ORAMED PHARMACEUTICALS INC.
Form 424B3
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PROSPECTUS

ORAMED PHARMACEUTICALS INC.

45,521,111 SHARES OF COMMON STOCK

The selling stockholders identified in this prospectus may offer from time to time up to 39,174,923 shares of our common stock and 6,346,188 shares of our common stock issuable upon exercise of warrants and options.

This prospectus describes the general manner in which the shares may be offered and sold by the selling stockholders. If necessary, the specific manner in which the shares may be offered and sold will be described in a supplement to this prospectus.

While we will not receive any proceeds from the sale of the shares by the selling stockholders, we will receive cash proceeds equal to the total exercise price of any warrants or options that are exercised for cash.

Our common stock is quoted on the OTC Bulletin Board, or the OTCBB, under the symbol “ORMP.OB”. On June 28, 2011, the last reported bid price per share of our common stock as quoted on the OTCBB was $0.32 per share.

Investing in the shares involves risks. You should carefully read the “Risk Factors” beginning on page 6 of this prospectus before investing.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is July 11, 2011.

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You should rely only on the information contained in this prospectus. Neither we nor the selling stockholders have authorized any dealer, salesperson or other person to give any information or to make any representations to you other than the information contained in this prospectus. You must not rely on any information or representations not contained in this prospectus as if we had authorized it. The information contained in this prospectus is current only as of the date on the cover page of this prospectus and may change after that date. We do not imply that there has been no change in the information contained in this prospectus or in our affairs since that date by delivering this prospectus. Neither we nor the selling stockholders are making an offer of these securities in any state where the offer

is not permitted.

As used in this prospectus, the terms “we”, “us”, “our”, the “Company”, “Oramed” and “Oramed Pharmaceuticals” mean Oram
Pharmaceuticals Inc., unless otherwise indicated.

All dollar amounts refer to U.S. dollars unless otherwise indicated.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. Before making an investment decision, you should read the entire prospectus carefully, including the section entitled “Risk Factors”.

THE COMPANY

General

We are a pharmaceutical company engaged in the research and development of innovative pharmaceutical solutions, including an orally ingestible insulin capsule or tablet to be used for the treatment of individuals with diabetes, and the use of orally ingestible capsules, tablets or pills for delivery of other polypeptides.

Oral Insulin: We are seeking to revolutionize the treatment of diabetes through our proprietary flagship product, an orally ingestible insulin capsule (ORMD0801). Our technology allows insulin to travel from the gastrointestinal tract via the portal vein to the bloodstream, revolutionizing the manner in which insulin is delivered. It enables its passage in a more physiological manner than current delivery methods of insulin.

Our technology is a platform that has the potential to deliver medications and vaccines orally that today can only be delivered via injection.

Diabetes: Diabetes is a disease in which the body does not produce or properly use insulin. Insulin is a hormone that causes sugar to be absorbed into cells, where the sugar is converted into energy needed for daily life.

Intellectual Property: We own a portfolio of patents and patent applications covering our technologies and we are aggressively protecting these technology developments on a worldwide basis.

Management: We are led by a highly-experienced management team knowledgeable in the treatment of diabetes. Our Chief Medical and Technology Officer, Miriam Kidron, PhD, is a world-recognized pharmacologist and a biochemist and the innovator primarily responsible for our oral insulin technology development and know-how.

Scientific Advisory Board: Our management team has access to our internationally recognized Scientific Advisory Board whose members are thought-leaders in their respective areas. The Advisory Board is comprised of Dr. Nir Barzilai, Professor Ele Ferrannini, Professor Avram Hershko, Dr. Derek LeRoith, Dr. John Amatruda and Dr. Michael Berelowitz as Chairman.

Strategy

We plan to conduct further research and development on the technology covered by the patent application "Methods and Composition for Oral Administration of Proteins", which we acquired from Hadasit, as well as the other patents we have filed since. Through our research and development efforts, we are seeking to develop an oral dosage form that will withstand the harsh chemical environment of the stomach or intestines and will be effective in delivering active insulin for the treatment of diabetes. The proteins and vehicles that are added to the insulin in the formulation process must not modify chemically or biologically the insulin and the dosage form must be safe to ingest. We plan to continue to conduct clinical trials to show the effectiveness of our technology. We intend to conduct the clinical trials necessary to file an Investigational New Drug (“IND”)

application with the U.S. Food and Drug Administration (the "FDA"). We also plan to conduct further research and development by deploying our proprietary drug delivery technology for the delivery of other polypeptides in addition to insulin, and to develop other innovative pharmaceutical products.

If our oral insulin capsule or other drug delivery solutions show significant promise in clinical trials, we plan to ultimately seek a strategic commercial partner, or partners, with extensive experience in the development, commercialization, and marketing of insulin applications and/or other orally digestible drugs. We anticipate such partner or partners would be responsible for, or substantially support, late stage clinical trials (Phase III) to increase the likelihood of obtaining regulatory approvals and registrations in the appropriate markets in a timely manner. We further anticipate that such partner, or partners, would also be responsible for sales and marketing of our oral insulin capsule in these markets. Such planned strategic partnership, or partnerships, may provide a marketing and sales infrastructure for our products as well as financial and operational support for global clinical trials, post marketing studies, label expansions and other regulatory requirements concerning future clinical development in the United States and elsewhere. Any future strategic partner, or partners, may also provide capital and expertise that would enable the partnership to develop new oral dosage form for other polypeptides. While our strategy is to partner with an appropriate party, no assurance can be given that any third party would be interested in partnering with us. Under certain circumstances, we may determine to develop one or more of our oral dosage form on our own, either world-wide or in select territories.

In addition to developing our own oral dosage form drug portfolio, we are, on an on-going basis, considering in-licensing and other means of obtaining additional technologies to complement and/or expand our current product portfolio. Our goal is to create a well-balanced product portfolio that will enhance and complement our existing drug portfolio.

Product Development

Orally Ingestible Insulin: During fiscal year 2007 we conducted several clinical studies of our orally ingestible insulin. The studies were intended to assess both the safety/tolerability and absorption properties of our proprietary oral insulin. Based on the pharmacokinetic and pharmacologic outcomes of these trials, we decided to continue the development of our oral insulin product.

On November 15, 2007, we successfully completed animal studies in preparation for the Phase 1B clinical trial of our oral insulin capsule (ORMD0801). On January 22, 2008, we commenced non-FDA approved Phase 1B clinical trials with our oral insulin capsule (ORMD0801), in healthy human volunteers with the intent of dose optimization. On March 11, 2008, we successfully completed our Phase 1B clinical trials.

On April 13, 2008, we commenced a non-FDA approved Phase 2A study to evaluate the safety and efficacy of our oral insulin capsule (ORMD0801) in type 2 diabetic volunteers at Hadassah Medical Center in Jerusalem. On August 6, 2008, we announced the successful results of this trial.

In July 2008 we were granted approval by the Institutional Review Board Committee of Hadassah Medical Center in Jerusalem to conduct a non-FDA approved Phase 2A study to evaluate the safety and efficacy of our oral insulin capsule (ORMD0801) on type 1 diabetic volunteers. On September 24, 2008, we announced the beginning of this trial. On July 21, 2009 we reported positive results from this trial.

On September 14, 2010, we reported the successful results of an exploratory clinical trial testing the effectiveness of our oral insulin capsule (ORMD0801) in type 1 diabetes patients suffering from uncontrolled diabetes. Unstable or labile diabetes is characterized by recurrent, unpredictable and dramatic blood glucose swings often linked with irregular hyperglycemia and sometimes serious hypoglycemia affecting type 1 diabetes patients. This newly completed exploratory study was a proof of concept study for defining a novel indication for ORMD0801. We believe the encouraging results justify further clinical development of ORMD0801 capsule application toward management of uncontrolled diabetes.

On February 10, 2010, we entered into agreements with Vetgenerics Research G. Ziv Ltd., a clinical research organization (CRO), to conduct a toxicology trial on our oral insulin capsules. On March 23, 2011, we reported that we successfully completed the resulting comprehensive toxicity study for our oral insulin capsule (ORMD0801).

On April 21, 2009, we entered into a consulting service agreement with ADRES Advanced Regulatory Services Ltd. (“ADRES”), pursuant to which ADRES will provide services for the purpose of filing an IND application with the FDA for a Phase 2 study according to the FDA requirements. The FDA approval process and, if approved, registration for commercial use as an oral drug can take several years.

In May 2009, we commenced a non-FDA approved Phase 2B study in South Africa to evaluate the safety, tolerability and efficacy of our oral insulin capsule (ORMD0801) on type 2 diabetic volunteers. On May 6, 2010, we reported that the capsule was found to be well tolerated and exhibited a positive safety profile. No

cumulative adverse effects were reported throughout this first study of extended exposure to the capsule.

GLP-1 Analog: On September 16, 2008 we announced the launch of pre-clinical trials of ORMD0901, a GLP-1 analog. The pre-clinical trials include animal studies which suggest that the GLP-1analog (exenatide -4) when combined with Oramed's absorption promoters is absorbed through the gastrointestinal tract and retains its biological activity.

On September 9, 2009, we received approval from the Institutional Review Board (IRB) in Israel to commence human clinical trials of an oral GLP-1 Analog. The approval was granted after successful pre-clinical results were reported. The trials are being conducted on healthy volunteers at Hadassah University Medical Center in Jerusalem. We anticipate that the results of these trials will be released in the near future.

Raw Materials: Our oral insulin capsule is currently manufactured by Swiss Caps AG, under a Clinical Trail Manufacturing Agreement.

On July 5, 2010, our subsidiary entered into a Manufacturing Supply Agreement (MSA) with Sanofi-Aventis Deutschland GMBH ("sanofi-aventis"). According to the MSA, sanofi-aventis will supply our subsidiary with specified quantities of recombinant human insulin to be used for clinical trials in the United States.

The raw materials required for the manufacturing of the capsule are purchased from third parties, under separate agreements. We generally depend upon a limited number of suppliers for the raw materials. Although alternative sources of supply for these materials are generally available, we could incur significant costs and disruptions in changing suppliers. The termination of our relationships with our suppliers or the failure of these suppliers to meet our requirements for raw materials on a timely and cost-effective basis could materially adversely affect our business, prospects, financial condition and results of operations.

Recent Business Developments

On December 23, 2010, our wholly owned Israeli subsidiary, Oramed Ltd., was awarded a government grant amounting to a total net amount of NIS 2.9 million (approximately $807,000), from the Office of the Chief Scientist of the Ministry of Industry, Trade and Labor of Israel (the "OCS"), which was designated for research and development expenses for the period of July 2010 to June 2011. We used these funds to support further research and development and clinical study of our oral insulin capsule and Oral GLP1-analog.

On June 1, 2010, our subsidiary, Oramed Ltd., entered into a joint venture agreement with D.N.A Biomedical Solutions Ltd. (formerly Laser Detect Systems Ltd), an Israeli company listed on the Tel Aviv Stock Exchange ("D.N.A"), for the establishment of a new company to be called Entera Bio Ltd. ("Entera").

Under the terms of a license agreement that was entered into between Oramed and Entera in August 2010, we out-licensed technology to Entera, on an exclusive basis, for the development of oral delivery drugs for certain indications to be agreed upon between the parties. The out-licensed technology differs from our main delivery technology that is used for oral insulin and GLP 1 analog and is subject to different patent applications. Entera's initial development effort is for an oral formulation for the treatment of osteoporosis.

On March 31, 2011, we consummated a transaction with D.N.A, whereby we sold to D.N.A 47% of Entera's outstanding share capital on an undiluted basis. We retained 3% of the Entera's outstanding share capital on an undiluted basis. As consideration for the Entera shares, Oramed received a promissory note issued by D.N.A in the principal amount of $450,000, with an annual interest rate of 0.45%, to be paid within four months from closing, and 8,404,667 ordinary shares of D.N.A, having an aggregate market value of approximately

$700,000. In addition, D.N.A invested $250,000 in our private placement in March 2011, for which it received 781,250 shares of our common stock and five-year warrants to purchase 273,438 shares of common stock at an exercise price of $0.50 per share.

As part of the transaction, we entered into a patent transfer agreement (which replaced the original license agreement) according to which, Oramed assigned to Entera all of its right, title and interest in and to the patent application that it had licensed to Entera in August 2010. Under this agreement, Oramed Ltd. is entitled to receive from Entera royalties of 3% of Entera's net revenues (as defined in the agreement) and a license back of that patent application for use in respect of diabetes and influenza

In March, 2011, we consummated a private placement that commenced in November 2010, with a number of accredited investors pursuant to which we agreed to sell to the investors an aggregate of 10,487,500 units at a purchase price of $0.32 per unit for total consideration of $3,356,000. Each unit consisted of one share of common stock and a five-year warrant to purchase 0.35 shares of common stock at an exercise price of $0.50 per share. We also issued 196,750 shares of common stock and warrants to purchase 70,863 shares of common stock as finders' fees in connection with the private placement. These amounts include the $250,000 investment by D.N.A made in connection with our technology transaction which closed on March 31, 2011.

In April 2011, we consummated a private placement with a number of “accredited investors” as defined in Rule 501(a) of Regulation D, pursuant to which we agreed to sell to the investors an aggregate of 1,124,375 units at a purchase price of $0.32 per unit for total consideration of $359,800. Each unit consisted of one share of common stock and a five-year warrant to purchase 0.35 of a share of common stock at an exercise price of $0.50 per Share.

THE OFFERING

Issuer	Oramed Pharmaceuticals Inc. Hi-Tech Park 2/5 Givat-Ram, PO Box 39098 Jerusalem 91390, Israel Telephone: 972-2-566-0001
Securities offered by the Selling Stockholders	39,174,923 shares of common stock and 6,346,188 shares of common stock issuable upon exercise of warrants and options.
Trading Market	The common stock offered in this prospectus is quoted on the OTCBB under the symbol “ORMP.OB”.
Common stock outstanding (as of June 29, 2011)	70,104,583 shares1.
Use of Proceeds	We will not receive any of the proceeds from the sale of the shares of our common stock being offered for sale by the selling stockholders. However, we may receive up to approximately $3.2 million in proceeds upon exercise of the warrants and options held by the selling stockholders, as the warrants and options have an average exercise price of $0.50 per share and are exercisable into 6,346,188 shares of our common stock. These potential proceeds will be used for the research and development of our products and for general working capital purposes. See “Use of Proceeds.”
Plan of Distribution	The selling stockholders, and their pledgees, donees, transferees or other successors in interest, may from time to time offer and sell, separately or together, some or all of the common stock covered by this prospectus. Registration of the common stock covered by this prospectus does not mean, however, that those shares necessarily will be offered or sold. See “Plan of Distribution.”
Risk Factors	Please read “Risk Factors” and other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in the securities offered in this prospectus.

1 Does not include 21,469,919 shares of our common stock issuable upon the exercise of outstanding options and warrants.

RISK FACTORS

An investment in our securities involves a high degree of risk. You should consider carefully the following information about these risks, together with the other information contained in this prospectus before making an investment decision. Our business, prospects, financial condition, and results of operations may be materially and adversely affected as a result of any of the following risks. The value of our securities could decline as a result of any of these risks. You could lose all or part of your investment in our securities. Some of the statements in "Risk Factors" are forward looking statements.

Risks Related to Our Business

There is substantial doubt as to our ability to continue as a going concern.

Our financial statements were prepared on the assumption that we will continue as a going concern. We estimate that our cash reserves will not be sufficient to permit us to continue at our anticipated level of operations for our fiscal year ending August 31, 2012. During 2011, we plan to increase research and development, product development, and administrative expenses relating to our business, including expenses related to research and development related to our oral delivery platform. We intend to use our cash reserves, as well as other funds in the event that they shall become available on commercially reasonable terms, to finance these activities and other activities described herein, although we can provide no assurance that these additional funds will be available in the amounts or at the times we may require. If sufficient capital is not available, we would likely be required to scale back or terminate our research and development efforts. See "Risk Factors -- We will need substantial additional capital in order to satisfy our business objectives."

We will need substantial additional capital in order to satisfy our business objectives.

To date, we have financed our operations principally through offerings of securities exempt from the registration requirements of the Securities Act. We believe that our available resources and cash flow will be sufficient to meet our anticipated working capital needs for a minimum of six months from the date of this prospectus. We estimate that we will require substantial additional financing at various intervals in order to continue our research and development programs, including significant requirements for operating expenses including intellectual property protection and enforcement, for pursuit of regulatory approvals, and for commercialization of our products. We can provide no assurance that additional funding will be available on a timely basis, on terms acceptable to us, or at all. In the event that we are unable to obtain such financing, we will not be able to fully develop and commercialize our technology. Our future capital requirements will depend upon many factors, including:

- continued scientific progress in our research and development programs;
- costs and timing of conducting clinical trials and seeking regulatory approvals and patent prosecutions;
- competing technological and market developments;
- our ability to establish additional collaborative relationships; and
- effects of commercialization activities and facility expansions if and as required.

If we cannot secure adequate financing when needed, we may be required to delay, scale back or eliminate one or more of our research and development programs or to enter into license or other arrangements with third parties to commercialize products or technologies that we would otherwise seek to develop ourselves and commercialize

ourselves. In such event, our business, prospects, financial condition, and results of operations may be adversely affected as we may be required to scale-back, eliminate, or delay development efforts or product introductions or enter into royalty, sales or other agreements with third parties in order to commercialize our products.

We are a development stage company with a history of losses and can provide no assurance as to our future operating results.

We are a development stage company with no revenues from our research and development activities. Consequently, we have incurred net losses and negative cash flows since inception. We currently have no product revenues, and may not succeed in developing or commercializing any products which could generate product or licensing revenues. We do not expect to have any products on the market for several years. In addition, development of our product candidates requires a process of pre-clinical and clinical testing, during which our products could fail. We may not be able to enter into agreements with one or more companies experienced in the manufacturing and marketing of therapeutic drugs and, to the extent that we are unable to do so, we will not be able to market our product candidates. Eventual profitability will depend on our success in developing, manufacturing, and marketing our product candidates. As of February 28, 2011 and August 31, 2010 and 2009, we had working capital of $3.3 million, $0.9 million and $2.8 million, respectively, and stockholders' equity of $3.2 million , $0.8 million and $2.7 million, respectively. We have generated no revenues to date. For the period from our inception on April 12, 2002 through February 28, 2011, the six month period ended February 28, 2011and the year ended August 31, 2010, we incurred net losses of $14.2 million, $1.2 million, and $3.0 million, respectively. We may never achieve profitability and expect to incur net losses in the foreseeable future. See "Management's Discussion and Analysis of Financial Condition and Results of Operations."

We rely upon patents to protect our technology. We may be unable to protect our intellectual property rights and we may be liable for infringing the intellectual property rights of others.

Our ability to compete effectively will depend on our ability to maintain the proprietary nature of our technologies. We currently hold several pending patent applications in the United States for our technologies covering oral administration of insulin and other proteins and oral administration of exenatides and proteins, and corresponding patent applications filed in Israel, South Africa and India. Further, we intend to rely on a combination of trade secrets and non-disclosure, and other contractual agreements and technical measures to protect our rights in our technology. We intend to depend upon confidentiality agreements with our officers, directors, employees, consultants, and subcontractors, as well as collaborative partners, to maintain the proprietary nature of our technology. These measures may not afford us sufficient or complete protection, and others may independently develop technology similar to ours, otherwise avoid our confidentiality agreements, or produce patents that would materially and adversely affect our business, prospects, financial condition, and results of operations. We believe that our technology is not subject to any infringement actions based upon the patents of any third parties; however, our technology may in the future be found to infringe upon the rights of others. Others may assert infringement claims against us, and if we should be found to infringe upon their patents, or otherwise impermissibly utilize their intellectual property, our ability to continue to use our technology could be materially restricted or prohibited. If this event occurs, we may be required to obtain licenses from the holders of this intellectual property, enter into royalty agreements, or redesign our products so as not to utilize this intellectual property, each of which may prove to be uneconomical or otherwise impossible. Licenses or royalty agreements required in order for us to use this technology may not be available on terms acceptable to us, or at all. These claims could result in litigation, which could materially adversely affect our business, prospects, financial condition, and results of operations.

The patent position of biopharmaceutical and biotechnology firms is generally uncertain and involves complex legal and factual questions. We do not know whether any of our current or future patent applications will result in the issuance of any patents. Even issued patents may be challenged, invalidated or circumvented. Patents may not provide a competitive advantage or afford protection against competitors with similar technology. Competitors or potential competitors may have filed applications for, or may have received patents and may obtain additional and proprietary rights to compounds or processes used by or competitive with ours. In addition, laws of certain foreign countries do not protect intellectual property rights to the same extent as do the laws of the United States.

