounts receivable, net	(1,381)	—	—
Inventory	(2,020)	—	—
Prepaid expenses and other current assets	(1,964)	(1,642)	(664)
Other assets	—	219	(149)
Accounts payable	(2,912)	4,832	3,600
Accrued expenses	5,451	(202)	227
Accrued payroll and related expenses	2,514	2,918	987
Deferred rent	824	335	124
Net cash used for operating activities	(152,368)	(85,081)	(58,709)
Investing activities			
Purchase of property and equipment	(2,340)	(9,194)	(2,218)
Net cash used for investing activities	(2,340)	(9,194)	(2,218)
Financing activities			
Net proceeds from royalty financing	124,289	—	—
Net proceeds from the issuance of common stock	109,809	117,480	—
Net proceeds from the exercise of stock options for common stock	1,908	2,693	149
Proceeds from issuance of common stock under ESPP	391	—	—
Net cash provided by financing activities	236,397	120,173	149
Net increase (decrease) in cash, cash equivalents and restricted cash	81,689	25,898	(60,778)
Cash, cash equivalents and restricted cash at beginning of period	91,824	65,926	126,704
Cash, cash equivalents and restricted cash at end of period	$173,513	$91,824	$65,926
Supplemental disclosure of cash flow information			
Interest paid	$506	$—	$—
Capitalized landlord funded tenant improvements	$—	$13,696	$—
Reconciliation of cash, cash equivalents and restricted cash to the consolidated balance sheets			
Cash and cash equivalents	$172,604	$90,915	$65,726
Restricted cash, current portion	—	—	200
Restricted cash, less current portion	909	909	—
Total cash, cash equivalents and restricted cash	$173,513	$91,824	$65,926

See accompanying notes to the consolidated financial statements.

La Jolla Pharmaceutical Company
Notes to Consolidated Financial Statements

1. Business

La Jolla Pharmaceutical Company (collectively with its wholly-owned subsidiaries, the Company) is a biopharmaceutical company focused on the discovery, development and commercialization of innovative therapies intended to significantly improve outcomes in patients suffering from life-threatening diseases. GIAPREZA™ (angiotensin II), formerly known as LJPC-501, was approved by the U.S. Food and Drug Administration (FDA) on December 21, 2017 as a vasoconstrictor indicated to increase blood pressure in adults with septic or other distributive shock. LJPC-0118, a clinical-stage investigational product, is being developed for the potential treatment of severe malaria, a serious and sometimes fatal disease caused by a parasite that commonly infects a certain type of mosquito, which feeds on humans. LJPC-401 (synthetic human hepcidin), a clinical-stage investigational product, is being developed for the potential treatment of conditions characterized by iron overload, such as hereditary hemochromatosis, beta thalassemia, sickle cell disease, myelodysplastic syndrome and polycythemia vera.

The Company was incorporated in 1989 as a Delaware corporation and reincorporated in California in 2012.

As of December 31, 2018, the Company had $172.6 million in cash and cash equivalents, compared to $90.9 million in cash and cash equivalents at December 31, 2017. Based on the Company's current operating plans and projections, the Company expects that its cash and cash equivalents as of December 31, 2018 will be sufficient to fund operations for at least one year from the date this Annual Report on Form 10-K is filed with the SEC.

2. Basis of Presentation and Summary of Significant Accounting Policies

Basis of Presentation and Use of Estimates

The Company's consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) and include the accounts of the Company and its wholly-owned subsidiaries. All intercompany transactions and balances have been eliminated in consolidation. The preparation of the Company's consolidated financial statements requires management to make estimates and assumptions that impact the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in its consolidated financial statements and the accompanying notes. Actual results may differ materially from these estimates.

Certain amounts previously reported in the financial statements have been reclassified to conform to the current year presentation. Such reclassifications did not affect net loss, shareholders' equity or cash flows.

Summary of Significant Accounting Policies

Cash, Cash Equivalents and Restricted Cash

The Company considers all highly liquid investments with maturities of three months or less when purchased as cash equivalents. The Company maintains its cash in checking and savings accounts. Income generated from cash held in savings accounts is recorded as interest income. The carrying value of the Company's money market savings accounts is included in cash equivalents and approximates the fair value. Cash is classified as restricted cash when certain funds are reserved for a specific purpose and are not available for immediate or general business use.

Accounts Receivable, Net

Accounts receivable are recorded net of customers' allowances for prompt-pay discounts, chargebacks and doubtful accounts. Allowances for prompt-pay discounts and chargebacks are based on contractual terms. The Company estimates the allowance for doubtful accounts based on existing contractual payment terms, actual payment patterns of its customers and individual customer circumstances. As of December 31, 2018, the Company did not have any allowances for doubtful accounts.

Inventory, Net

Inventory is stated at the lower of cost or estimated net realizable value on a first-in, first-out (FIFO) basis. The Company periodically analyzes inventory levels and writes down inventory as cost of product sales when: inventory has

La Jolla Pharmaceutical Company
Notes to Consolidated Financial Statements

become obsolete; inventory has a cost basis in excess of its estimated net realizable value; or inventory quantities are in excess of expected product sales.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist of cash. The Company maintains its cash in checking and money market savings accounts at federally insured financial institutions in excess of federally insured limits.