Patent litigation is becoming widespread in the biopharmaceutical and biotechnology industry and we cannot predict how this will affect our efforts to form strategic alliances, conduct clinical testing or manufacture and market any products under development. If challenged, our patents may not be held valid. We could also become involved in interference proceedings in connection with one or more of our patents or patent applications to determine priority of invention. If we become involved in any litigation, interference or other administrative proceedings, we will likely incur substantial expenses and the efforts of our technical and management personnel will be significantly diverted. In addition, an adverse determination could subject us to significant liabilities or require us to seek licenses that may not be available on favorable terms, if at all. We may be restricted or prevented from manufacturing and selling our products in the event of an adverse determination in a judicial or administrative proceeding or if we fail to obtain necessary licenses.

Our commercial success will also depend significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Patent applications are, in many cases, maintained in secrecy until patents are issued. The publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made and patent applications are filed. In the event of infringement or violation of another party's patent, we may be prevented from pursuing product development or commercialization. See “Business—Patents and Licenses.”

At present, our success depends primarily on the successful commercialization of our oral insulin capsule.

The successful commercialization of oral insulin capsule is crucial for our success. At present, our principal product is the oral insulin capsule. Our oral insulin capsule is in a very early stage of clinical development and faces a variety of risks and uncertainties. Principally, these risks include the following:

- future clinical trial results may show that the oral insulin capsule is not well tolerated by recipients at its effective doses or is not efficacious as compared to placebo;

- future clinical trial results may be inconsistent with previous preliminary testing results and data from our earlier studies may be inconsistent with clinical data;

- even if our oral insulin capsule is shown to be safe and effective for its intended purposes, we may face significant or unforeseen difficulties in obtaining or manufacturing sufficient quantities or at reasonable prices;

- our ability to complete the development and commercialization of the oral insulin capsule for our intended use is significantly dependent upon our ability to obtain and maintain experienced and committed partners to assist us with obtaining clinical and regulatory approvals for, and the manufacturing, marketing and distribution of, the oral insulin capsule on a worldwide basis;

- even if our oral insulin capsule is successfully developed, commercially produced and receive all necessary regulatory approvals, there is no guarantee that there will be market acceptance of the products; and

- our competitors may develop therapeutics or other treatments which are superior or less costly than our own with the result that our products, even if they are successfully developed, manufactured and approved, may not generate significant revenues.

If we are unsuccessful in dealing with any of these risks, or if we are unable to successfully commercialize our oral insulin capsule for some other reason, it would likely seriously harm our business.

We have limited experience in conducting clinical trials.

Clinical trials must meet FDA and foreign regulatory requirements. We have limited experience in designing, conducting and managing the preclinical studies and clinical trials necessary to obtain regulatory approval for our product candidates in any country. We have entered into agreements with Hadasit Medical Center, ETI Karle Clinical Pvt, Ltd., and OnQ Consulting to assist us in designing, conducting and managing our various clinical trials in Israel, South Africa, and India, respectively, as more fully described in “Our Business – Partnerships and Collaborative Agreements.” Any failure of such consultants to fulfill their obligations could result in significant additional costs as well as delays in designing, consulting and completing clinical trials on our products.

Notwithstanding the assistance of such consultants, we may encounter problems in clinical trials that may cause us or the FDA or foreign regulatory agencies to delay, suspend or terminate our clinical trials at any phase. These problems could include the possibility that we may not be able to conduct clinical trials at our preferred sites, enroll a sufficient number of patients for our clinical trials at one or more sites or begin or successfully complete clinical trials in a timely fashion, if at all. Furthermore, we, the FDA or foreign regulatory agencies may suspend clinical trials at any time if we or they believe the subjects participating in the trials are being exposed to unacceptable health risks or if we or they find deficiencies in the clinical trial process or conduct of the investigation. If clinical trials of any of the product candidates fail, we will not be able to market the product candidate which is the subject of the failed clinical trials. The FDA and foreign regulatory agencies could also require additional clinical trials, which would result in

increased costs and significant development delays. Our failure to adequately demonstrate the safety and effectiveness of a pharmaceutical product candidate under development could delay or prevent regulatory approval of the product candidate and could have a material adverse effect on our business, prospects, financial condition, and results of operations.

We can provide no assurance that our products will obtain regulatory approval or that the results of clinical studies will be favorable.

The testing, marketing and manufacturing of any of our products will require the approval of the FDA or regulatory agencies of other countries. We have completed certain non-FDA clinical trials and pre-clinical trials for our products but have yet to conduct any FDA approved trials. We have retained Advanced Regulatory Services Ltd. to assist us in the preparation of an IND Application with the FDA to conduct an FDA approved Phase 2 study on our oral insulin capsule product but no application has yet been filed.

We cannot predict with any certainty the amount of time necessary to obtain regulatory approvals, including from the FDA or other foreign regulatory authorities, and whether any such approvals will ultimately be granted. In any event, review and approval by the regulatory bodies is anticipated to take a number of years. Preclinical and clinical trials may reveal that one or more of our products are ineffective or unsafe, in which event further development of such products could be seriously delayed or terminated. Moreover, obtaining approval for certain products may require the testing on human subjects of substances whose effects on humans are not fully understood or documented. Delays in obtaining necessary regulatory approvals of any proposed product and failure to receive such approvals would have an adverse effect on the product's potential commercial success and on our business, prospects, financial condition, and results of operations. In addition, it is possible that a product may be found to be ineffective or unsafe due to conditions or facts which arise after development has been completed and regulatory approvals have been obtained. In this event we may be required to withdraw such product from the market. See "Our Business – Governmental Regulation."

We are dependent upon third party suppliers of our raw materials.

We are dependent on outside vendors for our entire supply of the oral insulin capsule. While we believe that there are numerous sources of supply available, if the third party suppliers were to cease production or otherwise fail to supply us with quality raw materials in sufficient quantities on a timely basis and we were unable to contract on acceptable terms for these services with alternative suppliers, our ability to produce our products and to conduct testing and clinical trials would be materially adversely affected.

We are highly dependent upon our ability to enter into agreements with collaborative partners to develop, commercialize, and market our products.

Our long-term strategy is to ultimately seek a strategic commercial partner, or partners, such as large pharmaceutical companies, with extensive experience in the development, commercialization, and marketing of insulin applications and/or other orally digestible drugs. We anticipate such partner or partners would be responsible for, or substantially support, late stage clinical trials (Phase III) and sales and marketing of our oral insulin capsule and other products. Such planned strategic partnership, or partnerships, may provide a marketing and sales infrastructure for our products as well as financial and operational support for global clinical trials, post marketing studies, label expansions and other regulatory requirements concerning future clinical development in the United States and elsewhere.

While our strategy is to partner with an appropriate party, no assurance can be given that any third party would be interested in partnering with us. We currently lack the resources to manufacture any of our product candidates on a large scale and we have no sales, marketing or distribution capabilities. In the event we are not able to enter into a collaborative agreement with a partner or partners, on commercially reasonable terms, or at all, we may be unable to commercialize our products, which would have a material adverse effect upon our business, prospects, financial condition, and results of operations.

The biotechnology and biopharmaceutical industries are characterized by rapid technological developments and a high degree of competition. We may be unable to compete with more substantial enterprises.

The biotechnology and biopharmaceutical industries are characterized by rapid technological developments and a high degree of competition. As a result, our products could become obsolete before we recoup any portion of our related research and development and commercialization expenses. These industries are highly competitive, and this competition comes both from biotechnology firms and from major pharmaceutical and chemical companies. Many of these companies have substantially greater financial, marketing, and human resources than we do (including, in some cases, substantially greater experience in clinical testing, manufacturing, and marketing of pharmaceutical products). We also experience competition in the development of our products from universities and other research

institutions and compete with others in acquiring technology from such universities and institutions. In addition, certain of our products may be subject to competition from products developed using other technologies. See “Our Business – Competition”.

We have limited senior management resources and may be required to obtain more resources to manage our growth.

We expect the expansion of our business to place a significant strain on our limited managerial, operational, and financial resources. We will be required to expand our operational and financial systems significantly and to expand, train, and manage our work force in order to manage the expansion of our operations. Our failure to fully integrate our new employees into our operations could have a material adverse effect on our business, prospects, financial condition, and results of operations. Our ability to attract and retain highly skilled personnel is critical to our operations and expansion. We face competition for these types of personnel from other technology companies and more established organizations, many of which have significantly larger operations and greater financial, technical, human, and other resources than we have. We may not be successful in attracting and retaining qualified personnel on a timely basis, on competitive terms, or at all. If we are not successful in attracting and retaining these personnel, our business, prospects, financial condition, and results of operations will be materially adversely affected. See "Management's Discussion and Analysis of Financial Condition and Results of Operations," "Our Business – Strategy" and "Business—Employees."

We depend upon our senior management and skilled personnel and their loss or unavailability could put us at a competitive disadvantage.

We currently depend upon the efforts and abilities of our senior executives, as well as the services of several key consultants and other key personnel, including Dr. Miriam Kidron, our Chief Medical and Technology Officer. The loss or unavailability of the services of any of these individuals for any significant period of time could have a material adverse effect on our business, prospects, financial condition, and results of operations. We do not maintain "keyman" life insurance policies for any of our senior executives. In addition, recruiting and retaining qualified scientific personnel to perform future research and development work will be critical to our success. There is currently a shortage of employees with expertise in developing, manufacturing and commercialization of products and related clinical and regulatory affairs, and this shortage is likely to continue. Competition for skilled personnel is intense and turnover rates are high. Our ability to attract and retain qualified personnel may be limited. Our inability to attract and retain qualified skilled personnel would have a material adverse effect on our business, prospects, financial condition, and results of operations.

Fulfilling our obligations incident to being a public company will be expensive and time consuming.

As a public company, the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the SEC, requires us to implement additional corporate governance practices and adhere to a variety of reporting requirements and complex accounting rules. Compliance with these public company obligations increases our legal and financial compliance costs and place significant additional demands on our finance and accounting staff and on our financial, accounting and information systems.

We became a publicly traded company through the acquisition of a public shell company, and we could be liable for unanticipated claims or liabilities as a result thereof.

We were originally incorporated on April 12, 2002 as an exploration stage company engaged in the acquisition and exploration of mineral properties. We were unsuccessful in implementing its business plan as a mineral exploration company and became a public shell company. On May 27, 2004, we executed a share exchange with the shareholders of Integrated Security Technologies, Inc., a New Jersey private corporation ("ISTI"). However, due to disappointing results, on May 31, 2005, effective as of May 27, 2004 we terminated the share exchange agreement with the shareholders of ISTI, and we again became a public shell company. We remained a public shell company until March 8, 2006, when we became a pharmaceutical company engaged in the development of innovative pharmacological solutions.

We face substantial risks associated with being a former public shell company, including absence of accurate or adequate public information concerning the public shell company; undisclosed liabilities; improper accounting; claims or litigation from former officers, directors, employees or stockholders; contractual obligations; and regulatory requirements. Although management performed due diligence on us, there can be no assurance that such risks do not occur. The occurrence of any such risk could materially adversely affect our financial condition.

Entera Bio Ltd. will require additional funding and may not be successful.

As of March 31, 2011, we held approximately 3% of Entera's outstanding shares and are entitled to receive royalties in the amount of 3% of Entera's net revenues (as defined in our patent transfer agreement). Entera will have to raise large amounts of capital to fund its operations, and it may not be able to raise sufficient amounts. Our ownership stake will be diluted if Entera raises funds from third parties. There can be no assurance that Entera’s operations will ever result in profits that are distributed to us as shareholders or in net revenues requiring that royalties be paid to us under the terms of our patent transfer agreement.

Healthcare policy changes, including pending proposals to reform the U.S. healthcare system, may harm our future business.

Healthcare costs have risen significantly over the past decade. There have been and continue to be proposals by legislators, regulators and third-party payors to keep these costs down. Certain proposals, if passed, would impose limitations on the prices we will be able to charge for the products that we are developing, or the amounts of reimbursement available for these products from governmental agencies or third-party payors. These limitations could in turn reduce the amount of revenues that we will be able to generate in the future from sales of our products and licenses of our technology.

In March 2010, the United States Congress enacted and President Obama signed into law healthcare reform legislation that may significantly impact the pharmaceutical industry. In addition to requiring most individuals to have health insurance and establishing new regulations on health plans, this legislation will require discounts under the Medicare drug benefit program and increased rebates on drugs covered by Medicaid. In addition, the legislation imposes an annual fee, which will increase annually, on sales by branded pharmaceutical manufacturers starting in 2011. The financial impact of these discounts, increased rebates and fees and the other provisions of the legislation on our business is unclear and there can be no assurance that our business will not be materially adversely affected. In addition, these and other ongoing initiatives in the United States have increased and will continue to increase pressure on drug pricing. The announcement or adoption of any such initiative could have an adverse effect on potential revenues from any product that we may successfully develop.

Various healthcare reform proposals have also emerged at the state level. We cannot predict what healthcare initiatives, if any, will be implemented at the federal or state level, or the effect any future legislation or regulation will have on us. However, an expansion in government’s role in the U.S. healthcare industry may lower the future revenues for the products we are developing and adversely affect our future business, possibly materially.

Risks Related to our Common Stock

As the market price of our common stock may fluctuate significantly, this may make it difficult for you to sell your shares of common stock when you want or at prices you find attractive.

The price of our common stock is quoted on the Over-the-Counter Bulletin Board, or OTCBB, and constantly changes. In recent years, the stock market in general has experienced extreme price and volume fluctuations. We expect that the market price of our common stock will continue to fluctuate. These fluctuations may result from a variety of factors, many of which are beyond our control. These factors include:

- Clinical trial results and the timing of the release of such results,
- The amount of cash resources and ability to obtain additional funding,
- Announcements of research activities, business developments, technological innovations or new products by companies or their competitors,
- Entering into or terminating strategic relationships,
- Changes in government regulation,
- Departure of key personnel,

- Disputes concerning patents or proprietary rights,
- Changes in expense level,
- Future sales of our equity or equity-related securities,
- Public concern regarding the safety, efficacy or other aspects of the products or methodologies being developed,
- Activities of various interest groups or organizations,
- Media coverage, and
- Status of the investment markets.

Future sales of common stock or the issuance of securities senior to our common stock or convertible into, or exchangeable or exercisable for, our common stock could materially adversely affect the trading price of our common stock, and our ability to raise funds in new equity offerings.

Future sales of substantial amounts of our common stock or other equity-related securities in the public market or privately, or the perception that such sales could occur, could adversely affect prevailing trading prices of our common stock and could impair our ability to raise capital through future offerings of equity or other equity-related securities. We anticipate that we will need to raise capital though offerings of equity and equity related securities. We can make no prediction as to the effect, if any, that future sales of shares of our common stock or equity-related securities, or the availability of shares of common stock for future sale, will have on the trading price of our common stock.

Our common stock is deemed to be a “penny stock,” which may make it more difficult for investors to sell their shares due to suitability requirements. Low-priced stocks are sometimes the subject of fraud and abuse.

The Securities and Exchange Commission, or the SEC, has adopted regulations that generally define “penny stock” to be an equity security that has a market price of less than $5.00 per share, subject to specific exemptions, such as if the issuer of the security has net tangible assets in excess of $2,000,000. The market price of our common stock is currently less than $5.00 per share, and our net tangible assets as of February 28, 2011 were less than $2,000,000. Therefore, our common stock is currently a “penny stock” according to SEC rules. Designation as a "penny stock" requires any broker or dealer selling these securities to disclose certain information concerning the transaction, obtain a written agreement from the purchaser, furnish the customer a document describing the risks of investing in penny stocks and send monthly account statements showing the market value of each penny stock held in the customer’s account. These rules may restrict the ability of brokers or dealers to sell penny stocks.

You should be aware that, according to the SEC, the market for penny stocks has suffered in recent years from patterns of fraud and abuse. These could affect low-priced stocks, such as ours, even if they do not qualify as "penny stocks" under the SEC rules. Such patterns include:

- Control of the market for the security0 by one or a few broker-dealers;
- “Boiler room” practices involving high-pressure sales tactics;
- Manipulation of prices through prearranged matching of purchases and sales;
- The release of misleading information;
- Excessive and undisclosed bid-ask differentials and markups by selling broker-dealers; and
- Dumping of securities by broker-dealers after prices have been manipulated to a desired level, which hurts the price of the stock and causes investors to suffer loss.

We are aware of the abuses that have occurred in the market for low-priced stocks. Although we do not expect to be in a position to dictate the behavior of the market or of broker-dealers who participate in the market, we will strive within the confines of practical limitations to prevent such abuses with respect to our common stock.

Future sales of our common stock by our existing stockholders could adversely affect our stock price.

The market price of our common stock could decline as a result of sales of a large number of shares of our common stock in the market, or the perception that these sales could occur. These sales also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. As of June 29, 2011, we had outstanding 70,104,583 shares of common stock. This prospectus relates to 39,174,923 shares of common stock held by the selling stockholders and 6,346,188 shares of common stock issuable upon exercise of warrants and options held by the selling stockholders.

Our issuance of warrants and options to investors, employees and consultants may have a negative effect on the trading prices of our common stock as well as a dilutive effect.

We have issued and may continue to issue warrants, options and convertible notes at, above or below the current market price. As of June 29, 2011, we had outstanding warrants and options exercisable for 21,469,919 shares of common stock (18,552,948 as of February 28, 2011 and 15,584,897 as of August 31, 2010). In addition to the dilutive effect of a large number of shares and a low exercise price for the warrants and options, there is a potential that a large number of underlying shares may be sold in the open market at any given time, which could place downward pressure on the trading of our common stock.

Because we will not pay cash dividends, investors may have to sell shares in order to realize their investment.

We have not paid any cash dividends on our common stock and do not intend to pay cash dividends in the foreseeable future. We intend to retain future earnings, if any, for reinvestment in the development and expansion of our business. Any credit agreements which we may enter into with institutional lenders or otherwise may restrict our ability to pay dividends. Whether we pay cash dividends in the future will be at the discretion of our board of directors and will be dependent upon our financial condition, results of operations, capital requirements, and any other factors that our board of directors decides is relevant. See “Market Price and Dividends” and “Description of Common Stock”.

Our shares of common stock are not listed for trading on a national securities exchange.

Our common stock currently trades on the OTCBB and is not listed for trading on any national securities exchange. Investments in securities trading on the OTCBB are generally less liquid than investments in securities trading on a national securities exchange. The failure of our shares to be approved for trading on a national securities exchange may have the effect of limiting the trading activity of our common stock and reducing the liquidity of an investment in our common stock.

Risks Related to Conducting Business in Israel

We are affected by the political, economic, and military risks of locating our principal operations in Israel.

Our operations are located in the State of Israel, and we are directly affected by political, economic, and security conditions in that country. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its Arab neighbors. Since October 2000, there has been a marked increase in hostilities between Israel and the Palestinians, and in 2007, Hamas, an Islamist movement responsible for many attacks against Israelis, took control of the Gaza Strip. Recent political events, including political uprisings and social unrest, in various countries in the Middle East and North Africa have weakened the stability of those countries, which could result in extremists coming to power. In addition, Iran has threatened to attack Israel and is widely believed to be developing nuclear weapons. Iran is also believed to have a strong influence among extremist groups in areas that neighbor Israel, such as Hamas in Gaza and Hezbollah in Lebanon. This situation may potentially escalate in the future to violent events which may affect Israel and us. Our business, prospects, financial condition, and results of operations could be materially adversely affected if major hostilities involving Israel should occur or if trade between Israel and its current trading partners is interrupted or curtailed.

All adult male permanent residents of Israel, unless exempt, may be required to perform military reserve duty annually. Additionally, all such residents are subject to being called to active duty at any time under emergency circumstances. Some of our officers, directors, and employees currently are obligated to perform annual military reserve duty. We can provide no assurance that such requirements will not have a material adverse effect on our business, prospects, financial condition, and results of operations in the future, particularly if emergency circumstances occur.

Because almost all of our officers and directors are located in non-U.S. jurisdictions, you may have no effective recourse against our management for misconduct.

Almost all of our directors and officers are nationals and/or residents of countries other than the United States, and all or a substantial portion of their assets are located outside the United States. As a result, it may be difficult for investors to enforce within the United States any judgments obtained against such officers or directors, including judgments predicated upon the civil liability provisions of the securities laws of the United States or any U.S. state. Additionally, it may be difficult to enforce civil liabilities under U.S. federal securities law in original actions instituted in Israel.

Israeli courts may refuse to hear a claim based on a violation of U.S. securities laws because Israel is not the most appropriate forum to bring such a claim. In addition, even if an Israeli court agrees to hear a claim, it may determine that Israeli law and not U.S. law is applicable to the claim. If U.S. law is found to be applicable, the content of applicable U.S. law must be proved as a fact, which can be a time-consuming and costly process. Certain matters of procedure will also be governed by Israeli law.

FORWARD-LOOKING STATEMENTS

This prospectus and any prospectus supplement may contain forward-looking statements within the meaning of the federal securities laws regarding our business, financial condition, results of operations and prospects. Words such as "expects," "anticipates," "intends," "plans," "believes," "seeks," "estimates" and similar expressions or variations of such word intended to identify forward-looking statements, but are not deemed to represent an all-inclusive means of identifying forward-looking statements as denoted in this prospectus. Additionally, statements concerning future matters are forward-looking statements.