The Company's products are distributed in the U.S. through distributors and select wholesalers (collectively, customers) that resell its products to hospitals, the end users. The following table includes the percentage of net product sales and accounts receivable balances for the Company's three major customers, each of which comprised 10% or more of its net product sales:

	Net Product Sales Year Ended December 31, 2018		Accounts Receivable As of December 31, 2018	
Customer A	37	%	44	%
Customer B	31	%	28	%
Customer C	30	%	26	%
Total	98	%	98	%

Property and Equipment, Net

Property and equipment is stated at cost less accumulated depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, which range from two to seven years. Amortization of leasehold improvements is computed using the straight-line method over the shorter of the lease term or the estimated useful life of the related assets. Maintenance and repairs are charged to operating expense as incurred. When assets are sold, or otherwise disposed of, the cost and related accumulated depreciation are removed from the accounts, and any gain or loss is included in operating expense.

Revenue Recognition

The Company adopted the Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) Topic 606 – Revenue from Contracts with Customers (ASC 606) at the time of its first commercial shipment of GIAPREZA in the first quarter of 2018. The Company had no revenue from product sales prior to the first quarter of 2018.

Under ASC 606, the Company recognizes revenue when its customers obtain control of the Company's product, which typically occurs on delivery. Revenue is recognized in an amount that reflects the consideration that the Company expects to receive in exchange for those goods. To determine revenue recognition for contracts with customers within the scope of ASC 606, the Company performs the following 5 steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

Revenue from product sales is recorded at the transaction price, net of estimates for variable consideration consisting of chargebacks, discounts, returns and Group Purchasing Organization (GPO) discounts, rebates and administrative fees. Variable consideration is estimated using the most-likely amount method, which is the single-most likely outcome under a contract and is typically at the stated contractual rate. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results vary materially from the Company's estimates, the Company will adjust these estimates, which will affect revenue from product sales and earnings in the period such estimates are adjusted. These items include:

- Chargebacks - Chargebacks are discounts the Company provides to distributors in the event that the sales prices to end users are below the distributors' acquisition price. Chargebacks are estimated based on known chargeback rates and recorded as a reduction of revenue on delivery to the Company's customers.
- Discounts - The Company offers customers various forms of incentives and consideration, including prompt-pay discounts, service fees and other contract fees. The Company estimates discounts and fees primarily based on

La Jolla Pharmaceutical Company
Notes to Consolidated Financial Statements

contractual terms. These discounts and fees are recorded as a reduction of revenue on delivery to the Company's customers.

- Returns - The Company offers customers a limited right of return, generally for damaged or expired product. The Company estimates returns based on an internal analysis, which includes actual experience and a review of comparable companies. The estimates for returns are recorded as a reduction of revenue on delivery to the Company's customers.
- GPO Discounts and Rebates - The Company offers cash discounts to GPO members. These discounts are taken when the GPO members purchase GIAPREZA from the Company's customers, who then charge the discount amount back to the Company. Additionally, the Company offers volume and contract-tier rebates to GPO members. Rebates are based on actual purchase levels during the quarterly rebate purchase period.
- GPO Administrative Fees - The Company pays administrative fees to GPOs for services and access to data. These fees are based on contracted terms and are paid after the quarter in which the product was purchased by the GPO members.

The Company will continue to assess its estimates of variable consideration as it accumulates additional historical data and will adjust these estimates accordingly.

Shipping and Handling Expense

Shipping and handling expense is included in cost of product sales.

Research and Development Expense

Research and development expense includes salaries and benefits, facilities and other overhead costs, research-related manufacturing costs, contract service and clinical and preclinical-related service costs performed by clinical research organizations, research institutions and other outside service providers. Research and development expense is expensed as incurred when these expenditures relate to the Company's research and development efforts and have no alternative future uses.

In accordance with certain research and development agreements, the Company is obligated to make certain upfront payments upon execution of the agreement. Advance payments, including nonrefundable amounts, for materials or services that will be used or rendered for future research and development activities are deferred and capitalized. Such amounts are recognized as an expense as the related goods are delivered or the related services are performed.

Acquisition or milestone payments that the Company makes in connection with in-licensed technology are expensed as incurred when there is uncertainty in receiving future economic benefits from the licensed technology. The Company considers the future economic benefits from the licensed technology to be uncertain until such licensed technology is incorporated into products that are approved for marketing by the FDA or when other significant risk factors are abated. For accounting purposes, management has viewed future economic benefits for all of the Company's licensed technology to be uncertain.

Patent Costs

Legal costs in connection with approved patents and patent applications are expensed as incurred, as recoverability of such expenditures is uncertain. These costs are recorded in selling, general and administrative expense in the consolidated statements of operations.

Share-based Compensation

The Company accounts for share-based payment arrangements in accordance with ASC 718, Compensation - Stock Compensation and ASC 505-50, Equity - Equity Based Payments to Non-Employees, which requires the recognition of compensation expense, using a fair-value based method, for all costs related to share-based payments, including stock options and restricted stock awards. These standards require companies to estimate the fair value of share-based payment awards on the date of the grant using an option-pricing model. The Company has elected to account for forfeitures as they occur.

Income Taxes

The Company accounts for income taxes using the asset and liability method. Deferred tax assets and liabilities are determined based on the differences between the financial statement carrying amounts and the income tax basis of assets and liabilities. Deferred tax assets and liabilities are measured using enacted tax rates applicable to taxable income in the years in

which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rate is recognized in income in the period that includes the enactment date. A valuation allowance is applied against any deferred tax asset if, based on available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. For uncertain tax positions that meet a “more likely than not” threshold, the Company recognizes the benefit of uncertain tax positions in the consolidated financial statements. The Company’s practice is to recognize interest and penalties, if any, related to uncertain tax positions in income tax expense in the consolidated statements of operations.