Although forward-looking statements in this prospectus reflect the good faith judgment of our management, such statements can only be based on facts and factors currently known by us. Consequently, forward-looking statements are inherently subject to risks and uncertainties and actual results and outcomes may differ materially from the results and outcomes discussed in or anticipated by the forward-looking statements. Factors that could cause or contribute to such differences in results and outcomes include, without limitation, those specifically addressed under the heading "Risks Related to Our Business" above, as well as those discussed elsewhere in this prospectus. Readers are urged not to place undue reliance on these forward-looking statements, which speak only as of the date of this prospectus. We undertake no obligation to revise or update any forward-looking statements in order to reflect any event or circumstance that may arise after the date of this prospectus. Readers are urged to carefully review and consider the various disclosures made throughout the entirety of this prospectus which attempt to advise interested parties of the risks and factors that may affect our business, financial condition, results of operations and prospects.

USE OF PROCEEDS

We will not receive any of the proceeds from the sale of the shares of our common stock being offered for sale by the selling stockholders. However, we may receive up to approximately $3.2 million in proceeds upon exercise of the warrants and options held by the selling stockholders, as the warrants and options have an average exercise price of $0.50 per share and are exercisable into 6,346,188 shares of our common stock. None of the selling stockholders have presently advised us of their intention to exercise any warrants or options at this time. All potential proceeds will be used for the research and development of our products and for general working capital purposes. We will incur all costs associated with this registration statement and prospectus.

MARKET PRICE AND DIVIDENDS

Market Price for our Common Stock

Our common stock is quoted on the OTCBB under the symbol “ORMP.OB”. We had 70,104,583 shares of common stock issued and outstanding and approximately 73 holders of record of the common stock as of June 28, 2011 We believe that a number of stockholders hold their shares of our common stock in brokerage accounts and registered in the name of stock depositories. The quarterly high and low reported bid prices for our common stock as quoted on the OTCBB for the periods indicated are as follows:

	High	Low
Fiscal Year Ending August 31, 2011		
First Quarter	$0.42	$0.28
Second Quarter	$0.37	$0.27
Third Quarter	$0.33	$0.26
Fourth Quarter (through June 28, 2011)	$0.34	$0.29
Year Ended August 31, 2010		
First Quarter	$0.64	$0.43
Second Quarter	$0.48	$0.37
Third Quarter	$0.55	$0.41
Fourth Quarter	$0.51	$0.36
Year Ended August 31, 2009		
First Quarter	$0.76	$0.36
Second Quarter	$0.52	$0.25
Third Quarter	$0.62	$0.20
Fourth Quarter	$0.59	$0.40

The foregoing quotations were provided by Yahoo! Finance and the quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not represent actual transactions. On June 28, 2011, the last reported bid price per share of common stock as quoted on the OTCBB was $0.32 per share.

Dividend Policy

We have never paid any cash dividends on our capital stock and do not anticipate paying any cash dividends on our common stock in the foreseeable future. We intend to retain future earnings to fund ongoing operations and future capital requirements of our business. Any future determination to pay cash dividends will be at the discretion of our board of directors and will be dependent upon our financial condition, results of operations, capital requirements and such other factors as our board deems relevant.

MANAGEMENT'S DISCUSSION AND ANALYSIS

OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read in conjunction with our consolidated financial statements and notes thereto that appear elsewhere in this prospectus. In addition to historical consolidated financial information, the following discussion contains forward-looking statements that reflect our plans, estimates and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this prospectus, particularly in the section entitled “Risk Factors.”

Overview of Operations

We are a pharmaceutical company engaged in the research and development of innovative pharmaceutical solutions, including an orally ingestible insulin capsule or tablet to be used for the treatment of individuals with diabetes, and the use of orally ingestible capsules, tablets or pills for delivery of other polypeptides.

Short Term Business Strategy

We plan to conduct further research and development on the technology covered by the patent application "Methods and Composition for Oral Administration of Proteins", which we acquired from Hadasit, as well as the other patents we have filed since. Through our research and development efforts, we are seeking to develop an oral dosage form that will withstand the harsh chemical environment of the stomach or intestines and will be effective in delivering active insulin for the treatment of diabetes. The enzymes and vehicles that are added to the insulin in the formulation process must not modify chemically or biologically the insulin and the dosage form must be safe to ingest. We plan to continue to conduct clinical trials to show the effectiveness of our technology. We intend to conduct the clinical trials necessary to file an Investigational New Drug (“IND”) application with the U.S. Food and Drug Administration (the “FDA”). Additional clinical trials are planned in other countries such as Israel, India and South Africa, in order to substantiate our results as well as for purposes of making future filings for drug approval in these countries. We also plan to conduct further research and development by deploying our proprietary drug delivery technology for the delivery of other polypeptides in addition to insulin, and to develop other innovative pharmaceutical products.

Long Term Business Strategy

If our oral insulin capsule or other drug delivery solutions show significant promise in clinical trials, we plan to ultimately seek a strategic commercial partner, or partners, with extensive experience in the development, commercialization, and marketing of insulin applications and/or other orally digestible drugs. We anticipate such partner or partners would be responsible for, or substantially support, late stage clinical trials (Phase III) to increase the likelihood of obtaining regulatory approvals and registrations in the appropriate markets in a timely manner. We further anticipate that such partner, or partners, would also be responsible for sales and marketing of our oral insulin capsule in these markets. Such planned strategic partnership, or partnerships, may provide a marketing and sales infrastructure for our products as well as financial and operational support for global clinical trials, post marketing studies, label expansions and other regulatory requirements concerning future clinical development in the United States and elsewhere. Any future strategic partner, or partners, may also provide capital and expertise that would enable the partnership to develop new oral dosage form for other polypeptides. While our strategy is to partner with an appropriate party, no assurance can be given that any third party would be interested in partnering with us. Under certain circumstances, we may determine to develop one or more of our oral dosage form on our own, either world-wide or in select territories.

Other Planned Strategic Activities

In addition to developing our own oral dosage form drug portfolio, we are, on an on-going basis, considering in-licensing and other means of obtaining additional technologies to complement and/or expand our current product portfolio. Our goal is to create a well-balanced product portfolio that will enhance and complement our existing drug portfolio.

Results of Operations

Going concern assumption

The accompanying financial statements have been prepared assuming that we will continue as a going concern. We have net losses for the period from inception (April 12, 2002) through February 28, 2011 of $14.2 million, as well as negative cash flow from operating activities. Based upon our existing spending plans, estimated at $5.4 million for the twelve months following March 1, 2011, and our cash availability, we do not have sufficient cash resources to meet our liquidity requirements through February 29, 2012. Accordingly, these factors raise substantial doubt about our ability to continue as a going concern. Management is in the process of evaluating various financing alternatives as we will need to finance future research and development activities and general and administrative expenses through fund raising in the public or private equity markets. Although there is no assurance that we will be successful with those initiatives, management believes that it will be able to secure the necessary financing as a result of ongoing financing discussions with third party investors and existing shareholders.

The financial statements do not include any adjustments that may be necessary should we be unable to continue as a going concern. Our continuation as a going concern is dependent on our ability to obtain additional financing as may be required and ultimately to attain profitability.

Critical accounting policies

Our significant accounting policies are more fully described in the notes to our consolidated financial statements. We believe that the accounting policies below are critical for one to fully understand and evaluate our financial condition and results of operations.

The discussion and analysis of our financial condition and results of operations is based on our financial statements, which we prepared in accordance with U.S. generally accepted accounting principles. The preparation of our financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate such estimates and judgments. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Valuation of options and warrants: We granted options to purchase shares of our common stock to employees and consultants and issued warrants in connection with some of our financings.

We account for share based payments in accordance with the guidance that requires awards classified as equity awards be accounted for using the grant-date fair value method. The fair value of share-based payment transactions is recognized as an expense over the requisite service period, net of estimated forfeitures. We estimated forfeitures based on historical experience and anticipated future conditions.

We elected to recognize compensation cost for an award with only service conditions that has a graded vesting schedule using the accelerated method based on the multiple-option award approach.

When stock options are granted as consideration for services provided by consultants and other non-employees, the transaction is accounted for based on the fair value of the consideration received or the fair value of the stock options issued, whichever is more reliably measurable, pursuant to the guidance. The fair value of the options granted is measured on a final basis at the end of the related service period and is recognized over the related service period using the straight-line method.

Taxes on income: Deferred taxes are determined utilizing the asset and liability method based on the estimated future tax effects of differences between the financial accounting and tax bases of assets and liabilities under the applicable tax laws. Deferred tax balances are computed using the tax rates expected to be in effect when those differences reverse. A valuation allowance in respect of deferred tax assets is provided if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. We have provided a full valuation allowance with respect to its deferred tax assets.

Regarding our subsidiary, Oramed Ltd., the guidance prohibits the recognition of deferred tax liabilities or assets that arise from differences between the financial reporting and tax bases of assets and liabilities that are measured from the local currency into dollars using historical exchange rates, and that result from changes in exchange rates or indexing for tax purposes. Consequently, the abovementioned differences were not reflected in the computation of deferred tax assets and liabilities.

Comparison of six month and three month periods ended February 28, 2011 and 2010 and Fiscal Year 2010 to Fiscal Year 2009

The following table summarizes certain statements of operations data for the Company for the six month and three month periods ended February 28, 2011 and 2010:

	Six months ended		Three months ended	
Operating Data:	February 28, 2011	February 28, 2010	February 28, 2011	February 28, 2010
Research and development costs	$627,816	$516,057	$341,328	$183,572
General and administrative expenses	621,016	493,344	305,887	208,328
Financial (income) expense, net	(3,257)	(4,397)	(4,424)	311
Net loss for the period	1,245,575	1,005,004	$642,791	$392,211
Loss per common share – basic and diluted	$0.02	$0.02	$0.01	$0.01
Weighted average common shares outstanding	60,344,880	57,289,266	62,804,799	57,442,484

The following table summarizes certain statements of operations data for us for the twelve month periods ended August 31, 2010 and 2009:

	Year ended	
Operating Data:	August 31, 2010	August 31, 2009
Research and development expenses, net	$ 1,463,886	$ 1,574,074
General and administrative expenses	1,508,667	1,210,044
Financial income, net	(10,148)	(21,047)
Loss before taxes on income	(2,962,405)	(2,763,071)
Taxes on income	14,971	(2,597)
Net loss for the period	$ (2,977,376)	$ (2,760,474)
Loss per common share – basic and diluted	$ (0.05)	$ (0.05)
Weighted average common shares outstanding	57,389,991	56,645,820

Research and development expenses

Research and development expenses include costs directly attributable to the conduct of research and development programs, including the cost of salaries, payroll taxes, employee benefits, costs of registered patents materials, supplies, the cost of services provided by outside contractors, including services related to our clinical trials, clinical trial expenses, the full cost of manufacturing drug for use in research, preclinical development. All costs associated with research and development are expensed as incurred.

Clinical trial costs are a significant component of research and development expenses and include costs associated with third-party contractors. We outsource a substantial portion of our clinical trial activities, utilizing external entities such as contract research organizations, independent clinical investigators, and other third-party service providers to assist us with the execution of our clinical studies. For each clinical trial that we conduct, certain clinical trial costs are expensed immediately, while others are expensed over time based on the expected total number of patients in the trial, the rate at which patients enter the trial, and the period over which clinical investigators or contract research

organizations are expected to provide services.

Clinical activities which relate principally to clinical sites and other administrative functions to manage our clinical trials are performed primarily by contract research organizations, or CROs. CROs typically perform most of the start-up activities for our trials, including document preparation, site identification, screening and preparation, pre-study visits, training, and program management.

Clinical trial and pre-clinical trial expenses include regulatory and scientific consultants' compensation and fees, research expenses, purchase of materials, cost of manufacturing of the oral insulin capsules, payments for patient recruitment and treatment, costs related to the maintenance of our registered patents, costs related to the filings of patent applications, as well as salaries and related expenses of research and development staff.

In August 2009, Oramed Ltd., our wholly owned Israeli subsidiary, was awarded a government grant amounting to a total net amount of NIS 3.1 million (approximately $813,000), from the Office of the Chief Scientist of the Ministry of Industry, Trade and Labor of Israel, or the OCS. This grant was used for research and development expenses for the period of February 2009 to June 2010. The funds were used by us to support further research and development and clinical study of our oral insulin capsule and Oral GLP1-analog. In December 2010, Oramed Ltd., was awarded another grant amounting to a total net amount of NIS 2.9 million (approximately $807,000) from the OCS, which was designated for research and development expenses for the period of July 2010 to June 2011. We used the funds to support further research and development and clinical study of our oral insulin capsule and Oral GLP1-analog. The two grants are subject to repayment according to the terms determined by the OCS and applicable law. See "--Government Grants" below.

During the six months ended February 28, 2011 research and development expenses totaled $627,816, compared to $516,057 for the six months ended February 28, 2010. The increase is mainly attributable to an increase in stock based compensation costs due to amortization of options granted in the prior period. At this stage, we do not expect our stock based compensation costs to continue to increase. The research and development costs include stock based compensation costs, which during the six months ended February 28, 2011 totaled $162,896 as compared to $42,508 during the six months ended February 28, 2010.

The increase in research and development expenses during the three months ended February 28, 2011 as compared to the three months ended February 28, 2010 is attributable to the same reasons described in the immediate preceding paragraph.

During the year ended August 31, 2010, research and development expenses totaled $1,463,886, compared to $1,574,074 for the year ended August 31, 2009. The decrease is mainly attributable to a decrease in the purchase of clinical materials. The research and development costs include stock based compensation costs, which during the year ended August 31, 2010 totaled $341,203, as compared to $264,861 during the year ended August 31, 2009.

Government Grants

The Government of Israel encourages research and development projects through the OCS, pursuant to the Law for the Encouragement of Industrial Research and Development, 1984, as amended, commonly referred to as the "R&D Law". Under the R&D Law, a research and development plan that meets specified criteria is eligible for a grant of up to 50% of certain approved research and development expenditures. Each plan must be approved by the OCS.

In the six and three months ended February 28, 2011, we recognized research and development grants in an amount of $208,674 and $56,698, respectively. As of February 28, 2011, we had no contingent liabilities to the OCS.

In the years ended August 31, 2010 and 2009, we recognized research and development grants in an amount of $350,198 and $400,405, respectively. As of August 31, 2010, we had no contingent liabilities to the OCS.

Under the terms of the grants we received from the OCS, we are obligated to pay royalties of 3% to 3.5% on all revenues derived from the sale of the products developed pursuant to the funded plans, including revenues from licenses. Pursuant to a proposed amendment to the R&D Law, our royalty rate may be 3% to 6% per annum. Royalties are payable up to 100% of the amount of such grants, or up to 300% as detailed below, linked to the U.S.

Dollar, plus annual interest at LIBOR. The payment of royalties is on all revenues derived from the sale of the products developed pursuant to the funded plans, including revenues from licensed ancillary services.

The R&D Law generally requires that a product developed under a program be manufactured in Israel. However, upon notification to the OCS (and provided that the OCS does not object within 30 days), up to 10% of a company's approved Israeli manufacturing volume, measured on an aggregate basis, may be transferred outside of Israel. In addition, upon the approval of the Chief Scientist, a greater portion of the manufacturing volume may be performed outside of Israel, provided that the grant recipient pays royalties at an increased rate, which may be substantial, and the aggregate repayment amount is increased up to 300% of the grant, depending on the portion of the total manufacturing volume that is performed outside of Israel. The R&D Law further permits the OCS, among other things, to approve the transfer of manufacturing rights outside Israel in exchange for an import of different manufacturing into Israel as a substitute, in lieu of the increased royalties. The R&D Law also allows for the approval of grants in cases in which the applicant declares that part of the manufacturing will be performed outside of Israel or by non-Israeli residents and the research committee is convinced that doing so is essential for the execution of the program. This declaration will be a significant factor in the determination of the OCS whether to approve a program and the amount and other terms of benefits to be granted. For example, an increased royalty rate and repayment amount might be required in such cases.

The R&D Law also provides that know-how developed under an approved research and development program may not be transferred to third parties in Israel without the approval of the research committee. Such approval is not required for the sale or export of any products resulting from such research or development. The R&D Law further provides that the know-how developed under an approved research and development program may not be transferred to any third parties outside Israel, except in certain special circumstances and subject to the OCS' prior approval. The OCS may approve the transfer of OCS-funded know-how outside Israel, generally in the following cases: (a) the grant recipient pays to the OCS a portion of the sale price paid in consideration for such OCS-funded know-how or the price paid in consideration for the sale of the grant recipient itself, as the case may be (according to certain formulas), or (b) the grant recipient receives know-how from a third party in exchange for its OCS-funded know-how, or (c) such transfer of OCS-funded know-how arises in connection with certain types of cooperation in research and development activities.

The R&D Law imposes reporting requirements with respect to certain changes in the ownership of a grant recipient. The law requires the grant recipient and its controlling shareholders and foreign interested parties to notify the OCS of any change in control of the recipient or a change in the holdings of the means of control of the recipient that results in a non-Israeli becoming an interested party in the recipient, and requires the new interested party to undertake to the OCS to comply with the R&D Law. In addition, the rules of the OCS may require additional information or representations in respect of certain such events. For this purpose, "control" is defined as the ability to direct the activities of a company other than any ability arising solely from serving as an officer or director of the company. A person is presumed to have control if such person holds 50% or more of the means of control of a company. "Means of control" refers to voting rights or the right to appoint directors or the chief executive officer. An "interested party" of a company includes a holder of 5% or more of its outstanding share capital or voting rights, its chief executive officer and directors, someone who has the right to appoint its chief executive officer or at least one director, and a company with respect to which any of the foregoing interested parties owns 25% or more of the outstanding share capital or voting rights or has the right to appoint 25% or more of the directors. Accordingly, any non-Israeli who acquires 5% or more of our ordinary shares will be required to notify the OCS that it has become an interested party and to sign an undertaking to comply with the R&D Law.

General and administrative expenses

General and administrative expenses include the salaries and related expenses of our management, consulting costs, legal and professional fees, traveling, business development costs, insurance expenses and other general costs.

For the six months ended February 28, 2011, general and administrative expenses totaled $621,016 compared to $493,344 for the six months ended February 28, 2010. Costs incurred related to general and administrative activities during the six months ended February 28, 2011 reflect an increase in professional fee expenses as well as stock options granted to employees and consultants. During the six months ended February 28, 2011, as part of our general and administrative expenses, we incurred $172,901 related to stock options granted to employees and consultants, as compared to $113,195 during the six months ended February 28, 2010.

The increase in general and administrative expenses during the three months ended February 28, 2011 as compared to the three months ended February 28, 2010 is attributable to the same reasons described in the immediate preceding paragraph .

For the year ended August 31, 2010, general and administrative expenses totaled $1,508,667 compared to $1,210,044 for the year ended August 31, 2009. Costs incurred related to general and administrative activities during the year ended August 31, 2010 reflect an increase of professional, legal and consulting expenses and an increase in business development costs. During the year ended August 31, 2010, as part of our general and administrative expenses, we incurred $466,623 related to stock options granted to employees and consultants, as compared to $288,338 during the

year ended August 31, 2009.

Financial income/expense, net

During the six month periods ended February 28, 2011 and 2010, we generated interest income on available cash and cash equivalents which was offset by bank charges and imputed interest.

During the year ended August 31, 2010, we generated interest income on available cash and cash equivalents balance which were offset by bank charges. During the year ended August 31, 2009, we incurred imputed interest expenses on convertible notes issued as well as bank charges.

The decrease in the interest income for the year ending August 31, 2010, as compared with the year ended August 31, 2009, is attributable to the decrease in interest rates in both the United States and the State of Israel, and to decrease in cash and cash equivalents.

Liquidity and Capital Resources

Since inception through February 28, 2011, we incurred losses in an aggregate amount of $14.2 million. Since inception through February 28, 2011, we have financed our operations through the private placements of equity and debt financings, raising a total of $11.1 million, net of transaction costs. We will seek to obtain additional financing through similar sources. As of February 28, 2011, we had $1.9 million of available cash as well as $1.8 million in short term interest bearing investments. We anticipate that we will require approximately $5.4 million to finance our activities during the twelve months following March 1, 2011.

Management is in the process of evaluating various financing alternatives as we will need to finance future research and development activities and general and administrative expenses through fund raising in the public or private equity markets. Although there is no assurance that we will be successful with those initiatives, management believes that it will be able to secure the necessary financing as a result of ongoing financing discussions with third party investors and existing shareholders as well as receive additional funding from the OCS.

During our fiscal years 2009 and 2010 we issued 1,312,515 common shares to various third party vendors for services rendered. The aggregate value of those shares was approximately $589,000. We also consummated a private placement by selling 937,500 units at a purchase price of $0.32 per unit for a total consideration of $300,000. Each unit consisted of one share of common stock and 0.35 share purchase warrant. Each share purchase warrant entitles the holder to purchase one share of common stock for a period of five years at an exercise price of $0.50.