Interest Expense

Interest expense and the amortization of issuance costs related to the deferred royalty obligation (see Note 8) are recognized over the expected repayment term of the deferred royalty obligation using the effective interest method. The assumptions used in determining the expected repayment term of the deferred royalty obligation require the Company to make estimates that could impact the effective interest rate. Each reporting period, the Company estimates the expected repayment term of the deferred royalty obligation based on forecasted net product sales of GIAPREZA. Changes in interest expense resulting from changes in the effective interest rate, if any, are recorded on a prospective basis.

Net Loss per Share

Basic net loss per share is calculated by dividing net loss by the weighted average number of common shares outstanding during the period, excluding unvested restricted stock awards. Diluted net loss per share is calculated by dividing net loss by the weighted average number of common shares outstanding plus potential common shares. Convertible preferred stock, stock options, warrants and unvested restricted stock awards are considered potential common shares and are included in the calculation of diluted net loss per share using the treasury stock method when their effect is dilutive. Potential common shares are excluded from the calculation of diluted net loss per share when their effect is anti-dilutive. As of December 31, 2018, 2017 and 2016, there were 14.0 million shares, 13.6 million shares and 10.7 million shares, respectively, of potential common shares, which were excluded from the calculation of diluted net loss per share because their effect was anti-dilutive.

Comprehensive Loss

Comprehensive loss is defined as a change in equity during a period from transactions and other events and circumstances from non-owner sources. There have been no items qualifying as other comprehensive loss, and, therefore, comprehensive loss for the periods reported was comprised solely of the Company’s net loss.

Segment Reporting

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. The Company views its operations and manages its business in one operating segment.

Fair Value Measurements

The Company follows the provisions of ASC 820-10, Fair Value Measurements and Disclosures (ASC 820-10), which defines fair value, establishes a framework for measuring fair value in GAAP and requires certain disclosures about fair value measurements. Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a

market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability.

As a basis for considering such assumptions, ASC 820-10 establishes a three-tier fair value hierarchy which prioritizes the inputs used in measuring fair value as follows: Level 1) observable inputs such as quoted prices in active markets; Level 2) inputs other than the quoted prices in active markets that are observable either directly or indirectly; and Level 3) unobservable inputs, in which there is little or no market data, which require the Company to develop its own assumptions. The hierarchy requires the Company to use observable market data, when available, and to minimize the use of unobservable inputs when determining fair value.

Cash equivalents consist of money market accounts with maturities of 90 days or less. Due to the high ratings and short-term nature of these funds, the Company considers the inputs to the value of all cash and cash equivalents as Level 1.

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The Company's financial instruments include cash and cash equivalents, accounts receivable, inventory, prepaid expenses and other current assets, accounts payable and accrued expenses. The carrying amounts reported in the balance sheets for these financial instruments approximate fair value because of their short-term nature.

Recent Accounting Pronouncements

Recently Adopted Accounting Pronouncements

In the first quarter of 2018, the Company adopted Accounting Standard Update (ASU) 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash. The standard clarifies the presentation of restricted cash and cash equivalents and requires companies to include restricted cash and cash equivalents in the beginning and ending balances of cash and cash equivalents on the statement of cash flows. The standard also requires additional disclosures to describe the amount and detail of the restriction by balance sheet line item. Accordingly, restricted cash is included as a component of cash, cash equivalents and restricted cash in the consolidated statements of cash flows for all periods presented, and the Company has disclosed the amount and detail of the restriction by balance sheet line item.

In the first quarter of 2018, the Company adopted ASU 2014-09, Revenue from Contracts with Customers (Topic 606). The standard is based on the principle that revenue should be recognized to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. Since its initial release, there have been issued several amendments to the standard, which include clarification of accounting guidance related to identification of performance obligations and principal versus agent considerations. Refer to the revenue recognition disclosure above.

Not Yet Adopted Accounting Pronouncements

In June 2018, the FASB issued ASU 2018-07, Stock Compensation (Topic 718): Improvements to Nonemployee Share-based Payment Accounting. The standard expands the scope of ASC 718 to include share-based payments granted to nonemployees in exchange for goods and services. The provisions of this standard are effective for annual periods beginning after December 15, 2018, and for interim periods within those years. Early adoption is permitted. The Company will adopt the standard in the first quarter of 2019 and expect the standard will have no material impact on its financial position or results of operations.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842). The standard requires lessees to recognize right-of-use assets and lease liabilities on the balance sheet for most leases and provide enhanced disclosures. The provisions of this standard are effective for annual periods beginning after December 15, 2018, and for interim periods within those years. Early adoption is permitted. In July 2018, the FASB issued additional guidance for companies to elect transition using either: (i) a modified retrospective approach for leases that exist on adoption and in the comparative periods presented; or (ii) an optional approach to initially apply the new lease guidance on the adoption date, without adjusting the comparative periods presented. The Company plans to elect the optional approach and will adopt the standard beginning in the first quarter of 2019. The Company has completed its assessment of the standard and expects to record a right-of use asset of approximately $16.8 million with a corresponding lease liability of $31.8 million as of January 1, 2019 for its 10-year operating lease agreement for its corporate headquarters, which commenced October 30, 2017.

3. Balance Sheet Details

Inventory, Net

Inventory, net consisted of the following (in thousands):

	December 31, 2018	2017
Work in process	$1,907	$ —
Finished goods	113	—
Total inventory, net	$2,020	$ —

As of December 31, 2018, total inventory is recorded net of $0.8 million of inventory reserves.

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Property and Equipment, Net

Property and equipment, net consisted of the following (in thousands):

	December 31,	
	2018	2017
Lab equipment	$9,047	$7,812
Furniture and fixtures	2,573	2,282
Computer hardware	1,296	1,238
Software	733	619
Leasehold improvements	14,504	14,852
Total property and equipment, gross	28,153	26,803
Accumulated depreciation and amortization	(5,886)	(2,235)
Total property and equipment, net	$22,267	$24,568

Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31,	
	2018	2017
Accrued interest expense	$6,763	$—
Accrued clinical trials	2,430	577
Accrued manufacturing costs	1,823	—
Accrued other	1,972	126
Total accrued expenses	$12,988	$703

4. Company-wide Realignment

On October 18, 2018, the Company effected a Company-wide realignment to increase its efficiency and focus on achieving its corporate goals. For the year ended December 31, 2018, total expenses related to the Company-wide realignment were $4.0 million, with $1.6 million included in research and development expense and $2.4 million included in general and administrative expense. Total expenses were comprised of $7.7 million for severance costs, offset by a $3.7 million reversal of non-cash, stock-based compensation expense related to forfeited, unvested equity awards. The Company expects to make the final payment resulting from the Company-wide realignment in the first quarter of 2019. As of December 31, 2018, the Company has paid $5.4 million of the $7.7 million cash charges, and the remaining $2.3 million of the cash charges were included in accrued payroll and related expenses.

5. Licensed Technology

The George Washington University

In December 2014, the Company entered into a patent license agreement with the George Washington University (GW), which the parties amended and restated on March 1, 2016. Pursuant to this license agreement, GW exclusively licensed to the Company certain intellectual property rights relating to GIAPREZA, including the exclusive rights to certain issued patents and patent applications covering GIAPREZA. Under this license agreement, the Company is obligated to use commercially reasonable efforts to develop, commercialize, market and sell GIAPREZA. The Company has paid a one-time license initiation fee, annual maintenance fees, an amendment fee and additional payments following the achievement of certain development and regulatory milestones including FDA approval. The

Company may be obligated to make additional milestone payments of up to $0.5 million in the aggregate. Following the commencement of commercial sales of GIAPREZA, the Company is obligated to pay tiered royalties in the low- to mid- single digits on products covered by the licensed rights. The patents and patent applications covered by the GW license agreement expire between 2029 and 2038, and the obligation to pay royalties under this agreement extend through the last-to-expire patent covering GIAPREZA.

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Inserm Transfert SA

In February 2014, the Company entered into a license agreement with Inserm Transfert SA (Inserm). Pursuant to this license agreement, Inserm exclusively licensed to the Company certain intellectual property rights relating to LJPC-401. Under this license agreement, the Company has paid a one-time license initiation fee, annual maintenance fees and additional payments following the achievement of certain development milestones. The Company may be obligated to make additional payments of up to $3.7 million upon the achievement of certain development milestones and regulatory approval on products covered by the licensed patent rights. Following the commencement of commercial sales of a product covered by the licensed intellectual property, the Company will be obligated to pay tiered royalties in the low- to mid- single digits on products covered by the licensed rights. The patents and patent applications covered by the Inserm license agreement expire between 2022 and 2038, and the obligation to pay royalties under this agreement extend through the last-to-expire patent covering a licensed product.

Other In-Licensed Technology

The Company continues to seek additional technology for potential new development programs and, as a result, has entered into various licensing agreements for intellectual property rights. The Company has incurred licensing and milestone fees of $0.7 million, $1.6 million and $0.5 million recorded in research and development expense in connection with its licensing agreements for the years ended December 31, 2018, 2017 and 2016, respectively. See Note 11 for future minimum licensing payment commitments.

6. Contract Revenue - Related Party

In 2015, the Company entered into a services agreement with a related party. Pursuant to the services agreement, the Company provides certain services to this related party, including, but not limited to, research and development and clinical study design and management for projects undertaken. In exchange for providing such services, the Company receives payments at a negotiated, arms-length rate. As a result, the consideration received by the Company for its services is considered to be no less favorable to the Company than comparable terms that the Company could obtain from an unaffiliated third party in an arms-length transaction. The services agreement may be canceled by either party upon 60-days’ written notice to the other party.

The Company had no contract revenue during the years ended December 31, 2018 and 2017. During the year ended December 31, 2016, the Company recognized approximately $0.6 million of contract revenue for services provided under the services agreement.

In addition, the Company has a non-voting profit interest in the related party, which provides the Company with the potential to receive a portion of the future distributions of profits, if any. Investment funds affiliated with the Chairman of the Company’s board of directors have a controlling interest in, and the Company’s Chief Executive Officer (CEO) has a non-voting profit interest in, the related party.

7. Shareholders’ Equity

Common Stock

2017 Common Stock Offering

In March 2017, the Company offered and sold an aggregate of 3,731,344 shares of common stock in an underwritten public offering at a price of $33.50 per share for gross proceeds of approximately $125.0 million. The Company received proceeds of approximately $117.5 million, net of approximately $7.5 million in underwriting commissions, discounts and other issuance costs.

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2018 Common Stock Offering

In March 2018, the Company offered and sold an aggregate of 3,910,000 shares of common stock in an underwritten public offering at a price of $29.50 per share for gross proceeds of approximately $115.3 million. The Company received proceeds of approximately $109.8 million, net of approximately $5.5 million in underwriting commissions, discounts and other issuance costs.

Preferred Stock

As of December 31, 2018, the Company is authorized to issue 8,000,000 shares of preferred stock, with a par value of $0.0001 per share, in one or more series, of which 11,000 are designated as Series C-1[2] Convertible Preferred Stock (Series C-1[2] Preferred) and 10,000 are designated as Series F Convertible Preferred Stock (Series F Preferred). The Series C-1[2] Preferred is convertible into common stock at a rate of approximately 1,724 shares of common stock for each share of Series C-1[2] Preferred and the Series F Preferred is convertible into common stock at a rate of approximately 286 shares of common stock for each share of Series F Preferred.