Our recent financing activities include the following:

- In September 2010 and January 2011, we issued a total of 353,714 shares of our common stock, valued at $119,800, in the aggregate, to Swiss Caps AG as remuneration for services rendered.

- In March 2011, we completed a private placement with a number of “accredited investors” as defined in Rule 501(a) of Regulation D, pursuant to which we agreed to sell to the investors an aggregate of 10,487,500 units at a purchase price of $0.32 per unit for total consideration of $3,356,000. Each unit consisted of one share of common stock and a five-year warrant to purchase 0.35 of a share of common stock at an exercise price of $0.50 per Share. These amounts include the $250,000 investment by D.N.A made in connection with our technology transaction on March 31, 2011.

- On March 31, 2011, we consummated a transaction with D.N.A for the sale of 781,250 shares of common stock and warrants to purchase up to 273,438 shares of common stock, for a total purchase price of $250,000 in cash. The shares and warrants were sold in units at a price per unit of $0.32, each unit consisting of one share of

common stock and a warrant to purchase 0.35 of a share of common stock. The warrants have an exercise price of $0.50 per share, subject to adjustment, and a term of five years commencing from the closing of the transaction. D.N.A's $250,000 investment in Oramed is included in the private placement described in the immediately preceding paragraph.

- In April 2011, we completed a private placement with a number of “accredited investors” as defined in Rule 501(a) of Regulation D, pursuant to which we agreed to sell to the investors an aggregate of 1,124,375 units at a purchase price of $0.32 per unit for total consideration of $359,800. Each unit consisted of one share of common stock and a five-year warrant to purchase 0.35 of a share of common stock at an exercise price of $0.50 per Share.

- In May 2011, we issued 176,923 shares of our common stock, valued at $47,769, in the aggregate, to Swiss Caps AG as remuneration for services rendered in the past.

- In May 2011, we issued 200,00 shares of our common stock, valued at $60,000, in the aggregate, to New Castle Consulting, LLC as remuneration for services to be rendered.

Employee's and Consultant’s Stock Options and Warrants

Employee and consultant stock options grant and warrant issuance activities for the fiscal year 2010 include the following:

- On November 23, 2009 we granted options under the 2008 Stock Incentive Plan to purchase up to 100,000 shares of our common stock at an exercise price of $0.76 to a consultant.

- On November 23, 2009 we granted options under the 2008 Stock Incentive Plan to purchase up to 36,000 shares of our common stock at an exercise price of $0.46 to an employee of our subsidiary.

- On March 16, 2010, 50,000 options were granted to a consultant of our subsidiary at an exercise price of $0.50 per share. The options vest in three equal annual installments commencing on March 16, 2011 and will expire on March 15, 2015.

- On March 16, 2010, 100,000 options were granted to a consultant of the Company at an exercise price of $0.43 per share. The options vest in three equal monthly installments commencing on March 30, 2010 and will expire on March 15, 2015.

- On March 16, 2010, 13,200 options were granted to a consultant of the Company at an exercise price of $0.43 per share. The options vest in six monthly installments commencing on March 30, 2010 and will expire on March 15, 2015.

- On March 25, 2010, 100,000 options were granted to a consultant of the Company at an exercise price of $0.50 per share. The options vest in four equal quarterly installments commencing on May 17, 2010 and will expire on March 24, 2015.

- On April 21, 2010, 864,000 options were granted to each of Nadav Kidron and Miriam Kidron under the 2008 Stock Option Plan at an exercise price of $0.49 per share, 108,000 of such options vested immediately on the date of grant and the remainder will vest in twenty equal monthly installments, commencing on May 31, 2010. The options have an expiration date of April 20, 2020.

- On July 8, 2010, 300,000 options were granted to a director at an exercise price of $0.48 per share. The options vest in three equal annual installments commencing on July 8, 2011 and will expire on July 7, 2020.

Employee and consultant stock options grant and warrant issuance activities for the fiscal year 2011 include the following:

- On February 15, 2011, 250,000 options were granted to a consultant of the Company at an exercise price of $0.50 per share. The options vest in five equal quarterly installments commencing on February 16, 2011 and will expire on February 16, 2021.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements.

Planned Expenditures

The estimated expenses referenced herein are in accordance with our business plan. Since our technology is still in the development stage, it can be expected that there will be changes in some budgetary items. Our planned expenditures for the twelve months beginning March 1, 2011 are as follows:

Category		Amount
Research and development costs, net of OCS funds	$	4,358,000
General and administrative expenses		1,044,000
Financial income, net		1,000
Taxes on income		-
Total	$	5,404,000

As previously indicated, we are planning to conduct further clinical studies as well as file an IND application with the FDA for our orally ingested insulin. Our ability to proceed with these activities is dependent on several major factors including the ability to attract sufficient financing on terms acceptable to us.

OUR BUSINESS

General

We are a pharmaceutical company engaged in the research and development of innovative pharmaceutical solutions, including an orally ingestible insulin capsule or tablet to be used for the treatment of individuals with diabetes, and the use of orally ingestible capsules, tablets or pills for delivery of other polypeptides.

Oral Insulin: We are seeking to revolutionize the treatment of diabetes through our proprietary flagship product, an orally ingestible insulin capsule (ORMD0801) currently in Phase 2 clinical trials. Our technology allows insulin to travel from the gastrointestinal tract via the portal vein to the bloodstream, revolutionizing the manner in which insulin is delivered. It enables its passage in a more physiological manner than current delivery methods of insulin.

Through our research and development efforts, we are developing an oral dosage form that will withstand the harsh chemical environment of the stomach or intestines and will be effective in delivering active insulin for the treatment of diabetes. The proteins and vehicles that are added to the insulin in the formulation process must not modify chemically or biologically, and the insulin and the dosage form must be safe to ingest.

Our research and development team has performed numerous animal studies to optimize the composition and functionality of their oral insulin (ORMD0801) modality and to demonstrate its safety and efficacy. Our studies have confirmed the feasibility of lowering blood glucose levels with an orally administered form of insulin that is both safe and effective.

Our technology is a platform that has the potential to deliver medications and vaccines orally that today can only be delivered via injection.

Diabetes: Diabetes is a disease in which the body does not produce or properly use insulin. Insulin is a hormone that causes sugar to be absorbed into cells, where the sugar is converted into energy needed for daily life. The cause of diabetes is attributed both to genetics (type 1 diabetes) and, most often, to environmental factors such as obesity and lack of exercise (type 2 diabetes).

According to the International Diabetes Federation ("IDF"), an estimated 285 million people worldwide suffered from diabetes in 2010. In the United States there were approximately 26.8 million people with diabetes, or 8.7% of the United States population in 2010. The IDF predicts that the number of people worldwide with diabetes will exceed 435 million in 2030 if the current rate of growth continues unchecked.

Diabetes now affects seven percent of the world’s adult population and claims four million lives every year. The disease is a leading cause of blindness, kidney failure, heart attack, stroke and amputation. Diabetes was estimated to cost the world economy at least $376 billion in 2010, or 11.6% of total world healthcare expenditure. By 2030, this number is projected to exceed $490 billion. More than 80% of diabetes spending is in the world’s richest countries and not in the poorer countries, where over 70% of people with diabetes now live.

The regions with the highest comparative prevalence rates are North America, where 10.2% of the adult population has diabetes, followed by the Middle East and North Africa with 9.3%. The regions with the highest number of people living with diabetes are the Western Pacific, where some 77 million people have diabetes and South East Asia with 59 million.

Each year seven million people develop diabetes. The most dramatic increases in type 2 diabetes have occurred in populations where there have been rapid and major improvements in living standards, demonstrating the important

role played by lifestyle factors and the potential for reversing the global epidemic.

Intellectual Property: We own a portfolio of patents and patent applications covering our technologies and we are aggressively protecting these technology developments on a worldwide basis.

Management: We are led by a highly-experienced management team knowledgeable in the treatment of diabetes. Our Chief Medical and Technology Officer, Miriam Kidron, PhD, is a world-recognized pharmacologist and a biochemist and the innovator primarily responsible for our oral insulin technology development and know-how.

Scientific Advisory Board: Our management team has access to our internationally recognized Scientific Advisory Board whose members are thought-leaders in their respective areas. The Advisory Board is comprised of Dr. Nir Barzilai, Professor Ele Ferrannini, Professor Avram Hershko, Dr. Derek LeRoith, Dr. John Amatruda and Dr. Michael Berelowitz acting as Chairman.

Strategy

Short Term Business Strategy

We plan to conduct further research and development on the technology covered by the patent application "Methods and Composition for Oral Administration of Proteins", which we acquired from Hadasit, as well as the other patents we have filed since. Through our research and development efforts, we are seeking to develop an oral dosage form that will withstand the harsh chemical environment of the stomach or intestines and will be effective in delivering active insulin for the treatment of diabetes. The enzymes and vehicles that are added to the insulin in the formulation process must not modify chemically or biologically the insulin, and the dosage form must be safe to ingest. We plan to continue to conduct clinical trials to show the effectiveness of our technology. We intend to conduct the clinical trials necessary to file an Investigational New Drug ("IND") application with the U.S. Food and Drug Administration (the "FDA"). Additional clinical trials are planned in other countries such as Israel, India and South Africa, in order to substantiate our results as well as for purposes of making future filings for drug approval in these countries. We also plan to conduct further research and development by deploying our proprietary drug delivery technology for the delivery of other polypeptides in addition to insulin, and to develop other innovative pharmaceutical products.

Long Term Business Strategy

If our oral insulin capsule or other drug delivery solutions show significant promise in clinical trials, we plan to ultimately seek a strategic commercial partner, or partners, with extensive experience in the development, commercialization, and marketing of insulin applications and/or other orally digestible drugs. We anticipate such partner or partners would be responsible for, or substantially support, late stage clinical trials (Phase III) to increase the likelihood of obtaining regulatory approvals and registrations in the appropriate markets in a timely manner. We further anticipate that such partner, or partners, would also be responsible for sales and marketing of our oral insulin capsule in these markets. Such planned strategic partnership, or partnerships, may provide a marketing and sales infrastructure for our products as well as financial and operational support for global clinical trials, post marketing studies, label expansions and other regulatory requirements concerning future clinical development in the United States and elsewhere. Any future strategic partner, or partners, may also provide capital and expertise that would enable the partnership to develop new oral dosage form for other polypeptides. While our strategy is to partner with an appropriate party, no assurance can be given that any third party would be interested in partnering with us. Under certain circumstances, we may determine to develop one or more of our oral dosage form on our own, either world-wide or in select territories.

Other Planned Strategic Activities

In addition to developing our own oral dosage form drug portfolio, we are, on an on-going basis, considering in-licensing and other means of obtaining additional technologies to complement and/or expand our current product portfolio. Our goal is to create a well-balanced product portfolio that will enhance and complement our existing drug portfolio.

Product Development

Orally Ingestible Insulin: During fiscal year 2007 we conducted several clinical studies of our orally ingestible insulin. The studies were intended to assess both the safety/tolerability and absorption properties of our proprietary oral insulin. Based on the pharmacokinetic and pharmacologic outcomes of these trials, we decided to continue the development of our oral insulin product.

On November 15, 2007, we successfully completed animal studies in preparation for the Phase 1B clinical trial of our oral insulin capsule (ORMD0801). On January 22, 2008, we commenced the non-FDA approved Phase 1B clinical trials with our oral insulin capsule, in healthy human volunteers with the intent of dose optimization. On March 11, 2008, we successfully completed our Phase 1B clinical trials.

On April 13, 2008, we commenced a non-FDA approved Phase 2A study to evaluate the safety and efficacy of our oral insulin capsule (ORMD0801) in type 2 diabetic volunteers at Hadassah Medical Center in Jerusalem. On August 6, 2008, we announced the successful results of this trial.

In July 2008 we were granted approval by the Institutional Review Board Committee of Hadassah Medical Center in Jerusalem to conduct a non-FDA approved Phase 2A study to evaluate the safety and efficacy of our oral insulin capsule (ORMD0801) on type 1 diabetic volunteers. On September 24, 2008, we announced the beginning of this trial. On July 21, 2009 we reported positive results from this trial.

On September 14, 2010, we reported the successful results of an exploratory clinical trial testing the effectiveness of our oral insulin capsule (ORMD0801) in type 1 diabetes patients suffering from uncontrolled diabetes. Unstable or labile diabetes is characterized by recurrent, unpredictable and dramatic blood glucose swings often linked with irregular hyperglycemia and sometimes serious hypoglycemia affecting type 1 diabetes patients. This newly completed exploratory study was a proof of concept study for defining a novel indication for ORMD0801. The encouraging results justify further clinical development of ORMD0801 capsule application toward management of uncontrolled diabetes.

On February 10, 2010, we entered into agreements with Vetgenerics Research G. Ziv Ltd., a clinical research organization, to conduct a toxicology trial on our oral insulin capsules. On March 23, 2011, we reported that we successfully completed the resulting comprehensive toxicity study for our oral insulin capsule (ORMD0801). The study was completed under conditions prescribed by the FDA Good Laboratory Practices regulations and is the last study required to be performed before filing an IND filing.

On April 21, 2009, we entered into a consulting service agreement with ADRES Advanced Regulatory Services Ltd. (“ADRES”), pursuant to which ADRES will provide services for the purpose of filing an IND application with the FDA for a Phase 2 study according to the FDA requirements. The FDA approval process and, if approved, registration for commercial use as an oral drug can take several years.

In May 2009, we commenced a non-FDA approved Phase 2B study in South Africa to evaluate the safety, tolerability and efficacy of our oral insulin capsule (ORMD0801) on type 2 diabetic volunteers. On May 6, 2010, we reported that the capsule was found to be well tolerated and exhibited a positive safety profile. No cumulative adverse effects were reported throughout this first study of extended exposure to the capsule.

GLP-1 Analog: On September 16, 2008 we announced the launch of pre-clinical trials of ORMD0901, a GLP-1-analog. The pre-clinical trials include animal studies which suggest that the GLP-1analog (exenatide-4) when combined with Oramed’s absorption promoters is absorbed through the gastrointestinal tract and retains its biological activity.

On September 9, 2009, we received approval from the Institutional Review Board (IRB) in Israel to commence human clinical trials of an oral GLP-1 analog. The approval was granted after successful pre-clinical results were reported. The trials are being conducted on healthy volunteers at Hadassah University Medical Center in Jerusalem. We anticipate that the results of these trials will be released in the near future.

Glucagon-like peptide-1 (GLP-1) is an incretin hormone - a type of gastrointestinal hormone that stimulates the secretion of insulin from the pancreas. The incretin concept was hypothesized when it was noted that glucose ingested by mouth (oral) stimulated two to three times more insulin release than the same amount of glucose administered intravenously. In addition to stimulating insulin release, GLP-1 was found to suppress glucagon release (hormone involved in regulation of glucose) from the pancreas, slow gastric emptying to reduce the rate of absorption of nutrients into the blood stream, and increase satiety. Other important beneficial attributes of GLP-1 are its effects of increasing the number of beta cells (cells that manufacture and release insulin) in the pancreas and, possibly, protection of the heart.

Raw Materials: Our oral insulin capsule is currently manufactured by Swiss Caps AG, under a Clinical Trail Manufacturing Agreement.

On July 5, 2010, our subsidiary entered into a Manufacturing Supply Agreement (MSA) with Sanofi-Aventis Deutschland GMBH ("sanofi-aventis"). According to the MSA, sanofi-aventis will supply our subsidiary with specified quantities of recombinant human insulin to be used for clinical trials in the United States.

The raw materials required for the manufacturing of the capsule are purchased from third parties, under separate agreements. We generally depend upon a limited number of suppliers for the raw materials. Although alternative sources of supply for these materials are generally available, we could incur significant costs and disruptions in changing suppliers. The termination of our relationships with our suppliers or the failure of these suppliers to meet our requirements for raw materials on a timely and cost-effective basis could materially adversely affect our business, prospects, financial condition and results of operations.

Patents and Licenses

We maintain a proactive intellectual property strategy which includes patent filings in multiple jurisdictions, including the United States and other commercially significant markets. We hold 34 patent applications currently pending with respect to various compositions, methods of production oral administration of proteins and exenatide. Expiration dates for pending patents will fall in 2026 – 2028.

Consistent with our strategy to seek protection in key markets worldwide, we have been and will continue to pursue the patent applications and corresponding foreign counterparts of such applications. We believe that our success will depend on our ability to obtain patent protection for our intellectual property.

Our patent strategy is as follows:

- Aggressively protect all current and future technological developments to assure strong and broad protection by filing patents and/or continuations in part as appropriate;

- Protect technological developments at various levels, in a complementary manner, including the base technology, as well as specific applications of the technology; and

- Establish comprehensive coverage in the U.S. and in all relevant foreign markets in anticipation of future commercialization opportunities.

The validity, enforceability, written supports, and breadth of claims in our patent applications involve complex legal and factual questions and, therefore, may be highly uncertain. No assurance can be given that any patents based on pending patent applications or any future patent applications filed by us will be issued, that the scope of any patent protection will exclude competitors or provide competitive advantages to us, that any of the patents that have been or may be issued to us will be held valid or enforceable if subsequently challenged, or that others will not claim rights in or ownership of the patents and other proprietary rights held or licensed by us. Furthermore, there can be no assurance that others have not developed or will not develop similar products, duplicate any of our technology or design around any patents that have been or may be issued to us. Since patent applications in the United States are maintained in secrecy for the initial period of time following filing, we also cannot be certain that others did not first file applications for inventions covered by our pending patent applications, nor can we be certain that we will not infringe any patents that may be issued to others on such applications.

We also rely on trade secrets and unpatentable know-how that we seek to protect, in part, by confidentiality agreements. Our policy is to require our employees, consultants, contractors, manufacturers, outside scientific collaborators and sponsored researchers, board of directors, technical review board and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific limited circumstances. We also require signed confidentiality or material transfer agreements from any company that is to receive our confidential information. In the case of employees, consultants and contractors, the agreements provide that all inventions conceived by the individual while rendering services to us shall be assigned to us as the exclusive property of our company. There can be no assurance, however, that all persons who we desire to sign such agreements will sign, or if they do, that these agreements will not be breached, that we would have adequate remedies for any breach, or that our trade secrets or unpatentable know-how will not otherwise become known or be independently developed by competitors.

Our success will also depend in part on our ability to commercialize our technology without infringing the proprietary rights of others. No assurance can be given that patents do not exist or could not be filed which would have an adverse affect on our ability to market our technology or maintain our competitive position with respect to our technology. If our technology components, products, processes or other subject matter are claimed under other existing United States or foreign patents or are otherwise protected by third party proprietary rights, we may be subject to infringement actions. In such event, we may challenge the validity of such patents or other proprietary rights or we may be required to obtain licenses from such companies in order to develop, manufacture or market our technology. There can be no assurances that we would be able to obtain such licenses or that such licenses, if available, could be obtained on commercially reasonable terms. Furthermore, the failure to either develop a commercially viable alternative or obtain such licenses could result in delays in marketing our proposed technology or the inability to proceed with the development, manufacture or sale of products requiring such licenses, which could have a material adverse affect on our business, financial condition and results of operations. If we are required to defend ourselves against charges of patent infringement or to protect our proprietary rights against third parties, substantial costs will be incurred regardless of whether we are successful. Such proceedings are typically protracted with no certainty of success. An adverse outcome could subject us to significant liabilities to third parties and force us to curtail or cease our development and commercialization of our technology.

Partnerships and Collaborative Arrangements

We believe that working together with strategic partners will expedite product formulation, production and approval.

On February 17, 2006, we entered into an agreement with Hadasit to provide consulting and clinical trial services.

On October 30, 2006, we entered into a Clinical Trial Manufacturing Agreement with Swiss Caps AG (“Swiss”), pursuant to which Swiss currently manufactures the oral insulin capsule developed by us.

During April 2008, we entered into a five year master services agreement with SAFC, an operating division of Sigma-Aldrich, Inc., pursuant to which SAFC is providing services for individual projects, which may include strategic planning, expert consultation, clinical trial services, statistical programming and analysis, data processing, data management, regulatory, clerical, project management, central laboratory services, pre-clinical services, pharmaceutical sciences services, and other research and development services.

On April 21, 2009, we entered into a consulting service agreement with ADRES, pursuant to which ADRES will provide services for the purpose of filing an IND application with the FDA for a Phase 2 study in accordance with FDA requirements. The FDA approval process and, if approved, registration for commercial use as an oral drug can take several years.

On July 8, 2009 we entered into an additional agreement with Hadasit, to facilitate additional clinical trials to be performed at Hadassah Medical Center in Jerusalem.

On February 10, 2010, we entered into agreements with Vetgenerics Research G. Ziv Ltd., a clinical research organization (CRO), to conduct a toxicology trial on our oral insulin capsules.

On May 2, 2010, we entered into an additional agreement with SAFC Pharma, a division of the Sigma-Aldrich Corporation, to develop a process to produce one of our oral capsule ingredients.

On July 5, 2010, our subsidiary entered into an MSA with sanofi-aventis. According to the MSA, sanofi-aventis will supply our subsidiary with specified quantities of recombinant human insulin to be used for clinical trials in the United States.

Out-Licensed Technology

On June 1, 2010, our subsidiary, Oramed Ltd., entered into a joint venture agreement with D.N.A Biomedical Solutions Ltd. (formerly Laser Detect Systems Ltd), an Israeli company listed on the Tel Aviv Stock Exchange ("D.N.A"), for the establishment of a new company to be called Entera Bio Ltd. ("Entera"). Under the terms of a license agreement that was entered into between Oramed and Entera in August 2010, we out-licensed technology to Entera, on an exclusive basis, for the development of oral delivery drugs for certain indications to be agreed upon between the parties. The out-licensed technology differs from our main delivery technology that is used for oral insulin and GLP 1 Analog and is subject to different patent applications. Entera's initial development effort is for an oral formulation for the treatment of osteoporosis. The license was royalty-free unless our ownership interest in Entera decreased to 30% or less of its outstanding share capital, in which case royalties would be payable with respect to revenues derived from certain indications. Under certain circumstances, Entera may have received ownership of the licensed technology, in which case we would have received a license back on the same terms. D.N.A initially invested $600,000 in Entera, and Entera was initially owned in equal parts by Oramed and D.N.A. Entera's Chief Executive Officer, Dr. Phillip Schwartz, will be granted options to purchase ordinary shares of Entera, reflecting 9.9% of Entera's share capital, upon full exercise.

On February 22, 2011, Oramed Ltd. entered into a share purchase agreement with D.N.A for the sale of 47% of Entera's outstanding share capital on an undiluted basis. As consideration for the Entera shares, Oramed received a promissory note issued by D.N.A in the principal amount of $450,000, with an annual interest rate of 0.45%, to be paid within four months from closing, and 8,404,667 ordinary shares of D.N.A, having an aggregate market value of approximately $700,000. In addition, D.N.A agreed to invest $250,000 in our private placement, for which it received 781,250 shares of our common stock and five-year warrants to purchase 273,438 shares of common stock at an exercise price of $0.50 per share.

As part of the transaction, we entered into a patent transfer agreement (to replace the original license agreement upon closing) according to which Oramed assigned to Entera all of its right, title and interest in and to the patent application that it had licensed to Entera in August 2010. Under this agreement, Oramed Ltd. is entitled to receive from Entera royalties of 3% of Entera's net revenues (as defined in the agreement) and a license back of that patent application for use in respect of diabetes and influenza.

The closing of the abovementioned transactions took place on March 31, 2011. On the closing date, Oramed, Entera and D.N.A terminated the joint venture agreement entered into on June 1, 2010 in connection with the formation of Entera.

Government Regulation

Jerome Durso has served as our Chief Operating Officer since February 2017. Mr. Durso has 25 years of experience in building and leading commercial and business operations at life sciences companies both in the United States and abroad. Prior to joining the Company, Mr. Durso served as a consultant to the biopharmaceutical industry from September 2015 to February 2017. Mr. Durso has spent the majority of his career at Sanofi, a global pharmaceutical company, where he most recently served as Senior Vice President, Chief Commercial Officer of the Global Diabetes Division from June 2011 to April 2015. From 2010 to 2011, Mr. Durso was Senior Vice President, Chief Commercial Officer of Sanofi s U.S. pharmaceuticals business. Prior to that, he served in a number of commercial leadership roles of increasing responsibility in business unit and brand management, marketing and sales since he first joined Sanofi in 1993. Mr. Durso earned his bachelor s degree in marketing from the University of Notre Dame.

Lisa Bright has served as our President, International since July 2016. Ms. Bright has over 25 years of experience in the biopharmaceutical industry. Ms. Bright joined the Company in November 2014 as Senior Vice President and Head of Europe and then served as Chief Commercial and Corporate Affairs Officer from February 2015 to July 2016. Prior to joining the Company, Ms. Bright worked at Gilead Sciences Ltd. starting in 2008, where she held positions of increasing responsibility, including: General Manager United Kingdom & Ireland; Vice President, Northern Europe; Vice President, Head of Sovaldi Launch Planning for Europe, Asia, Middle East and Australasia; and Vice President, Government Affairs Europe, Middle East and Australasia. Prior to holding these positions, Ms. Bright held a range of senior positions at GlaxoSmithKline plc, including Vice President and Managing Director of New Zealand and Vice President Sales for the United Kingdom. Ms. Bright has been a director of Ascendis Pharma A/S since April 2017. Ms. Bright has a B.Sc. in pharmacology from University College London.

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David Ford has served as our Chief Human Resources Officer since May 2017. He brings over 25 years of experience in a variety of human resources roles across the United States, Europe, Latin America and New Zealand. Prior to joining the Company, Mr. Ford spent nearly 15 years at Sanofi, where he most recently served as Vice President Human Resources for the Sanofi Genzyme global business unit from January 2016 to May 2017. Prior to that role, from November 2011 through December 2015, Mr. Ford served as Vice President Human Resources for the Sanofi North American businesses. Mr. Ford joined the pharmaceutical industry in 2002 as the HR Director United Kingdom and Republic of Ireland for Sanofi-Synthelabo. Mr. Ford holds a master s degree in business administration from INSEAD, Fontainebleau (France).

Sandip Kapadia has served as our Chief Financial Officer and Treasurer since July 2016. Mr. Kapadia has over 20 years of experience in building and leading finance and administration teams at life sciences companies both in the United States and abroad. Mr. Kapadia joined the Company from Sandoz, Inc., a division of Novartis AG, where he served as Vice President and Chief Financial Officer North America from July 2014 to June 2016. From March 2012 to June 2014, Mr. Kapadia was Vice President and Chief Financial Officer of Novartis Pharmaceuticals UK Limited. Mr. Kapadia also served as Vice President and Chief Financial Officer of Novartis Pharmaceuticals B.V. located in the Netherlands from 2009 to 2012. Prior to that, he served as Head of Finance Oncology Business Unit for both Novartis Pharmaceuticals A.G. and Novartis Pharmaceuticals Corporation. Mr. Kapadia earned his bachelor s degree in business administration and accounting from Montclair State University, an M.B.A from Rutgers Graduate School of Management and is a certified public accountant.

Richard Kim has served as our President, U.S. Commercial & Strategic Marketing since February 2018, having previously served as Senior Vice President, Commercial U.S. since July 2015. He has over 20 years of commercial, marketing and managerial experience in the biopharmaceutical industry in the United States and abroad. Prior to joining the Company, Mr. Kim worked at Bristol-Myers Squibb starting in 2004, where he most recently served as General Manager, Hepatitis C Worldwide Commercialization. Prior to that, Mr. Kim held a number of roles of increasing responsibility at Bristol-Myers Squibb, including Vice President, SPRYCEL Brand Lead, Oncology Global Marketing; Vice President, U.S. In-Line Oncology and Global Marketing for Necitumumab; and Vice President, East Area Sales, Cardiovascular and Metabolics. Prior to holding these positions, Mr. Kim held a range of senior positions in the United States, Canada and Australia at Schering-Plough, which was acquired by Merck & Co., Inc. Mr. Kim earned his bachelor s degree in chemistry from the University of Alberta.

David Shapiro, M.D. has served as our Chief Medical Officer since November 2017, having previously served as our Chief Medical Officer and Executive Vice President, Development since 2008. Dr. Shapiro has over 25 years of clinical development experience in the pharmaceutical industry. Dr. Shapiro founded a consulting company, Integrated Quality Resources, that focused on development stage biopharmaceutical companies and was active in this role from 2005 to 2008. From 2000 to 2005, Dr. Shapiro was Executive Vice President, Medical Affairs and Chief Medical Officer of Idun Pharmaceuticals, Inc., prior to its acquisition by Pfizer Inc. From 1995 to 1998, he was President of the Scripps Medical Research Center at Scripps Clinic. He also served as Vice President, Clinical Research at Gensia and as Director and Group Leader, Hypertension Clinical Research at Merck Research Laboratories from 1985 to 1990. Dr. Shapiro has authored more than 20 peer-reviewed publications and organized and chaired several conferences aimed at improving product development. Dr. Shapiro served for two terms on the Executive Committee of the Board of the American Academy of Pharmaceutical Physicians. Dr. Shapiro has been a director of Arcturus Therapeutics Ltd. since November 2017. Dr. Shapiro received his medical degree from Dundee University & Medical School, and undertook his postgraduate medical training in the university affiliated hospitals in Oxford, United Kingdom and the University of Vermont. He is an elected Fellow of both the Royal College of Physicians of London and the Faculty of Pharmaceutical Physicians of the United Kingdom.

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Ryan Sullivan has served as our General Counsel and Secretary since February 2018. Prior to joining the Company, Mr. Sullivan worked at Anacor Pharmaceuticals, Inc., which was acquired by Pfizer Inc. At Anacor, Mr. Sullivan served as Executive Vice President, General Counsel and Secretary from February 2016 until June 2016 and as Senior Vice President, General Counsel and Secretary from April 2014 until February 2016. Before joining Anacor, Mr. Sullivan worked as an attorney in the legal group of Warner Chilcott plc prior to its acquisition by Actavis plc (now Allergan plc). During his tenure at Warner Chilcott from July 2007 until December 2013, Mr. Sullivan served in a number of positions of increasing responsibility, including most recently as General Counsel and Secretary. Before joining Warner Chilcott, Mr. Sullivan practiced in the New York corporate law group of Cahill Gordon & Reindel LLP. Mr. Sullivan earned his bachelor s of science degree from Cornell University and his juris doctor degree from Cornell Law School.

Christian Weyer, M.D., M.A.S. has served as our EVP, Research & Development since November of 2017. Dr. Weyer s career in metabolic drug development spans more than 20 years, involving clinical studies and regulatory submissions at all stages of product development and across the continuum of diabetes, obesity and NAFLD/NASH. Prior to joining the Company, Dr. Weyer was President and Chief Development Officer at ProSciento, Inc., a leading clinical R&D service provider focused on diabetes, NAFLD/NASH and obesity, from December 2015 to November 2017. Dr. Weyer has served as a senior executive in several companies, including as President, Chief Executive Officer and a director of Fate Therapeutics, Inc. from October 2012 to November 2015, where he steered the company s transition into a publicly-traded cellular therapeutics company, and as Senior Vice President of R&D at Amylin Pharmaceuticals, Inc., where he contributed to the development and approval of several first-in-class medicines for diabetes and lipodystrophy. Before joining Amylin, Dr. Weyer worked at the National Institutes of Health, NIDDK, conducting clinical research on the pathogenesis of obesity and type 2 diabetes. Dr. Weyer received his M.D. and clinical training at the Department of Metabolic Disorders, World Health Organization Collaborating Center for Diabetes Treatment and Prevention, at the University of Düsseldorf, Germany and holds a postdoctoral master s degree in advanced clinical research from the University of California, San Diego.

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EXECUTIVE COMPENSATION

Compensation Discussion and Analysis

This Compensation Discussion and Analysis describes our executive compensation philosophy and how we implemented it through our 2017 compensation program for our principal executive officer, our principal financial officer and our three other most highly compensated executive officers serving at the end of 2017 (the named executive officers):

Name	Title
Mark Pruzanski, M.D.	President and Chief Executive Officer (CEO)
Sandip Kapadia	Chief Financial Officer
Jerome Durso[1]	Chief Operating Officer
David Ford[2]	Chief Human Resources Officer
David Shapiro, M.D.[3]	Chief Medical Officer

(1) Mr. Durso joined the Company in February 2017.

(2) Mr. Ford joined the Company in May 2017.

(3) Dr. Shapiro served as Chief Medical Officer and Executive Vice President, Development until his roles were bifurcated in November 2017, after which time he continued as Chief Medical Officer.

Executive Summary

2017 was a productive year for us. We achieved a number of significant commercial and product development milestones and continued to refine and strengthen our executive compensation programs and corporate governance practices. Highlights are described below.

KEY BUSINESS ACHIEVEMENTS

Recognized Significant Ocaliva Revenues in the United States. We recognized $115.8 million in U.S. net sales of Ocaliva® (obeticholic acid or OCA) in 2017, its first full year of sales in the United States following its launch in June 2016, as compared to $18.2 million in 2016.

Successful Launch of Ocaliva in Europe and Canada. Ocaliva was granted conditional approval for the treatment of primary biliary cholangitis (PBC) by the European Commission in December 2016 and by Health Canada in May 2017. These approvals allowed us to commence our European commercial launch of Ocaliva in certain European countries in January 2017 and in Canada in July 2017. As a result, we recognized $13.4 million in ex-U.S. net sales of Ocaliva in 2017.

Advanced NASH Development Program. We continued our ongoing Phase 3 clinical trial in non-cirrhotic nonalcoholic steatohepatitis (NASH) patients with liver fibrosis, known as the REGENERATE trial. In May 2017, we completed enrollment of the interim analysis cohort for the REGENERATE trial, and we currently expect top-line results from the interim analysis in the first half of 2019. In addition, in July 2017, we announced that the CONTROL trial, a Phase 2 clinical trial designed to characterize the lipid metabolic effects of OCA and cholesterol management effects of concomitant statin administration in NASH patients met its primary endpoint. We also continued to work towards expanding our overall NASH development program with additional trials and studies, including our ongoing Phase 3 trial in NASH patients with compensated cirrhosis, known as the REVERSE trial, which we announced in

February 2018.

Other Product Development Achievements. In addition to PBC and NASH, we continued to invest in research of OCA for additional patient populations with other liver diseases. For example, in July 2017, we announced top-line results of our Phase 2 AESOP trial in primary sclerosing cholangitis (PSC), which evaluated the effects of 24 weeks of treatment with varying doses of OCA compared to placebo. This trial achieved its primary endpoint, which we believe establishes a proof-of-concept of OCA in a second cholestatic liver disease.

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Resolved Ocaliva Label Update. In September 2017, we issued a dear healthcare provider letter and the U.S. Food and Drug Administration (the FDA) also subsequently issued its own safety communication to reinforce recommended dosing in accordance with the Ocaliva label, following the reporting of deaths in certain PBC patients prescribed Ocaliva with moderate or severe hepatic impairment. In an analysis performed by us and in consultation with the FDA, we concluded that these patients were prescribed once daily doses of Ocaliva, which is seven times higher than the recommended weekly dose in such patients. Both communications reminded healthcare providers of the importance of the recommended reduced dosing of Ocaliva in PBC patients with moderate or severe hepatic impairment, while reiterating the importance of monitoring PBC patients for progression of their disease and the occurrence of liver-related adverse reactions. In February 2018, we announced that the Ocaliva label in the United States had been updated by the FDA to include a boxed warning and a dosing table that reinforce the existing dosing schedule for patients with Child-Pugh Class B or C or decompensated cirrhosis, and the FDA issued an updated drug safety communication to accompany the revised label. We are focused on the safety of all of the patients using Ocaliva within and outside of our ongoing clinical studies and, with this updated label, remain confident in the benefit that Ocaliva provides when used as directed in patients with PBC.

Strengthened Executive Leadership Team. We continued to strengthen our leadership team with the addition of a number of talented executives with extensive experience in the biopharmaceutical industry, including Jerome Durso, our new Chief Operating Officer, David Ford, our new Chief Human Resources Officer, Christian Weyer, M.D., M.A.S., our new EVP, Research & Development, and Ryan Sullivan, our new General Counsel and Secretary. We believe that these individuals will provide critical leadership and support for our product development and commercialization efforts, as well as our operations as a commercial-stage public company.

CEO COMPENSATION HIGHLIGHTS

Our CEO

Dr. Mark Pruzanski co-founded our Company and has served as our CEO since our inception in 2002. Dr. Pruzanski has been critical in driving many of our achievements over the past 15 years.

Market-Based CEO Compensation. For 2017, we determined total CEO compensation (including annual equity awards) with reference to the 50th percentile of the competitive market based on our compensation peer group. In 2018, we continued this approach and again determined total CEO compensation (including annual equity awards) with reference to this percentile.

Break-Down of 2017 CEO Compensation

Significant Performance Elements. In 2017, we incorporated significant performance elements into Dr. Pruzanski s annual and long-term incentive compensation arrangements. Approximately 89% of Dr. Pruzanski s 2017 total direct compensation consisted of variable compensation elements dependent on our achievement of corporate performance goals and objectives and our stock price performance.

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TSR-Based Performance Share Units. In 2018, we introduced performance share unit awards (TSR PSUs) that vest, if at all, based on the Total Shareholder Return (TSR) of our common stock relative to that of the companies comprising the S&P Biotechnology Select Industry Index (TSR Peer Group) over a 3-year period, subject to continued employment. As a result, 100% of Dr. Pruzanski s 2018 annual equity awards consisted of performance-based equity awards, with approximately half of the grant date fair value comprised of TSR PSUs and the remaining half comprised of stock options.

Executive Leadership. Our CEO leads a highly-experienced executive team that has enabled our company to achieve the milestones described above.

COMPENSATION AND GOVERNANCE BEST PRACTICES

What We Do

Independent Chairman, Lead Independent Director and Majority Independent Board. Paolo Fundarò serves as our Board s Chairman, and all of the members of our Board (except Dr. Pruzanski) are independent directors. In February 2018, we appointed Gino Santini to serve as our Board s Lead Independent Director, which we believe enhances our Board governance structure and will contribute to the overall effectiveness of our Board. In addition, in April 2018, we appointed Nancy Miller-Rich as a new independent director to our Board.

Independent Compensation Committee. Our Compensation Committee, which is composed entirely of independent directors, provides independent oversight of our compensation programs.

Independent Compensation Consultant. Our Compensation Committee uses an independent executive compensation consulting firm that reports directly to the committee.

Annual Compensation Review and Analysis. Our Compensation Committee conducts an annual assessment of executive compensation to ensure that we provide competitive compensation packages to attract, retain, reward and incentivize our executive management team to achieve success for us and our stockholders.

Multiple Performance Elements. In accordance with our performance-based compensation philosophy, our executive compensation program incorporates multiple performance elements, including target-based cash incentive bonuses payable upon the achievement of corporate and individual goals and objectives, and long-term equity incentive compensation, a substantial portion of which consists of stock options and, commencing with our 2018 annual equity grants, TSR PSUs.

Market Benchmarking and Use of Reference Peer Group. Our Compensation Committee, with the assistance of its independent compensation consultant, annually analyzes similar life science companies to identify a relevant group of peer companies for purposes of ensuring the reasonableness and competitiveness of our executive compensation program.

Stock Ownership Requirements. We have adopted minimum stock ownership guidelines for our Board, CEO and other executive officers, including our named executive officers, which require, within specified periods of time, our non-employee directors to hold Company equity equal to at least 3x their annual cash retainer and our CEO and other executive officers to hold Company equity equal to at least 3x and 1x, respectively, their annual base salary.

Clawback Policy. In early 2018, we adopted a clawback policy that permits the Company to recover, from any current or former executive officer, including any named executive officer, whose fraud or intentional misconduct contributes to the circumstances requiring the Company to prepare an accounting restatement due to material non-compliance of the Company with any financial reporting requirement under U.S. federal securities laws, up to 100% of any incentive-based compensation received by such officer from the Company during the one-year period preceding the date on which the Company is required to prepare such accounting restatement.

Compensation Risk Assessment. In 2018, we strengthened our annual compensation risk assessment review process.

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What We Don t Do

No excise tax gross-ups. We have not provided excise tax gross-ups to any of our named executive officers.
No single-trigger change-in-control protections. The change-in-control protections for our named executive officers are limited to double-trigger arrangements, which do not provide for automatic payment upon the occurrence of a change in control. Instead, such arrangements require both a change in control and a qualifying termination of employment to occur.
Limited perquisites. Our named executive officers generally receive the same benefits as are available to all of our salaried employees, with limited recurring exceptions primarily consisting of fully-paid health insurance premiums.
No automatic or guaranteed annual salary increases. We do not provide for any formulaic or guaranteed base salary increases for our named executive officers.
No guaranteed bonuses. We do not provide guaranteed bonuses to our named executive officers.
No hedging or pledging of Company stock. Our named executive officers and other employees are restricted from engaging in speculative trading activities, including hedging or pledging their company securities as collateral.

STOCKHOLDER ENGAGEMENT

Annual Say-on-Pay . We have determined to hold an advisory vote on the compensation of our named executive officers (a say-on-pay vote) every year. Our 2017 advisory say-on-pay proposal was approved by over 99% of the votes cast on the proposal. Our Compensation Committee took this result into consideration when designing the structure of our 2018 annual compensation program, including the performance-based elements thereof, such as the TSR PSUs granted to our executive officers in early 2018.
Communication with Stockholders. We believe that stockholder engagement is important and we regularly communicate with our largest stockholders. As we mature as a company, we will continue to expand our stockholder engagement efforts. We welcome feedback with respect to our executive compensation practices from all of our stockholders.
Focus on Stockholder Value. Our Compensation Committee members, who are themselves stockholders, approved the compensation for our CEO and other named executive officers with the goal of driving long-term company performance and stockholder returns.