As of December 31, 2018 and 2017, there were 3,906 shares of Series C-1[2] Preferred and 2,737 shares of Series F Preferred issued and outstanding. As such, as of December 31, 2018 and 2017, the issued and outstanding Series C-1[2] Preferred and Series F Preferred were convertible into 6,735,378 and 782,031 shares of common stock, respectively. In January 2019, all of the Series F Preferred was converted into 782,031 shares of common stock by the preferred holder.

The holders of preferred stock do not have voting rights, other than for general protective rights required by the California General Corporation Law. The Series C-1[2] Preferred and the Series F Preferred do not have dividends. The Series C-1[2] Preferred and the Series F Preferred have a liquidation preference in an amount equal to $1,000 per share. As of December 31, 2018 and 2017, the aggregate liquidation preference was approximately $3.9 million and $2.7 million on the Series C-1[2] Preferred and Series F Preferred, respectively.

Share-based Compensation Expense

Stock Options

2013 Equity Incentive Plan

In September 2013, the Company adopted an equity compensation plan entitled the 2013 Equity Incentive Plan (2013 Equity Plan). The 2013 Equity Plan is an omnibus equity compensation plan that permits the issuance of various types of equity-based compensation awards, including stock options, restricted stock awards, stock appreciation rights and restricted stock units, as well as cash awards, to employees, directors and eligible consultants. The 2013 Equity Plan has a 10-year term and permits the issuance of incentive stock options under Section 422 of the Internal Revenue Code of 1986, as amended (IRC). The administrator under the plan has broad discretion to establish the terms of awards, including the size, term, exercise price and vesting conditions. Generally, grants to employees vest over four years, with 25% vesting on the one-year anniversary and the remainder vesting either quarterly or monthly thereafter; grants to non-employee directors generally vest over one year on the one-year anniversary.

At the 2016 and 2017 Annual Meetings of Shareholders, the Company’s shareholders approved and adopted an amendment to the 2013 Equity Plan to increase the number of shares of common stock authorized for issuance up to a total of 4,600,000 and 8,100,000 shares, respectively.

As of December 31, 2018, there were 1,340,450 shares of common stock available for future grants under the 2013 Equity Plan.

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Stock Option Activity

The Company's stock option activity under its option plans was comprised of the following:

	Outstanding Stock Options and 2013 Equity Plan			
	Shares Underlying Stock Options	Weighted-average Exercise Price per Share	Weighted-average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2015	2,318,685	$ 22.01		
Granted	483,200	$ 17.83		
Exercised	(17,548)	$ 8.52		
Forfeited	(156,875)	$ 26.35		
Outstanding at December 31, 2016	2,627,462	$ 21.07		
Granted	3,704,725	$ 25.94		
Exercised	(174,628)	$ 15.42		
Forfeited	(120,257)	$ 22.82		
Outstanding at December 31, 2017	6,037,302	$ 24.19		
Granted	1,978,219	$ 23.66		
Exercised	(106,370)	$ 17.95		
Forfeited	(1,442,937)	$ 28.07		
Outstanding at December 31, 2018	6,466,214	$ 23.26	7.65 years	$ 200,279
Vested and expected to vest at December 31, 2018	6,466,214	$ 23.26	7.65 years	$ 200,279
Exercisable at December 31, 2018	3,118,365	$ 22.61	6.33 years	$ 200,279

The weighted-average grant date fair values of the stock options granted was $20.52, $23.80 and $15.33 per underlying share for the years ended December 31, 2018, 2017 and 2016, respectively. As of December 31, 2018, $64.5 million of total unrecognized share-based compensation expense related to unvested stock options remains and is expected to be recognized over a weighted-average period of approximately 2.8 years. During the years ended December 31, 2018, 2017 and 2016 stock options to purchase 106,370, 174,628 and 17,548 shares of common stock were exercised with an intrinsic value of $1.4 million, $3.3 million and $0.1 million, respectively. The total fair value of equity awards vested during the years ended December 31, 2018, 2017 and 2016 was $38.0 million, $12.1 million and $14.5 million, respectively.

2018 Employee Stock Purchase Plan

In July 2018, the Company's board of directors approved the adoption of the 2018 Employee Stock Purchase Plan (ESPP), which was subsequently adopted and approved by the Company's shareholders at the 2018 Annual Meeting of Shareholders, in order to provide a means for eligible employees to accumulate shares of the Company's common stock over time through regular payroll deductions. Under the ESPP, eligible employees may purchase shares of the Company's common stock twice per month at a price equal to 85% of the closing price of shares of the Company's common stock on the date of each purchase. Eligible employees purchasing shares under the ESPP are subject to an annual cap equal to the lesser of $25,000 or 10% of the employee's annual cash compensation. Shares purchased under the ESPP cannot be sold for a period of one year following the purchase date (or such shorter period of time if the participating employee's employment terminates before this one-year anniversary).

A total of 750,000 shares of common stock have been reserved for issuance under the ESPP. As of December 31, 2018, 717,701 shares of common stock remained available for future grants under the ESPP. During the year ended

December 31, 2018, the Company recorded $0.2 million of stock-based compensation related to the ESPP.

Restricted Stock Award Activity

Restricted stock awards (RSAs) are grants that entitle the holder to acquire shares of common stock for no cash consideration or at a fixed price, which is typically nominal. The Company accounts for RSAs as issued and outstanding common stock, even though: (a) shares covered by an RSA cannot be sold, pledged or otherwise disposed of until the award

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vests; and (b) any unvested shares may be reacquired by the Company for the original purchase price following the awardee's termination of service. The valuation of RSAs is based on the fair market value of the underlying shares on the grant date.

In September 2013, the Company issued RSAs consisting of 1,327,048 shares to its CEO, 79,622 shares to a director and an aggregate of 336,185 shares to three non-officer employees. The RSA grants to the CEO, director and one of the employees were for the replacement of canceled stock options and restricted stock units granted in April 2012, which was done in order to complete the capital restructuring that took place in September 2013. These RSAs were granted outside of the 2013 Equity Plan, but are governed in all respects by the 2013 Equity Plan. These RSAs were granted with a combination of performance-based and time-based vesting components. As of December 31, 2017, all performance-based and time-based vesting conditions had been satisfied. In July 2015, the vesting conditions for 1,042,680 shares of unvested and outstanding RSAs awarded to the CEO were amended to provide that vesting and delivery of the shares were deferred until March 15, 2017, subject to the CEO's continued service with the Company through such date. In December 2016, vesting and delivery was accelerated for 500,000 shares of the RSAs that had been deferred until March 15, 2017. As of December 31, 2017, the remaining 542,680 shares of the RSAs had vested and been delivered.

The Company's RSA activity was comprised of the following:

	Number of Shares	Weighted-average Grant Date Fair Market Value
Unvested at December 31, 2015	1,072,899	$ 13.00
Vested	(530,219)	$ 12.78
Unvested at December 31, 2016	542,680	$ 13.22
Vested	(542,680)	$ 13.22
Unvested at December 31, 2017	—	—

There was no activity for the year ended December 31, 2018.

Stock Option Valuation

The fair value of each stock option award is estimated on the grant date using a Black-Scholes option pricing model (Black-Scholes model), which uses the assumptions noted in the following table. Expected volatility is based on historical volatility of the Company's common stock. In determining the expected life of employee stock options, the Company uses the "simplified" method. The expected life assumptions for non-employees' options are based upon the contractual term of the stock options. The risk-free interest rate is based on the U.S. Treasury yield for a period consistent with the expected term of the stock options in effect at the time of the grants. The dividend yield assumption is based on the expectation of no future dividend payments by the Company.

The Company estimates the fair value of each stock option grant on the grant date using the Black-Scholes model with the following weighted-average assumptions:

	Year Ended December 31,		
	2018	2017	2016
Volatility	114 %	139 %	143 %

Expected life (years)	6.07	6.12	5.80
Risk-free interest rate	2.8 %	2.1 %	1.4 %
Dividend yield	—	—	—

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Share-based Compensation Expense

Total share-based compensation expense related to all share-based awards was comprised of the following (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Research and development	$21,113	$11,980	$5,657
Selling, general and administrative	14,038	9,815	8,889
Total share-based compensation expense	$35,151	$21,795	$14,546

Share-based compensation expense recognized for the years ended December 31, 2018, 2017 and 2016 is reduced by actual forfeitures in the period that the forfeiture occurs.

Third Party Share-based Compensation Expense

The Company initially estimates the fair value of stock options and warrants issued to non-employees, other than non-employee directors, on the grant date using the Black-Scholes model. Thereafter, the Company re-measures the fair value using the Black-Scholes model as of each balance sheet date as the stock options and warrants vest.

In December 2014, the Company granted warrants to purchase 51,000 shares of common stock to two outside third parties at an exercise price equal to the fair market value of the stock on the grant dates. One grant vests 25% on each anniversary date over four years. The other grant vested 100% on the one-year anniversary of the grant. In January 2016, the Company granted a warrant to purchase 17,000 shares of common stock to an outside third party at an exercise price equal to the fair market value of the stock on the date of each grant. The grant vested 100% on the one-year anniversary of the grant. In January 2017, the Company granted a warrant to purchase 25,013 shares of common stock to an outside third party at an exercise price equal to the fair market value of the stock on the date of each grant. The grant vests 100% on the one-year anniversary of the grant.

In March 2018, the Company issued 43,056 shares of common stock in a cashless exercise of 83,013 warrants to a third-party warrant holder. As of December 31, 2018, the Company had outstanding warrants to purchase 10,000 shares of common stock. For the year ended December 31, 2018, the Company did not recognize stock-based compensation expense for these warrant grants. For the years ended December 31, 2017 and 2016, the Company recognized compensation expense for these warrant grants of approximately $0.6 million and $0.2 million, respectively.

In August and November 2015, the Company granted stock options to purchase 50,000 shares of common stock to two consultants at exercise prices equal to the fair market value of the Company’s common stock on the grant dates. These grants were made from the 2013 Equity Plan. The vesting of these stock options was contingent on the achievement of a performance milestone by the end of 2016, at which time any unvested shares underlying the options would be canceled. The milestone was achieved in the fourth quarter of 2016 at a 75% achievement level, with 25% of the options canceling. For the years ended December 31, 2018 and 2017, the Company did not recognize stock-based compensation expense for these stock option grants. For the year ended December 31, 2016, the Company recognized stock-based compensation benefit for these stock option grants of approximately $0.1 million.

In September 2016, the Company granted a stock option to purchase 35,000 shares of common stock to a consultant at an exercise price equal to the fair market value of the Company’s common stock on the grant date. This grant was made from the 2013 Equity Plan. The stock option will vest with respect to 25% of the underlying shares on the

one-year anniversary of the grant, with the remainder to vest monthly over the next three years, subject to continued service during that time. In January 2017, this consultant became an employee of the Company.