Executive Compensation Philosophy

We have adopted a performance-based compensation philosophy that is intended to attract, retain, reward and incentivize our executive officers to achieve our near-term corporate goals, as well as our long-term strategic objectives. In particular, our philosophy is designed to achieve the following objectives:

reward the achievement of measurable corporate objectives and align executive officers incentives with increasing stockholder value;
attract, retain and motivate highly-talented individuals with the skills and demonstrated abilities necessary to deliver superior execution of our short- and long-term strategic plans and drive our continued success;
provide executive compensation that is competitive with that paid by our peers in the competitive and dynamic biopharmaceutical industry;
appropriately balance cash compensation designed to encourage the achievement of critical annual objectives with equity incentives designed to inspire the achievement of long-term goals and align the interests of our executive officers more closely with those of our stockholders; and
align the compensation principles for our executive officers with those for all employees to help create a company-wide performance culture.

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Our Executive Compensation Process

The Role of the Compensation Committee

Our Compensation Committee is responsible for the evaluation and oversight of our executive compensation program, policies and practices. Accordingly, our Compensation Committee reviews and approves all compensation provided to our named executive officers, including adjustments to base salaries, annual target-based cash incentive bonuses, equity incentive awards, severance arrangements and benefit programs. Our Compensation Committee consists of three members of our Board, each of whom has extensive experience in our industry and is an independent director under applicable Nasdaq and SEC rules. Our Compensation Committee uses its judgment and experience to develop and approve executive compensation decisions, including our Chief Executive Officer s compensation package. In doing so, our Compensation Committee meets with an independent compensation consultant in executive session without our Chief Executive Officer or any other member of management present. Our Compensation Committee also periodically evaluates the need for revisions to our executive compensation program to ensure our program is competitive with the companies with which we compete for executive talent.

Management s Involvement in the Executive Compensation Process

A small number of executive officers, including our Chief Executive Officer, participate in general sessions of our Compensation Committee. Management does not participate in executive sessions of our Compensation Committee. At the request of our Compensation Committee, our Chief Executive Officer provides input and recommendations to the committee on salary adjustments, annual target-based cash incentive bonus amounts and appropriate equity incentive compensation levels in relation to our executive officers other than himself. In formulating these recommendations, our Chief Executive Officer may consider data obtained from third-party sources, including data provided by compensation consultants other than the independent compensation consultant retained by our Compensation Committee.

Use of Independent Compensation Consultants by the Compensation Committee

In designing our executive compensation program, our Compensation Committee considers publicly available compensation data for other companies in the biopharmaceutical industry to help guide its executive compensation decisions at the time of hiring and for subsequent adjustments in compensation. In 2017, our Compensation Committee also retained the services of Radford, an independent compensation consultant and subdivision of Aon plc, to provide it with additional comparative data on executive compensation practices in our industry and to advise it on our executive compensation program generally. For 2017, Radford provided advice and data to our Compensation Committee on executive and director compensation matters, including the selection of our compensation peer group, comparative market pay levels, equity dilution and annual share utilization practices, incentive plan design and emerging market trends. Although our Compensation Committee considers the advice and recommendations of its compensation consultant about our executive compensation program, the committee ultimately makes its own decisions about these matters. Our Compensation Committee determined that the work of Radford did not raise any conflicts of interest in 2017. In making this assessment, our Compensation Committee considered the independence factors enumerated in Rule 10C-1(b) under the Exchange Act and the applicable Nasdaq rules.

Market Benchmarking and Peer Group

Our Compensation Committee references a peer group of publicly traded companies in the biopharmaceutical industry for purposes of gathering data to compare with our existing executive compensation levels and practices and as context for future compensation decisions. Our Compensation Committee, with the assistance of its independent compensation consultant, periodically reviews and updates the compensation peer group, as appropriate, to include companies that the Compensation Committee believes are competitors for executive talent and are similar to us based on a number of criteria, including stage of development, revenue, market capitalization and number of employees. Our Compensation Committee may consider peer group and other industry compensation data and the recommendations of its independent compensation consultant when making decisions related to executive compensation. Our Compensation Committee also considers peer companies identified by proxy advisory firms in the prior year s proxy cycle. Changes in the composition of our compensation peer group from 2016 to 2017 were largely the result of,

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among other things, the replacement of companies that had been acquired or that our Compensation Committee, with the assistance of its independent compensation consultant, no longer considered comparable to us in light of the criteria outlined above. The companies included in our compensation peer group for 2017 were as follows:

ACADIA Pharmaceuticals Inc.	Ionis Pharmaceuticals, Inc.	Seattle Genetics Inc.
Alkermes plc	Ironwood Pharmaceuticals, Inc.	Tesaro, Inc.
Alnylam Pharmaceuticals, Inc.	Neurocrine Biosciences, Inc.	The Medicines Company
bluebird bio, Inc.	Ophthotech Corporation	Ultragenyx Pharmaceutical Inc.
Exelixis, Inc.	Puma Biotechnology, Inc.	United Therapeutics Corporation
Incyte Corporation		

At the beginning of 2017, based on the input and analysis provided by Radford and the recommendation of our Chief Executive Officer (except with respect to his own compensation), our Compensation Committee determined that 2017 target total direct compensation for our Chief Executive Officer and other named executive officers employed by the Company would be determined with reference to the 50th percentile of compensation for executives holding similar positions at the companies in our compensation peer group. In determining each named executive officer s equity incentive award, our Compensation Committee examined peer group compensation data provided by Radford and other related compensation data. When hiring our new Chief Operating Officer and new Chief Human Resources Officer during 2017, our Compensation Committee continued to use this approach, although it supplemented annual compensation with one-time sign-on equity awards as necessary and appropriate to achieve the Company s recruitment and retention objectives and to closely align the interests of the new named executive officer with those of our stockholders.

Annual Compensation Review Process

On an annual basis, our Compensation Committee meets to review the performance of our Chief Executive Officer and our other named executive officers. At these meetings, our Compensation Committee typically invites our Chief Executive Officer to participate in the discussion (excluding discussions pertaining to his own compensation) in order to seek our Chief Executive Officer s input and recommendations with respect to each named executive officer (other than himself) as to:

- the achievement of stated corporate performance objectives;
- the level of contributions made to the general management and guidance of the Company; and
- the amount of any salary increases, cash incentive bonus payouts and new equity awards.

Our Compensation Committee takes into consideration these recommendations and other relevant performance and competitive market factors when it makes its determination on executive compensation matters. Our Compensation Committee also meets to review and decide compensation matters periodically throughout the year.

Consideration of Prior Stockholder Advisory Vote to Approve Named Executive Officer Compensation

We have determined to hold an advisory vote on the compensation of our named executive officers (a say-on-pay vote) every year. Each year, our Compensation Committee considers the outcome of the prior year s say-on-pay vote when making decisions relating to the compensation of our named executive officers and our executive compensation programs and policies. At our 2017 Annual Meeting of Stockholders, our stockholders demonstrated strong support of

our named executive compensation programs, with our 2017 advisory say-on-pay proposal being approved by over 99% of the votes cast on the proposal. Our Compensation Committee took this result into consideration when designing the structure of our 2018 annual compensation program, including the performance-based elements thereof, such as the TSR PSUs granted to our executive officers in early 2018. Our Compensation Committee will continue to take into account future stockholder advisory votes to approve executive compensation and other relevant market developments affecting executive officer compensation in order to determine whether any subsequent changes to our programs and policies are warranted to reflect stockholder concerns or to address market developments.

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Additional Compensation Risk Management Initiatives

We strive to incorporate best practices in our executive compensation program, including by adopting from time to time additional compensation policies and practices that discourage excessive or unnecessary risk-taking. For example, in early 2018, we adopted a clawback policy that permits the Company to recover, from any current or former executive officer, including any named executive officer, whose fraud or intentional misconduct contributes to the circumstances requiring the Company to prepare an accounting restatement due to material non-compliance of the Company with any financial reporting requirement under U.S. federal securities laws, up to 100% of any incentive-based compensation received by such officer from the Company during the one-year period preceding the date on which the Company is required to prepare such accounting restatement. We also strengthened our annual compensation risk assessment review process in 2018.

We have adopted minimum stock ownership guidelines for our Board, Chief Executive Officer and other executive officers, including our named executive officers, which require, within a five-year period, our non-employee directors to hold Company equity equal to at least 3x their annual cash retainer and our Chief Executive Officer and other executive officers to hold Company equity equal to at least 3x and 1x, respectively, their annual base salary. Until the ownership guidelines are satisfied, our non-employee directors and executive officers are required to maintain a minimum retention ratio of at least 50% of their annual equity awards, net of shares sold or withheld solely to pay applicable exercise fees and/or withholding taxes. Any non-employee director or executive officer failing to meet the guidelines within the allotted compliance period will be required to maintain a minimum retention ratio of 100% of net shares after the applicable exercise fees and/or withholding taxes.

We have not provided excise tax gross-ups to any of our named executive officers and change-in-control protections for our named executive officers are limited to double-trigger arrangements, which do not provide for automatic payment upon the occurrence of a change in control. Instead, such arrangements require both a change in control and a qualifying termination of employment to occur. Our named executive officers generally receive the same benefits as are available to all of our salaried employees, with limited recurring exceptions primarily consisting of fully-paid health insurance premiums. We do not provide for any formulaic or guaranteed base salary increases for our named executive officers and we do not provide guaranteed bonuses to our named executive officers. In addition, our employees, including our named executive officers, are restricted from engaging in speculative trading activities, including hedging or pledging their company securities as collateral.

Components of Our Executive Compensation Program

The primary elements of our executive compensation program are:

base salary;
annual target-based cash incentive bonuses;
equity incentive awards;
broad-based health and welfare benefits; and
balanced severance arrangements.

Our Compensation Committee believes that a significant amount of executive compensation should be in the form of at risk incentives and that the pay mix should be strongly weighted toward equity incentive awards in order to provide alignment with long-term stockholder value. However, we do not have a formal or informal policy for a pre-set allocation between long-term and short-term compensation, between cash and non-cash compensation or among different forms of non-cash compensation. Instead, our Compensation Committee, after reviewing information provided by its independent compensation consultant and other relevant data, determines what it believes to be the

appropriate level and mix of the various compensation components. We generally strive to provide our named executive officers with a balance of short-term and long-term incentives to encourage consistently strong performance. Ultimately, the objective in allocating between long-term and currently paid compensation is to ensure adequate base compensation to attract and retain personnel, while providing incentives to maximize long-term value for the Company and its

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stockholders. Therefore, we provide base salaries that meet competitive salary norms and recognize individual performance on an annual basis. We provide an opportunity to earn annual target-based cash incentive bonuses to incentivize and reward superior short-term performance. To further focus our named executive officers on longer-term performance and the creation of stockholder value, we rely upon equity-based awards that vest over a meaningful period of time and the value of which is dependent on stock price performance.

Base Salary

We use base salaries to recognize the experience, skills, knowledge and responsibilities of our employees, including our named executive officers. Base salaries for newly-hired named executive officers typically are established through an arm s-length negotiation at the time the individual is hired, taking into account factors such as the position for which the individual is being considered, the individual s qualifications, prior experience and prior base salary (to the extent available) and competitive market demand. None of our named executive officers is currently party to an employment agreement that provides for automatic or scheduled increases in base salary. However, on an annual basis, our Compensation Committee reviews and evaluates, with input from our Chief Executive Officer (other than with respect to his own base salary), the need for adjustment of the base salaries of our named executive officers based on changes and expected changes in the scope of their responsibilities. Our Compensation Committee also considers promotions, the contributions made by and performance of the named executive officer during the prior fiscal year, the individual s performance over a period of years, overall economic and labor market conditions, the relative ease or difficulty of replacing the individual with a well-qualified person, our overall growth and development as a company, general salary trends in our industry and among our compensation peer group and where the individual s salary falls in the salary range presented by that data. For more information regarding our compensation peer group, see Our Executive Compensation Process Market Benchmarking and Peer Group above. In making decisions regarding salary increases, our Compensation Committee may also draw upon the experience of members of our Board with other companies.

For 2017, our Compensation Committee determined annual base salaries for each of our named executive officers (other than newly-hired named executive officers) based on their overall individual performance in 2016, their increased level of experience and to ensure that their salaries remained competitive with those of similarly-situated executives in our compensation peer group. The annual base salaries for Mr. Durso and Mr. Ford were negotiated in the context of competitive recruitment processes and were determined by our Compensation Committee, which considered the factors described in the preceding paragraph, as well as compensation peer group data and other input provided by Radford and the recommendation of our Chief Executive Officer. For 2017 and, as applicable, 2016, the annual base salaries for each of our named executive officers were as follows:

Named Executive Officer	2017 Salary	2016 Salary	Change from 2016
Mark Pruzanski, M.D.	$ 675,000	$ 620,000	8.87%
Sandip Kapadia	$ 425,000	$ 400,000	6.25%
Jerome Durso[1]	$ 520,000		New hire
David Ford[2]	$ 380,000		New hire
David Shapiro, M.D.	$ 489,300	$ 475,000	3.01%

(1) Mr. Durso joined the Company in February 2017. Mr. Durso s prorated salary for 2017 was $441,333.

(2) Mr. Ford joined the Company in May 2017. Mr. Ford s prorated salary for 2017 was $246,269.

The change to the annual base salary of each named executive officer, as applicable, was effective as of January 1,

2017. Please refer to Compensation Decisions Relating to Fiscal Year 2018 below for a listing of the annual base salaries of each of our named executive officers for 2018.

Annual Target-Based Cash Incentive Bonuses

As part of our performance-based compensation philosophy, our annual target-based cash incentive bonus program is designed to reward our named executive officers for the achievement of specified, measurable annual corporate objectives. At the beginning of each year, the cash incentive bonus opportunity for each

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named executive officer is established as a target percentage of such officer s base salary. The actual annual cash incentive bonus amounts payable to our named executive officers are determined after year end based on our Compensation Committee s evaluation of performance against the corporate objectives and, in the case of our named executive officers other than our Chief Executive Officer, the achievement of individual performance levels. Individual performance of the named executive officers (other than our Chief Executive Officer) is determined by our Compensation Committee after considering the overall performance of the officer and taking into account the recommendations of the Chief Executive Officer.

Our Compensation Committee believes that a cash incentive bonus program based on the evaluation of multiple corporate objectives and individual performance (with respect to our named executive officers other than our Chief Executive Officer) is best-suited for a biopharmaceutical company at our stage of development due to the uncertainties inherent in the development, regulatory approval and commercialization of new drug treatments. Our Compensation Committee also considers the practices of our compensation peer group and overall industry practices as part of its review of our cash incentive bonus program. In order to better align cash incentive bonus payouts with performance, our Compensation Committee may take additional significant corporate achievements into account for the current year s cash incentive bonus calculation that were not contemplated at the time the current year corporate objectives were determined. Our Compensation Committee also has the authority to shift corporate objectives to subsequent fiscal years and to eliminate them for the current year s cash incentive bonus calculation if it determines that underachievement of a goal was primarily caused by circumstances that were beyond the named executive officer s control or if it determines that the business priorities for the year had shifted. Each of our Compensation Committee and Board has authority, in its sole discretion, to review and approve management s evaluation of how we performed against our corporate objectives and the recommended cash incentive bonus payout levels. This authority includes the ability to rate the accomplishment of particular objectives at below, equal to or greater than 100% of target based on the Company s performance.

The target annual cash incentive bonus for each named executive officer is set by our Compensation Committee as a percentage of such officer s base salary. The target percentages approved by our Compensation Committee are typically based on an evaluation of compensation peer group data, as well as consideration of the level of qualification and experience of each named executive officer as well as internal pay comparisons. Based on this evaluation, our Compensation Committee determined to maintain the 2017 annual cash incentive bonus target percentages for our named executive officers at their 2016 levels.

Our annual corporate objectives have historically included the achievement of specific clinical, regulatory, operational and/or financial milestones, with a focus on the advancement of our product candidates in clinical development, the pursuit of various internal initiatives and ensuring adequate funding for our growth. As we continue to transition from a development-stage company to a commercial-stage company, we have begun to introduce precommercial and commercial-related milestones into our annual corporate objectives, with added focus on precommercial and commercial preparedness, commercial sales metrics and regulatory achievements. The corporate objectives are proposed by senior management each year and approved by our Compensation Committee and Board in the beginning of our fiscal year, with such modifications as our Compensation Committee and Board deem appropriate. In connection with such approval, our Compensation Committee and Board conduct a rigorous review designed to ensure that such objectives reflect the corporate performance measures that we believe are most important to the success of our company and will drive stockholder value. In addition, the corporate objectives are set at challenging levels so as to require our named executive officers to expend substantial effort and commitment leveraging their individual and collective skills and competencies to attain such goals and objectives.

For 2017, our annual corporate objectives are summarized below:

achieve certain U.S. and ex-U.S. commercial sales metrics for Ocaliva in PBC;
achieve certain milestones related to our REGENERATE trial in non-cirrhotic NASH patients with liver fibrosis and with respect to additional clinical trials and studies in NASH;
achieve certain milestones related to our research activities for indications other than PBC and NASH; and

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implement certain corporate infrastructure and human resources-related initiatives.

In February 2018, our Compensation Committee considered our performance in light of the above goals, together with other information available to it, and determined that we achieved our 2017 corporate objectives at a level of 85%.

Our Chief Executive Officer s cash incentive bonus is determined solely based on the achievement of corporate goals, whereas the cash incentive bonus for our other named executive officers is based on both our corporate goals and individual performance. Our Compensation Committee s assessment of the individual performance of our named executive officers (other than our Chief Executive Officer) may result in such officers receiving cash incentive bonuses that are higher or lower than the amounts that they would otherwise receive if such bonuses were based on the achievement of corporate goals alone. For 2017, our Compensation Committee reviewed our performance against our 2017 corporate objectives and determined the individual performance of the named executive officers (other than our Chief Executive Officer) after evaluating their individual performance levels in consultation with the Chief Executive Officer. For 2017, the target and actual cash incentive bonuses for each of our named executive officers were as follows:

Named Executive Officer	Target Bonus (as % of Base Salary)	Actual Bonus (as % of Target)
Mark Pruzanski, M.D.	70 %	85 %
Sandip Kapadia	50 %	89 %
Jerome Durso	50 %	100 %
David Ford	50 %	89 %
David Shapiro, M.D.	50 %	70 %

Please refer to Compensation Decisions Relating to Fiscal Year 2018 below for a listing of the target annual cash incentive bonuses for each of our named executive officers for 2018.

Equity Incentive Awards

Our equity incentive program is the vehicle used for providing long-term incentives to our executive officers, including our named executive officers. We believe that equity awards provide our named executive officers with a strong link to our long-term performance, create an ownership culture and help to align the long-term interests of such officers and our stockholders. In addition, we believe that equity awards with a time- or performance-based vesting feature promote retention because these features incentivize our named executive officers to remain in our employment during the vesting period.

To date, we have used equity awards both to compensate our named executive officers in the form of new hire grants at the commencement of their employment and to provide ongoing long-term incentives to such officers as our business has developed. We also generally plan to continue to grant equity awards on at least an annual basis to all of our named executive officers. Typically, stock option and restricted stock (or restricted stock unit) awards granted to our named executive officers vest over a period of four years, subject to continued employment. The exercise price for any Company stock option is set at no less than the fair market value of our common stock on the date of grant, as determined by reference to the closing market price of our common stock on such date.

Annual Equity Awards

In determining the size of the annual equity awards granted to our named executive officers, our Compensation Committee considers recommendations developed by its independent compensation consultant, including information regarding comparative stock ownership of, and equity awards received by, the executives in our compensation peer group and our industry. In addition, our Compensation Committee considers each named executive officer s individual performance and the extent to which such officer has vested in previous equity awards, as well as our overall corporate performance and the potential for enhancing the long-term creation of value for our stockholders.

Annual equity awards to our named executive officers are typically granted each year in conjunction with the review of their individual performance and our overall corporate performance for the previous year. This review typically occurs at meetings of our Compensation Committee held during the first quarter of each year.

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This allows our Compensation Committee to review various metrics related to our performance in the previous year before making award determinations.

In determining the annual equity awards to be granted to our named executive officers in 2017, our Compensation Committee considered, among other things, the value of the annual equity awards received by executives in our compensation peer group and our industry and the size of the annual equity awards as a percentage of our outstanding stock, dilution to existing stockholders and the retention value in the outstanding equity program based on the value of outstanding unvested awards, all of which were considered in light of individual and corporate performance in 2016. To promote our performance-based compensation philosophy, individual equity awards were positioned higher or lower within the compensation peer group range based on the individual performance of each named executive officer.