In February 2017, the Company granted stock options to purchase 42,000 shares of common stock to three consultants at exercise prices equal to the fair market value of the Company's common stock on the grant dates. These grants were made from the 2013 Equity Plan. Two of the stock options will vest with respect to 25% of the underlying shares on the one-year anniversary of the grant, with the remainder to vest monthly over the next three years, subject to continued service during that time. The other stock option will vest with respect to 25% of the underlying shares on the one-year anniversary of the grant, with the remainder to vest monthly over the next two years, subject to continued service during that time. In addition, an

employee converted to a consultant during April 2017. Two of his options were modified and are continuing to vest over the next two years. The Company recognized third-party compensation expense for these stock option grants of approximately $0.3 million and $0.4 million for the years ended December 31, 2018 and 2017, respectively.

8. Deferred Royalty Obligation

On May 10, 2018, the Company closed a $125.0 million royalty financing agreement (the Royalty Agreement) with HealthCare Royalty Partners (HCR). Under the terms of the Royalty Agreement, the Company received $125.0 million in exchange for tiered royalty payments on worldwide net product sales of GIAPREZA. HCR is entitled to receive quarterly royalties on worldwide net product sales of GIAPREZA beginning April 1, 2018. Quarterly payments to HCR under the Royalty Agreement start at a maximum royalty rate, with step-downs based on the achievement of annual net product sales thresholds. Through December 31, 2021, the royalty rate will be a maximum of 10%. Starting January 1, 2022, the maximum royalty rate may increase by 4% if an agreed-upon, cumulative sales threshold has not been met, and, starting January 1, 2024, the maximum royalty rate may increase by an additional 4% if a different agreed-upon, cumulative sales threshold has not been met. The Royalty Agreement is subject to maximum aggregate royalty payments to HCR of 180% of the $125.0 million to be received by the Company, at which time the payment obligations under the Royalty Agreement would expire. The Royalty Agreement was entered into by the Company’s wholly-owned subsidiary, La Jolla Pharma, LLC, and HCR has no recourse under the Royalty Agreement against La Jolla Pharmaceutical Company or any assets other than GIAPREZA.

On receipt of the $125.0 million payment from HCR, the Company recorded a deferred royalty obligation of $125.0 million, net of issuance costs of $0.7 million. During the year ended December 31, 2018, the Company recognized interest expense, including amortization of the obligation discount, of $7.3 million. The carrying value of the deferred royalty obligation as of December 31, 2018 was $124.3 million, net of an unamortized obligation discount of $0.7 million, and was classified as non-current. Accrued interest expense of $6.8 million is included in accrued expenses in the consolidated balance sheet as of December 31, 2018. For the year ended December 31, 2018, the Company made royalty payments to HCR of $0.5 million, and, as of December 31, 2018, the Company recorded royalty obligations payable of $0.4 million in accrued expenses.

In the event of certain material breaches of the Royalty Agreement, HCR would have the right to terminate the Royalty Agreement and demand payment of an amount equal to either $125.0 million, minus aggregate royalties paid to HCR, or $225.0 million, minus aggregate royalties paid to HCR, depending on the type of breach. The Company concluded that certain of these contract provisions that could result in an acceleration of amounts due under the Royalty Agreement are embedded derivatives that require bifurcation from the deferred royalty obligation and fair value recognition. The Company determined the fair value of each derivative by assessing the probability of each event occurring, as well as the potential repayment amounts and timing of such repayments that would result under various scenarios. As a result of this assessment, the Company determined that the fair value of the embedded derivatives is immaterial as of December 31, 2018. Each reporting period, the Company estimates the fair value of the embedded derivatives until the features lapse and/or the termination of the Royalty Agreement. Any change in the fair value of the embedded derivatives will be recorded as either a gain or loss on the consolidated statements of operations.

9. Defined Contribution Plan

The Company has a defined contribution plan (401(k) Plan) covering substantially all of the Company’s employees. The 401(k) Plan is a tax-qualified retirement saving plan, pursuant to which all employees are able to contribute the lesser of 50% of their annual compensation (as defined) or the limit prescribed by the Internal Revenue Service to the 401(k) Plan on a before-tax basis. The Company matches employee contributions to the 401(k) Plan based on each

participant's contribution during the plan year, up to 3.5% of each participant's annual compensation.

During the years ended December 31, 2018, 2017 and 2016, the Company made matching contributions to the 401(k) Plan of $1.4 million, $0.7 million and $0.4 million, respectively.

10. Income Taxes

The Company did not record a provision for income taxes for the years ended December 2018, 2017 and 2016 due to a full valuation allowance against its deferred tax assets.

On December 22, 2017, the Tax Cuts and Jobs Act (2017 Tax Act) was enacted. The 2017 Tax Act included a number of changes to existing U.S. tax laws that impacted the Company, most notably a reduction of the U.S. corporate tax rate from 34% to 21%, for tax years beginning after December 31, 2017. The 2017 Tax Act also provided for the implementation of a

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territorial tax system, a one-time transition tax on certain foreign earnings, the acceleration of depreciation for certain assets placed into service after September 27, 2017 and other prospective changes beginning in 2018, including repeal of the domestic manufacturing deduction, acceleration of tax revenue recognition, capitalization of research and development expenditures, additional limitations on executive compensation and limitations on the deductibility of interest.

Pursuant to the SEC Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act, the Company had not finalized its accounting for the income tax effects of the 2017 Act for the year ended December 31, 2017, but included a provisional amount related to the re-measurement of deferred tax assets based on the rates at which they were expected to reverse in the future, which is generally 21% plus the applicable state tax rate, with a corresponding change to the valuation allowance as of December 31, 2017. The Company finalized its accounting for the income tax effects of the 2017 Act during the year ended December 31, 2018 and, as such, the Company's financial results reflect the income tax effects of the 2017 Tax Act.

Significant components of the Company's deferred tax assets are as follows (in thousands):

	December 31,	
	2018	2017
Deferred tax assets:		
Deferred royalty obligation	$31,937	$ —
Stock-based compensation	11,904	6,744
Depreciation and amortization	1,033	511
Other	1,004	124
Total gross deferred tax assets	45,878	7,379
Valuation allowance	(45,878)	(7,379)
Net deferred tax assets	$—	$ —

The difference between the provision for income taxes and income taxes computed using the effective U.S. federal statutory rate is as follows (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Federal statutory rate	$(41,888)	$(39,033)	$(26,583)
State tax benefit	(14,449)	—	—
Research and development credits	(5,164)	(2,691)	(1,240)
Foreign rate differential	(58)	1,249	—
Change in valuation allowance	55,167	(35,246)	25,091
Stock-based compensation	4,041	2,253	—
Expired tax attributes	1,936	2,228	(5)
Impact of the 2017 Tax Act	—	71,199	—
Other permanent differences	415	41	2,737
Provision for income taxes	$—	$—	$—

As of December 31, 2018 and 2017, the Company established a full valuation allowance against its federal and state deferred tax assets due to the uncertainty surrounding the realization of such assets.

Pursuant to Section 382 and 383 of the IRC, utilization of the Company's federal net operating loss carryforwards and research and development credit carryforwards may be subject to annual limitations in the event of any significant future changes in its ownership structure. These annual limitations may result in the expiration of net operating loss and research and development credit carryforwards prior to utilization. The Company has not completed an IRC

Section 382 and 383 analysis regarding the limitation of net operating loss and research and development credit carryforwards.

As of December 31, 2018, the Company has estimated federal and state net operating loss carryforwards of approximately $560.2 million and $341.0 million, respectively. The difference between the federal and state tax net operating

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loss carryforwards is primarily attributable to the capitalization of research and development expenses for California income tax purposes. In addition, the Company has estimated federal and California research and development tax credit carryforwards of approximately $24.6 million and $15.4 million, respectively. The federal net operating loss carryforwards, federal research tax credit carryforwards and state net operating loss carryforwards will begin to expire in 2019, if not utilized. California research and development credit carryforwards will carry forward indefinitely until utilized. The Company believes that it experienced ownership changes in May 2010 and February 2009 at times when its enterprise value was minimal. As a result of the ownership changes and low enterprise values at such times, the Company's federal and California net operating loss carryforwards and federal research and development credit carryforwards as of December 31, 2017 will likely be subject to annual limitations under IRC Section 382 and 383 and, more likely than not, will expire unused.

There were no unrecognized tax benefits as of the December 31, 2018 and 2017. The Company does not anticipate there will be a significant change in unrecognized tax benefits within the next 12 months.

The Company had no accrual for interest or penalties on the Company's consolidated balance sheets as of December 31, 2018 or December 31, 2017, and has not recognized interest and/or penalties in the consolidated statements of operations for the years ended December 31, 2018, 2017 and 2016.

The Company is subject to taxation in the U.S. and various state jurisdictions. The Company's tax returns since inception are subject to examination by the U.S. and various state tax authorities. The Company is not currently undergoing a tax audit in any federal or state jurisdiction.

11. Commitments and Contingencies

Leases
On December 29, 2016, the Company entered into an agreement with BMR-Axiom LP to lease office and laboratory space as its new corporate headquarters located at 4550 Towne Centre Court, San Diego, California (Lease) for a period of 10 years commencing on October 30, 2017.

The Lease provides an option to extend the Lease for an additional 5.0 years at the end of the initial term. The Company provided a standby letter of credit for $0.9 million in lieu of a security deposit. This amount will decrease to $0.6 million after year two of the lease and decrease to $0.3 million after year 5 of the lease term. As of December 31, 2018, $0.9 million was pledged as collateral for such letter of credit and recorded as restricted cash. The Lease provided an allowance for tenant improvements of $13.7 million, which was classified as deferred rent on the Company's consolidated balance sheet and is being amortized as an offset to rent expense with a corresponding charge to depreciation expense on a straight-line basis over the term of the lease. The annual rent under the Lease is subject to escalation during the term. In addition to rent, the Lease requires the Company to pay certain taxes, insurance and operating costs relating to the leased premises. The Lease contains customary default provisions, representations, warranties and covenants.

Annual future minimum payments under operating leases as of December 31, 2018 are as follows (in thousands):

2019	$3,951
2020	4,070
2021	4,192
2022	4,318
2023	4,447
Thereafter	18,308
Total future minimum lease payments	$39,286

Rent expense was $2.8 million, $1.7 million and $1.1 million for the years ended December 31, 2018, 2017 and 2016, respectively.

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Licensing Agreements

In the normal course of business, the Company enters into licensing agreements under which the Company commits to certain annual maintenance payments. Annual future minimum licensing payments under the Company's agreements as of December 31, 2018 are as follows (in thousands):

2019	$120
2020	120
2021	120
2022	120
2023	120
Total future minimum license payments	$600

Supply Agreements

In the normal course of business, the Company enters into agreements for the manufacturing and supply of its clinical and commercial products. In 2017, the Company entered into agreements arranging for the manufacture and supply of GIAPREZA through 2022. During this time, the Company is obligated to make certain minimum purchases. Annual future minimum payments for manufacturing and supply agreements as of December 31, 2018 are as follows (in thousands):

2019	$2,759
2020	2,759
2021	2,759
Total future minimum manufacturing and supply agreement payments	$8,277