We believe that a mix of compensation components incentivizes consistently strong performance. In 2017, our Compensation Committee granted to our named executive officers a mix of equity incentive awards, including stock option and restricted stock awards. Our approach reflects what we believe is an appropriate equity allocation, providing our named executive officers with exposure to downside stock-price risk through stock options, while addressing the historically high volatility of our common stock through the restricted stock award component. This approach also helps manage overall dilution levels and the remaining equity pool available under our 2012 Equity Incentive Plan (2012 Plan) in light of our significant recent growth and future potential expansion of company headcount. In 2018, we retained the use of stock option and restricted stock (or restricted stock unit) awards and introduced as part of our annual equity award program performance share unit awards that vest, if at all, based on our TSR relative to that of our TSR Peer Group over a 3-year period, subject to continued employment. Approximately half of the grant date fair value of Dr. Pruzanski s 2018 annual equity award was comprised of such TSR PSUs and the remaining half was comprised of stock options. Our other named executive officers received an equal proportion of the grant date fair value of their 2018 annual equity awards in the form of such TSR PSUs, stock options and restricted stock units. Please refer to Compensation Decisions Relating to Fiscal Year 2018 below for a listing of grants made to each of our named executive officers in connection with our 2018 annual equity award program.

In February 2017, as part of our annual grant process, our Compensation Committee approved the grant of stock option and restricted stock awards to our named executive officers. The stock option awards granted in connection with our 2017 annual grant have (i) a four-year vesting period, with 25% of the shares subject to the award vesting in an initial annual installment following the relevant vesting commencement date and 1/48th of the shares subject to the award vesting each month thereafter, subject to continued employment and (ii) an exercise price of $107.18 per share, the last reported sale price of our common stock on the Nasdaq Global Select Market on the date of grant. The restricted stock awards granted in connection with our 2017 annual grant have a four-year vesting period, with 25% of the shares subject to the award vesting in an initial annual installment following the relevant vesting commencement date and 1/16th of the shares subject to the award vesting each quarter thereafter, subject to continued employment. The grants made to each of our named executive officers in connection with our 2017 annual equity award program are set forth in the following table. Please refer to Components of Our Executive Compensation Program Equity Incentive Awards New Hire Equity Awards below for a listing of grants made to Mr. Durso and Mr. Ford in 2017.

Named Executive Officer	Stock Options	Shares of Restricted Stock
Mark Pruzanski, M.D.	40,000	23,200
Sandip Kapadia	11,600	7,000
David Shapiro, M.D.	10,000	6,000

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New Hire Equity Awards

We grant a new hire equity award in connection with the commencement of a named executive officer s employment as appropriate and necessary to recruit talent, consistent with industry practice. The size of each new hire award is established through an arm s-length negotiation at the time the named executive officer is hired, taking into account factors such as the position for which the individual is being considered, the individual s qualifications and prior experience, any equity awards that the individual will forfeit by leaving his or her former employer and competitive market demand. Typically, stock option and restricted stock (or restricted stock unit) awards granted to our newly-hired named executive officers vest over a period of four years, subject to continued employment.

In connection with the competitive recruitment and hiring of our new Chief Operating Officer, Mr. Durso, and our new Chief Human Resources Officer, Mr. Ford, who commenced employment with the Company in February 2017 and May 2017, respectively, our Compensation Committee granted Mr. Durso and Mr. Ford stock option and restricted stock awards. The grants of such long-term equity incentive awards were instrumental to the recruitment of Mr. Durso and Mr. Ford and were determined by our Compensation Committee, which considered the factors described in the preceding paragraph, as well as compensation peer group data and other input provided by Radford and the recommendation of our Chief Executive Officer. In addition, such grants were designed to closely align the interests of Mr. Durso and Mr. Ford with those of our stockholders and satisfy our retention objectives.

The following table sets forth the new hire equity awards that were granted to Mr. Durso and Mr. Ford. The stock option awards granted to Mr. Durso and Mr. Ford have (i) a four-year vesting period, with 25% of the shares subject to the award vesting in an initial annual installment following the relevant vesting commencement date and 1/48th of the shares subject to the award vesting each month thereafter, subject to continued employment and (ii) an exercise price of $115.93 per share (in the case of Mr. Durso) and $114.90 per share (in the case of Mr. Ford), which was the last reported sale price of our common stock on the Nasdaq Global Select Market on the relevant date of grant. The restricted stock awards granted to Mr. Durso and Mr. Ford have a four-year vesting period, with 25% of the shares subject to the award vesting in an initial annual installment following the relevant vesting commencement date and 1/16th of the shares subject to the award vesting each quarter thereafter, subject to continued employment.

Named Executive Officer	Stock Options	Shares of Restricted Stock
Jerome Durso	20,000	15,000
David Ford	12,000	6,000

Benefits and Other Compensation

We believe that establishing competitive benefit packages for our employees is an important factor in attracting and retaining highly qualified personnel. We maintain broad-based benefits that are provided to all employees, including medical, dental, vision, group life insurance and long- and short-term disability insurance. For our U.S.-based employees, we also provide a 401(k) plan. Under our 401(k) plan, we are permitted to make discretionary contributions and matching contributions, subject to established limits and a vesting schedule. Since 2015, we have matched an employee s contributions to the 401(k) plan up to the first five percent of the employee s salary, subject to such limits. We provide pension, insurance and other benefits to employees located outside the United States in line with those provided to similar employees in their respective countries. Our named executive officers generally receive the same benefits as are available to all of our salaried employees, with limited recurring exceptions primarily consisting of fully-paid health insurance premiums. Our Compensation Committee in its discretion may revise, amend

or add to a named executive officer s benefits and perquisites if it deems it advisable. For example, in particular circumstances, we may agree to reimburse a named executive officer for certain expenses, such as commuting expenses, as an additional incentive to join us in a position where there is high market demand. Whether such expenses are covered and the amount of the reimbursement is determined on a case-by-case basis under the specific hiring circumstances. In 2017, Mr. Kapadia received an aggregate commuting allowance of $2,165 and Dr. Shapiro received an aggregate car allowance of $12,000. Mr. Kapadia ceased receiving such commuting allowance following the second quarter of 2017. See Summary Compensation Table below.

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Severance and Change in Control Benefits

Pursuant to employment agreements or arrangements that we have entered into with our named executive officers, such officers are entitled to specified benefits in the event of the termination of their employment under specified circumstances, including termination in connection with a change in control of the Company. We believe that providing such benefits is consistent with industry practices and helps us to compete for executive talent, as well as to retain and motivate our named executive officers and minimize management distraction created by uncertain job security, particularly in the event of a potential transaction that would be beneficial to our stockholders.

We have structured our change in control benefits as double trigger benefits. In other words, the change in control does not itself trigger benefits. Rather, benefits are paid only if the employment of the named executive officer is terminated under certain circumstances in connection with the change in control. We believe that a double trigger benefit is protective of stockholder value. It prevents unintended windfalls to named executive officers in the event of a change in control absent a qualifying termination, while still incentivizing named executive officers to pursue change in control transactions determined by our Board to be in the best interest of our stockholders.

Please refer to Employment Arrangements with Our Named Executive Officers below for a more detailed discussion of these benefits. We have provided estimates of the value of the severance payments and other benefits that would have been made or provided to our named executive officers under various termination circumstances under the caption Potential Payments and Benefits Upon Termination of Employment or Change in Control below.

Compensation Decisions Relating to Fiscal Year 2018

In February 2018, the annual base salaries of our named executive officers were set by our Compensation Committee as follows, effective January 1, 2018:

Named Executive Officer	2018 Salary	2017 Salary	Change from 2017
Mark Pruzanski, M.D.	$ 702,000	$ 675,000	4.00 %
Sandip Kapadia	$ 442,000	$ 425,000	4.00 %
Jerome Durso	$ 540,800	$ 520,000	4.00 %
David Ford	$ 392,000	$ 380,000	3.16 %
David Shapiro, M.D.	$ 489,300	$ 489,300	

In addition, in February 2018, our Compensation Committee determined to maintain the 2018 annual cash incentive bonus target percentages for our named executive officers at their 2017 levels, and approved cash incentive bonus targets for our named executive officers for 2018 as follows:

Named Executive Officer	Target Bonus (as % of Base Salary)
Mark Pruzanski, M.D.	70 %
Sandip Kapadia	50 %
Jerome Durso	50 %
David Ford	50 %

David Shapiro, M.D.	50	%
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In February 2018, our Compensation Committee approved the following equity grants to our named executive officers:

Named Executive Officer	TSR PSUs	Stock Options	Restricted Stock Units
Mark Pruzanski, M.D.	23,400	45,500	
Sandip Kapadia	5,400	10,500	6,900
Jerome Durso	10,600	20,700	13,600
David Ford	3,400	6,600	4,300
David Shapiro, M.D.	2,300	4,400	2,900

The stock option awards granted in connection with our 2018 annual grant have (i) a four-year vesting period, with 25% of the shares subject to the award vesting in an initial annual installment following the relevant vesting commencement date and 1/48th of the shares subject to the award vesting each month thereafter, subject to continued employment and (ii) an exercise price of $58.74 per share, the last reported sale price of our common stock on the Nasdaq Global Select Market on the date of grant. The restricted stock unit awards granted in connection with our 2018 annual grant have a four-year vesting period, with 25% of the shares subject to the award vesting in an initial annual installment following the relevant vesting commencement date and 1/16th of the shares subject to the award vesting each quarter thereafter, subject to continued employment. The TSR PSUs granted in connection with our 2018 annual grant vest, if at all, based on our TSR relative to that of our TSR Peer Group over a 3-year period, subject to continued employment. The percentage of such TSR PSUs that may vest following such period ranges from 0% to 150% as follows:

Relative TSR	Vesting Percentage
Below 25th Percentile	0 %
25th Percentile	50 %
50th Percentile	100 %
75th Percentile and Above	150 %

The percentage of such TSR PSUs that will vest in the event that our relative TSR falls between the 25th and 75th percentiles will be based on linear interpolation. In addition, if our relative TSR meets or exceeds the 50th percentile, but our absolute TSR over such period is negative, the percentage of such TSR PSUs that will vest will be capped at 100%.

Material Tax and Accounting Considerations

Section 162(m) of the Code generally restricts deductibility for federal income tax purposes of annual individual compensation in excess of $1 million paid to certain executive officers. Prior to the enactment of the Tax Cuts and Jobs Act of 2017 (the TCJA), Section 162(m) provided an exemption from this limitation for qualified performance-based compensation. The TCJA repealed the qualified performance-based compensation exemption, effective for taxable years beginning after December 31, 2017, but provides transition relief for certain contractual arrangements in place as of November 2, 2017 and not modified thereafter. We account for stock-based compensation, including annual and new hire equity awards, in accordance with the requirements of ASC 718.

Our Compensation Committee is informed about the tax deductibility and accounting treatment of compensation when making its compensation determinations. Our Compensation Committee s general policy is to develop and maintain

compensation programs that effectively attract, motivate and retain exceptional executives in a highly competitive environment, which may include payments that might not be deductible if our Compensation Committee believes they are in the best interests of the Company and its stockholders.

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Compensation Committee Report

The information contained in this report shall not be deemed to be soliciting material, filed with the SEC or incorporated by reference into any filing under the Securities Act or the Exchange Act, or subject to the liabilities of Section 18 of the Exchange Act, except to the extent that the Company specifically incorporates it by reference into a document filed under the Securities Act or the Exchange Act.

The Compensation Committee of the Board of Directors of the Company has reviewed and discussed the Compensation Discussion and Analysis required by Item 402(b) of Regulation S-K with the Company s management. Based on such review and discussions, the Compensation Committee recommended to the Board of Directors that the Compensation Discussion and Analysis be included in this proxy statement and incorporated by reference in the Company s Annual Report on Form 10-K for the year ended December 31, 2017.

By the Compensation Committee of the Board of Directors of Intercept Pharmaceuticals, Inc.,

Gino Santini, *Chairperson*
Srinivas Akkaraju, M.D., Ph.D.
Daniel Welch

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Summary Compensation Table

The following table summarizes the compensation that was earned by our named executive officers for the year ended December 31, 2017 and, as applicable, the years ended December 31, 2016 and 2015.

Name and Principal Position	Year[1]	Salary ($)[2]	Bonus ($)[3]	Stock Awards ($)[4]	Option Awards ($)[4]	Non-Equity Incentive Plan Compensation ($)[5]	All Other Compensation ($)[6]	Total ($)
Mark Pruzanski, M.D.	2017	675,000		2,486,576	2,583,556	401,625	7,930	6,154,687
President and Chief Executive Officer	2016	620,000		2,196,957	1,608,449	347,000	4,627	4,777,033
	2015	600,000		2,433,516	2,967,359	420,000	4,627	6,425,502
Sandip Kapadia	2017	425,000		750,260	749,231	188,594	23,930	2,137,016
Chief Financial Officer	2016	200,000	75,000	2,195,400	1,559,019	183,000	7,057	4,219,476
Jerome Durso								
Chief Operating Officer	2017	441,333		1,738,950	1,395,217	260,000	26,765	3,862,266
David Ford								
Chief Human Resources Officer	2017	246,269		689,400	788,343	168,625	20,010	1,912,647
David Shapiro, M.D.	2017	489,300		643,080	645,889	171,255	30,330	1,979,854
Chief Medical	2016	475,000		735,462	537,908	190,000	29,877	1,968,247
Officer	2015	460,000		829,974	1,194,237	184,000	29,877	2,698,088

(1) Mr. Kapadia, Mr. Durso and Mr. Ford joined the Company in July 2016, February 2017 and May 2017, respectively. Dr. Shapiro served as Chief Medical Officer and Executive Vice President, Development until his roles were bifurcated in November 2017, after which time he continued as Chief Medical Officer.

(2) Reflects (i) prorated 2016 salary for Mr. Kapadia, who was hired during 2016 and (ii) prorated 2017 salaries for Mr. Durso and Mr. Ford, each of whom were hired during 2017.

(3) Reflects for Mr. Kapadia in 2016, a sign-on cash bonus in the amount of $75,000 paid in connection with the commencement of his employment in July 2016.

(4) Amounts shown represent the aggregate grant date fair value for the fiscal years presented, computed in accordance with ASC 718, in respect of restricted stock and option awards, as applicable. Assumptions used in the calculation of these amounts are included in Note 14 to the Notes to Consolidated Financial Statements for the year ended December 31, 2017, included in our Annual Report. Amounts shown do not reflect the compensation actually received by the named executive officers. For Mr. Kapadia in 2016 and Mr. Durso and Mr. Ford in 2017, such amounts reflect such individuals new-hire equity awards.

(5) Amounts shown reflect target-based cash incentive bonuses earned with respect to the fiscal years presented based on our Compensation Committee s evaluation of the relevant named executive officer s performance against corporate objectives and, in the case of named executive officers other than our Chief Executive Officer, individual performance levels. See Compensation Discussion and Analysis Components of Our Executive Compensation Program Annual Target-Based Cash Incentive Bonuses above for a discussion of the target and actual cash

incentive bonuses for each of the named executive officers with respect to 2017.

(6) The following table sets forth the component amounts presented in the All Other Compensation column above for the year ended December 31, 2017:

Name	Contributions Under 401(k) Plan ($)[i]	Health Insurance ($)[ii]	Commuting/ Car Allowance ($)[iii]	Counsel Fees ($)[iv]
Mark Pruzanski, M.D.		7,930		
Sandip Kapadia	13,500	8,265	2,165	
Jerome Durso	13,500	8,265		5,000
David Ford	9,500	5,510		5,000
David Shapiro, M.D.	13,500	4,830	12,000	

(i) Represents the annual contribution of the Company under the terms of its 401(k) Plan.

(ii) Represents the amount paid by the Company for health insurance premiums above the amounts generally paid for the coverage of its employees.

(iii) Represents an aggregate commuting allowance of $2,165 paid to Mr. Kapadia and a car allowance of $1,000 per month paid to Dr. Shapiro. Mr. Kapadia ceased receiving such commuting allowance following the second quarter of 2017.

(iv) Represents the amount paid by the Company in respect of attorney s fees incurred by Mr. Durso and Mr. Ford in connection with the review and negotiation of their employment agreements.

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Grants of Plan-Based Awards Table

The following table sets forth information concerning the named executive officers 2017 annual cash incentive bonus award opportunities and 2017 grants of restricted stock and stock options under our 2012 Plan. All stock options granted to our named executive officers are incentive stock options, to the extent permissible under the Code.

Name	Grant Date	Estimated Future Payout Under Non-Equity Incentive Plan Awards Target ($)[4]	All Other Stock Awards: Number of Shares of Stock (#)[5]	All Other Option Awards: Number of Securities Underlying Options (#)[6]	Exercise or Base Price of Option Awards ($/Sh)[7]	Grant Date Fair Value of Stock and Option Awards ($)[8]
Mark Pruzanski, M.D.		472,500				
	02/01/17 [1]		23,200			2,486,576
	02/01/17 [1]			40,000	107.18	2,583,556
Sandip Kapadia		212,500				
	02/01/17 [1]		7,000			750,260
	02/01/17 [1]			11,600	107.18	749,231
Jerome Durso		260,000				
	02/23/17 [2]		15,000			1,738,950
	02/23/17 [2]			20,000	115.93	1,395,217
David Ford		190,000				
	05/08/17 [3]		6,000			689,400
	05/08/17 [3]			12,000	114.90	788,343
David Shapiro, M.D.		244,650				
	02/01/17 [1]		6,000			643,080
	02/01/17 [1]			10,000	107.18	645,889

(1) Represents annual equity grants made to Dr. Pruzanski, Mr. Kapadia and Dr. Shapiro in 2017, as more fully described under Compensation Discussion and Analysis Components of Our Executive Compensation Program Equity Incentive Awards Annual Equity Awards above. Such awards have a vesting commencement date of January 1, 2017.

(2) Represents grants made to Mr. Durso in connection with his appointment as Chief Operating Officer of the Company in February 2017, as more fully described under Compensation Discussion and Analysis Components of Our Executive Compensation Program Equity Incentive Awards New Hire Equity Awards above. Such awards have a vesting commencement date of February 23, 2017.

(3) Represents grants made to Mr. Ford in connection with his appointment as Chief Human Resources Officer of the Company in May 2017, as more fully described under Compensation Discussion and Analysis Components of Our Executive Compensation Program Equity Incentive Awards New Hire Equity Awards above. Such awards have a vesting commencement date of May 8, 2017.

(4) Represents the potential 2017 cash incentive bonus payouts assuming target achievement of corporate goals and, as applicable, individual performance, based upon the named executive officer s cash incentive bonus target and base salary in effect on December 31, 2017. No minimum threshold amount or maximum amount beyond the target

amount was established. See the column entitled Non-Equity Incentive Plan Compensation in the Summary Compensation Table for the cash incentive bonuses earned by the named executive officers in 2017 and paid in 2018.

(5) Represents grants of restricted stock made to the named executive officers in 2017. Such awards have a four-year vesting period, with 25% of the shares subject to the award vesting in an initial annual installment following the relevant vesting commencement date and 1/16th of the shares subject to the award vesting each quarter thereafter, subject to continued employment.

(6) Represents grants of stock options made to the named executive officers in 2017. Such awards have a four-year vesting period, with 25% of the shares subject to the award vesting in an initial annual

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installment following the relevant vesting commencement date and 1/48th of the shares subject to the award vesting each month thereafter, subject to continued employment.

(7) Represents the closing market price of the shares on the date of the grant.

(8) Amounts shown represent the aggregate grant date fair value, computed in accordance with ASC 718, in respect of restricted stock and option awards, as applicable, granted in 2017. Assumptions used in the calculation of these amounts are included in Note 14 to the Notes to Consolidated Financial Statements for the year ended December 31, 2017, included in our Annual Report.

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Outstanding Equity Awards at Fiscal Year-End Table

The following table sets forth information concerning unexercised stock options and unvested restricted stock for each of the named executive officers outstanding as of December 31, 2017. The closing market price of the shares on December 31, 2017 was $58.42.

	Option Awards					Stock Awards	
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable[10]		Option Exercise Price ($)	Option Expiration Date	Number of Units of Stock That Have Not Vested (#)[14]	Market Value of Units of Stock That Have Not Vested ($)
Mark Pruzanski, M.D.	50,039[1]			8.6667	08/16/20	294 [15]	17,175
	34,404[2]			8.6667	10/13/21	4,719 [16]	275,684
	46,158[3]			21.50	11/16/22	13,106[17]	765,653
	62,595[4]			31.90	05/07/23	23,200[18]	1,355,344
	5,614 [5]	119	[5]	266.01	04/11/24		
	11,465[6]	11,466	[6]	266.01	04/11/24		
	23,734[7]	8,816	[7]	161.16	10/01/25		
	14,615[8]	15,885	[8]	94.29	02/11/26		
		40,000	[11]	107.18	02/01/27		
Sandip Kapadia	6,375 [9]	11,625	[9]	146.36	07/01/26	10,312[19]	602,427
		11,600	[11]	107.18	02/01/27	7,000 [18]	408,940
Jerome Durso		20,000	[12]	115.93	02/23/27	15,000[20]	876,300
David Ford		12,000	[13]	114.90	05/08/27	6,000 [21]	350,520
David Shapiro, M.D.	5,786 [3]			21.50	11/16/22	94 [15]	5,491
	21,031[4]			31.90	05/07/23	1,609 [16]	93,998
	1,797 [5]	38	[5]	266.01	04/11/24		
	4,127 [6]	4,128	[6]	266.01	04/11/24	4,387 [17]	256,289
	9,552 [7]	3,548	[7]	161.16	10/01/25	6,000 [18]	350,520
	4,888 [8]	5,312	[8]	94.29	02/11/26		
		10,000	[11]	107.18	02/01/27		

(1) These options were granted on August 16, 2010.

(2) These options were granted on October 13, 2011.

(3) These options were granted on November 16, 2012.

(4) These options were granted on May 7, 2013.

(5) These options were granted on April 11, 2014, with a vesting commencement date of January 1, 2014.

(6) These options were granted on April 11, 2014, with a vesting commencement date of January 1, 2014. Such options vest upon the achievement of certain regulatory milestones related to OCA.

(7) These options were granted on October 1, 2015, with a vesting commencement date of January 1, 2015.

(8) These options were granted on February 11, 2016, with a vesting commencement date of January 1, 2016.

(9) These options were granted on July 1, 2016, with a vesting commencement date of July 1, 2016.

(10)

Unless otherwise noted, unexercisable stock option awards are subject to a four-year vesting period, with 25% of the shares subject to the award vesting in an initial annual installment following the relevant vesting commencement date and 1/48th of the shares subject to the award vesting each month thereafter, subject to continued employment.

(11) These options were granted on February 1, 2017, with a vesting commencement date of January 1, 2017.

(12) These options were granted on February 23, 2017, with a vesting commencement date of February 23, 2017.

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(13) These options were granted on May 8, 2017, with a vesting commencement date of May 8, 2017.

(14) Unvested restricted stock awards have a four-year vesting period, with 25% of the shares subject to the award vesting in an initial annual installment following the relevant vesting commencement date and 1/16th of the shares subject to the award vesting each quarter thereafter, subject to continued employment.

(15) This restricted stock was granted on April 11, 2014, with a vesting commencement date of January 1, 2014.

(16) This restricted stock was granted on October 1, 2015, with a vesting commencement date of January 1, 2015.

(17) This restricted stock was granted on February 11, 2016, with a vesting commencement date of January 1, 2016.

(18) This restricted stock was granted on February 1, 2017, with a vesting commencement date of January 1, 2017.

(19) This restricted stock was granted on July 1, 2016, with a vesting commencement date of July 1, 2016.

(20) This restricted stock was granted on February 23, 2017, with a vesting commencement date of February 23, 2017.

(21) This restricted stock was granted on May 8, 2017, with a vesting commencement date of May 8, 2017.

Option Exercises and Stock Vested Table

The following table sets forth the number of shares and value realized by the named executive officers during 2017 on the exercise of stock options and the vesting of restricted stock (or restricted stock units).

	Option Awards		Stock Awards	
Name	Number of Shares Acquired on Exercise (#)	Value Realized on Exercise ($)(1)	Number of Shares Acquired on Vesting (#)	Value Realized on Vesting ($)(2)
Mark Pruzanski, M.D.	40,000	4,885,196	15,624	1,606,766
Sandip Kapadia			4,688	508,454
Jerome Durso				
David Ford				
David Shapiro, M.D.	4,835	490,555	5,264	541,420

(1) The value realized on the exercise of options was calculated by multiplying the number of options exercised on the applicable exercise date by the difference between the closing market price of the shares on such date and the exercise price of the options.

(2) The value realized on the vesting of restricted stock (or restricted stock units) was calculated by multiplying the number of shares vesting on the applicable vesting date by the closing market price of the shares on such date.

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Equity Compensation Plan Information

The following table provides information as of December 31, 2017 with respect to shares that may be issued under our equity compensation plans.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance
Equity Compensation Plans Approved by Security Holders[1]	2,301,458[2]	$ 114.70 [3]	1,885,651 [4]
Equity Compensation Plans Not Approved by Security Holders			

(1) All of our equity compensation plans have been approved by security holders. Our equity compensation plans are described in Note 14 to the Notes to Consolidated Financial Statements for the year ended December 31, 2017, included in our Annual Report.

(2) Consists of 1,659,682 shares issuable upon the exercise of stock options, 426,323 shares of restricted stock and 66,428 shares issuable upon the vesting of restricted stock units outstanding under the 2012 Plan and 149,025 shares issuable upon the exercise of stock options outstanding under our 2003 Stock Incentive Plan (the 2003 Plan).

(3) Does not take into account outstanding shares of restricted stock or restricted stock units, which do not require the payment of any exercise price in connection with the vesting thereof.

(4) As of December 31, 2017, there were 1,885,651 shares available for future grants under the 2012 Plan. No shares are available for future grants under the 2003 Plan. Shares underlying awards outstanding under the 2003 Plan that expire or are forfeited or cancelled become available for issuance under the 2012 Plan. The number of shares available for future grants under the 2012 Plan automatically increases on January 1st of each year until (and including) January 1, 2022 by an amount equal to the lesser of (i) 1,211,533 shares, (ii) 4% of the total number of shares outstanding on such date and (iii) an amount determined by our Board or Compensation Committee. Accordingly, on January 1, 2018, the number of shares available for future grants increased by 1,010,693 shares.

Compensation Risk Management

The Company, with the assistance of an independent compensation consultant, Radford, has reviewed Company compensation policies and practices and determined that those policies and practices do not create risks that are reasonably likely to have a material adverse effect on the Company. In conducting this review, we considered various features of our compensation policies and practices that discourage excessive or unnecessary risk-taking, including, but not limited to, the following:

oversight of our compensation policies and practices by our Compensation Committee, including with respect to performance goal setting and the evaluation of achievement thereof;

an effective balance between fixed and variable compensation, and short-term and long-term incentive opportunities;
diversity in long-term incentive vehicles;
the adoption of performance measures that support the achievement of key goals and the Company s business strategy;
the incorporation of risk-mitigating features in the Company s compensation program; and
reasonable severance and change of control arrangements.

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Employment Arrangements with Our Named Executive Officers

We have entered into individual agreements with our named executive officers. In addition, the agreements governing equity awards granted to our employees, including our named executive officers, contain provisions relating to the treatment of such awards in the event of certain terminations. The material terms of these agreements are summarized below. See Termination-Related Provisions Definitions below for the meanings of certain terms used in this section.

Basic Terms

The employment agreements with each of our named executive officers provide for (i) an annual base salary, which is subject to annual review and increase (but not decrease), as determined by our Board or Compensation Committee, (ii) eligibility for an annual target-based cash incentive bonus equal to a percentage of such officer s base salary and (iii) eligibility to participate in the Company s benefit plans and arrangements, including fully-paid health insurance premiums, in each case, as described in greater detail under Compensation Discussion and Analysis Components of Our Executive Compensation Program above. The employment agreements with each of our named executive officers have initial terms of one year with automatic renewal each year thereafter unless either party elects not to renew or earlier terminates the agreement.

Termination-Related Provisions

Termination for Any Reason

Upon any termination of employment, each named executive officer is entitled to receive accrued but unpaid salary (including payment of accrued but unused vacation days), such officer s vested equity awards and any other accrued benefits under the Company s benefit plans or such officer s employment agreement. In addition, Dr. Pruzanski will be entitled to receive an amount equal to his cash incentive bonus for the year preceding the year in which termination occurs, to the extent unpaid, and a prorated cash incentive bonus for the year in which termination occurs, payable in a lump sum. All unvested equity awards held by the named executive officer would be forfeited and such officer would have, in the case of (i) Dr. Pruzanski, three years and (ii) the named executive officers other than Dr. Pruzanski, 90 days (or, in each case, the remaining term of the options if shorter) following termination to exercise any vested options.

Termination Without Cause or Resignation for Good Reason

In the event that the Company elects not to renew the employment agreement of a named executive officer, such officer is terminated by the Company without cause or such officer resigns with good reason, such officer will be entitled to receive (i) cash severance in an amount equal to 12 months of such officer s base salary in effect at the time of termination, payable over 12 months (or, in the case of Dr. Shapiro, in a lump sum), (ii) continued health benefits for up to 12 months following termination and (iii) the same benefits as described under Termination for Any Reason above, except that, in the case of (A) Dr. Pruzanski, all unvested equity awards held by Dr. Pruzanski will vest, Dr. Pruzanski will have three years (or the remaining term of the options if shorter) following termination to exercise any vested options and, in lieu of the prorated cash incentive bonus for the year in which termination occurs, Dr. Pruzanski will be entitled to an amount equal to the mean bonus earned by him during the prior three years, payable in a lump sum, and (B) the named executive officers other than Dr. Pruzanski, the number of unvested equity awards held by such officer that would otherwise have vested during the period from the date of termination to the first anniversary

thereof will vest, such officer will have one year (or the remaining term of the options if shorter) following termination to exercise any vested options and all remaining unvested equity awards held by such officer would be forfeited.

Termination Without Cause or Resignation for Good Reason in Connection with a Change in Control

In the event that the Company elects not to renew the employment agreement of a named executive officer, such officer is terminated by the Company without cause or such officer resigns with good reason, in each case, in anticipation of, within three months before (in the case of Dr. Pruzanski) or within 12 months following a change in control, such officer will be entitled to receive the same benefits as described under Termination Without Cause or Resignation for Good Reason above, except that, in the case of

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(i) Dr. Pruzanski, the cash severance will be in an amount equal to 24 months of Dr. Pruzanski s base salary in effect at the time of termination and payable in a lump sum, the health benefits will continue for up to 24 months following termination and, in lieu of the mean bonus earned by him during the prior three years, Dr. Pruzanski will be entitled to an amount equal to two times the mean bonus earned by him during the prior three years and (ii) the named executive officers other than Dr. Pruzanski, the cash severance amount will be payable in a lump sum, all unvested equity awards held by such officer will vest and such officer will have one year (or the remaining term of the options if shorter) following termination to exercise any vested options.

Termination in the Event of Death or Disability

In the event of termination by reason of a named executive officer s death or disability, such officer will be entitled to receive the same benefits as described under Termination for Any Reason above, except that, in the case of (i) Dr. Pruzanski, all unvested equity awards held by Dr. Pruzanski will vest, Dr. Pruzanski (or his estate or legal representative, as applicable) will have three years (or the remaining term of the options if shorter) following termination to exercise any vested options and, in the case of a termination due to disability, Dr. Pruzanski will be entitled to (A) continued health benefits for up to 12 months following termination and (B) solely to the extent that Dr. Pruzanski is not eligible to participate in Company-sponsored short- and long-term disability plans that provide for benefits of at least 60% of base salary, cash severance in an amount equal to 12 months of his base salary in effect at the time of termination, payable over 12 months, and (ii) the named executive officers other than Dr. Pruzanski, a prorated portion (based on the number of days accrued in the current vesting period prior to the date of termination) of the unvested options held by such officer that would otherwise have vested on the next vesting date will vest and such officer (or such officer s estate or legal representative, as applicable) will have one year (or the remaining term of the options if shorter) following termination to exercise any vested options and all remaining unvested equity awards held by such officer would be forfeited.

Release of Claims

Eligibility for the severance payments and benefits described above is conditioned upon the execution by the named executive officer (or such officer s legal representative, as applicable) and effectiveness, within a specified period of time following termination, of a general release of claims in favor of the Company.

Certain Code-Related Provisions

If any amounts owed to a named executive officer as a result of a termination in connection with a change in control of the Company would be subject to the excise tax imposed by Section 4999 of the Code, then such amounts will be payable either (i) in full or (ii) solely to the extent that the after-tax value of such amounts to such officer would be greater as a result of such reduction, as to such reduced amount that would maximize the after-tax value of such amounts to such officer.

In addition, the timing of payments may be modified by us to comply with Section 409A of the Code.

Definitions

Under the employment agreements with our named executive officers:

cause generally means (i) that the officer has engaged in material dishonesty, willful misconduct or gross negligence or has materially breached the employment agreement, and has failed to cure such conduct or breach within 30 days after receipt of written notice from us or (ii) the officer s conviction or entry of nolo contendere to any crime involving

moral turpitude, fraud or embezzlement or any felony;

change in control generally means (i) any sale, lease, exchange or other transfer (in one transaction or a series of transactions) of all or substantially all of the assets of the Company, (ii) any consolidation or merger of the Company where the stockholders of the Company immediately prior to the consolidation or merger, would not, immediately after the consolidation or merger, beneficially own, directly or indirectly, shares representing in the aggregate more than 50% of the combined voting power of all the outstanding securities of the corporation issuing cash or securities in the consolidation or merger (or of its ultimate parent corporation, if any) or (iii) a third person (other than the Company, any employee benefit plan of the Company or investors

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purchasing equity securities of the Company pursuant to a financing or a series of financings approved by our Board) becomes the beneficial owner, directly or indirectly, of securities representing 25% or more of the total number of votes that may be cast for the election of the directors of the Company; and

good reason generally means a material (i) change in the officer s duties, position, responsibilities or reporting requirements, (ii) relocation or (iii) breach of the employment agreement by us, in each case without the officer s consent and subject to the officer giving us sufficient notice and time to cure the event giving rise to such good reason.

Confidential Information and Assignment of Inventions Agreements

Each of our named executive officers has entered into an agreement with us with respect to proprietary information and inventions. Among other things, these agreements obligate each named executive officer to refrain from disclosing any of our proprietary information received during the course of employment or soliciting our employees and to assign to us any inventions conceived or developed during the course of employment.

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Potential Payments and Benefits Upon Termination of Employment or Change in Control

As described under Employment Arrangements with Our Named Executive Officers above, we have entered into individual agreements with our named executive officers providing for severance payments and benefits in the event of certain terminations of employment, including in connection with a change of control. In addition, the agreements governing equity awards granted to our employees, including our named executive officers, contain provisions relating to the treatment of such awards in the event of certain terminations. The following table sets forth estimates of the payments and benefits each named executive officer would have been entitled to receive from the Company upon a termination of employment under the circumstances described in the table effective December 31, 2017. In the case of Dr. Pruzanski, such payments and benefits are inclusive or in lieu of a cash payment in the amount of $472,500 that he would have been entitled to upon a termination of employment for any reason effective December 31, 2017.

In accordance with SEC rules, the potential payments were determined under the terms of the Company s contracts, agreements, plans and arrangements as in effect on December 31, 2017. The tables do not include any previously vested equity awards or accrued benefits. Because the payments to be made to a named executive officer depend on several factors, the actual amounts to be paid out upon a triggering event can only be determined at the time of the triggering event.

Name			Termination Due to Death ($)[4]	Termination Due to Disability ($)[5]	Termination Without Cause or Resignation for Good Reason ($)[6]	Termination Without Cause or Resignation for Good Reason In Connection with a Change of Control ($)[7]
Mark Pruzanski, M.D.						
	Cash Payments	(1)	472,500	1,147,500	1,039,750	2,079,500
	Value of Accelerated Vesting	(2)	2,413,856	2,413,856	2,413,856	2,413,856
	Health Insurance Benefits	(3)		29,342	29,342	58,684
	Total		2,886,356	3,590,698	3,482,948	4,552,040
Sandip Kapadia						
	Cash Payments	(1)			425,000	425,000
	Value of Accelerated Vesting	(2)			398,015	1,011,367
	Health Insurance Benefits	(3)			30,199	30,199
	Total				853,214	1,466,566

Jerome Durso				
	Cash Payments	(1)	520,000	520,000
	Value of Accelerated Vesting	(2)	383,410	876,300
	Health Insurance Benefits	(3)	30,199	30,199
	Total		933,609	1,426,499
David Ford				
	Cash Payments	(1)	380,000	380,000
	Value of Accelerated Vesting	(2)	131,445	350,520
	Health Insurance Benefits	(3)	30,199	30,199
	Total		541,644	760,719
David Shapiro, M.D.				
	Cash Payments	(1)	489,300	489,300
	Value of Accelerated Vesting	(2)	347,950	706,298
	Health Insurance Benefits	(3)	20,502	20,502
	Total		857,752	1,216,100

(1) Includes cash severance payments calculated based on base salary in effect on December 31, 2017.

(2) The value realized upon the accelerated vesting of (i) stock options is calculated by multiplying the number of options subject to accelerated vesting by the difference between the closing market price of the shares on December 31, 2017 and the weighted-average exercise price of such options and (ii) restricted stock is calculated by

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multiplying the number of shares of restricted stock subject to accelerated vesting by the closing market price of the shares on December 31, 2017. The closing market price of the shares on December 31, 2017 was $58.42.

(3) Represents the estimated cost to the Company of continuing health insurance benefits for the named executive officers.

(4) See Employment Arrangements with Our Named Executive Officers Termination-Related Provisions Termination in the Event of Death or Disability above for a description of the circumstances that would trigger the payment of amounts set forth in this column.

(5) See Employment Arrangements with Our Named Executive Officers Termination-Related Provisions Termination in the Event of Death or Disability above for a description of the circumstances that would trigger the payment of amounts set forth in this column. Assumes that Dr. Pruzanski is not eligible to participate in Company-sponsored short- and long-term disability plans that provide for benefits of at least 60% of base salary.

(6) See Employment Arrangements with Our Named Executive Officers Termination-Related Provisions Termination Without Cause or Resignation for Good Reason above for a description of the circumstances that would trigger the payment of amounts set forth in this column.

(7) See Employment Arrangements with Our Named Executive Officers Termination-Related Provisions Termination Without Cause or Resignation for Good Reason in Connection with a Change in Control above for a description of the circumstances that would trigger the payment of amounts set forth in this column.

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Pay Ratio Disclosure

In accordance with the requirements of Section 953(b) of the Dodd-Frank Act and Item 402(u) of Regulation S-K (collectively, the Pay Ratio Rule), we are providing the following estimated information for 2017:

the median of the annual total compensation of all of our employees (excluding our Chief Executive Officer) was $218,938;

the annual total compensation of our Chief Executive Officer was $6,154,687; and

the ratio of these two amounts was approximately 28 to 1. We believe that this ratio is a reasonable estimate calculated in a manner consistent with the requirements of the Pay Ratio Rule.

SEC rules for identifying the median employee and calculating annual total compensation allow companies to apply various methodologies and make various assumptions and, as result, the pay ratio reported by us may not be comparable to the pay ratio reported by other companies.

Methodology for Identifying Our Median Employee

Employee Population

To identify the median of the annual total compensation of all of our employees (other than our Chief Executive Officer), we first identified our total domestic and foreign employee population. We selected December 31, 2017 as the date upon which we would identify our median employee . We determined that, as of December 31, 2017, we had 507 employees. We did not make any adjustments to our employee population.

Determining our Median Employee

To identify our median employee from our total employee population, we compared each employee s aggregate 2017 base salary (annualized in the case of newly hired employees), cash incentive target and equity award grant date fair value, in each case, converted into U.S. dollars as necessary. We identified our median employee using this compensation measure, which was consistently applied to all our employees included in the calculation.

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RELATED PERSON TRANSACTIONS

Public Offering and Concurrent Private Placement

In April 2018, we issued and sold (i) 2,695,313 shares in a registered public offering, at a price to the public of $64.00 per share (the Public Offering) and (ii) 1,562,500 shares (the Private Placement Shares) in a private placement exempt from the registration requirements of the Securities Act, at a purchase price per share equivalent to the price to the public set in the Public Offering and pursuant to a securities purchase agreement (the Securities Purchase Agreement) that we entered into with Genextra, Samsara BioCapital, L.P. and certain other purchasers named therein (the Concurrent Private Placement).

Drs. Pruzanski and Gottesdiener and Mr. Bradbury purchased 7,812 shares, 1,171 shares and 7,812 shares, respectively, in the Public Offering and Genextra and Samsara BioCapital, L.P. purchased 390,625 shares and 234,375 shares, respectively, in the Concurrent Private Placement. Genextra is our largest existing stockholder. Mr. Fundarò is the Chief Financial Officer of Genextra and Dr. Akkaraju is a managing member of Samsara BioCapital GP, LLC, the general partner of Samsara BioCapital, L.P.

Pursuant to the Securities Purchase Agreement, we granted to the purchasers in the Concurrent Private Placement (the Private Placement Purchasers) certain registration rights requiring us, upon request delivered by one or more of the Private Placement Purchasers (and/or certain affiliate transferees thereof) on or after June 5, 2018 and subject to certain terms and conditions, to register the resale by such Private Placement Purchasers (and/or such affiliates) of the Private Placement Shares held by them.

Limitation on Liability and Indemnification Matters

Our Restated Certificate of Incorporation and Restated Bylaws provide that we will indemnify our directors and officers, and may indemnify our employees and other agents, to the fullest extent permitted by law. Under our Restated Certificate of Incorporation and/or Restated Bylaws, we are also empowered to purchase insurance on behalf of our directors, officers, employees and other agents and to enter into indemnification agreements with our directors, officers, employees and other agents. We have entered into indemnification agreements with directors and officers, which provide for indemnification for all reasonable expenses and liabilities incurred in connection with any action or proceeding brought against them in connection with their services. We believe that these arrangements are necessary to attract and retain qualified directors and officers and to allow them to exercise their judgment in the best interest of the Company and its stockholders. We have also obtained director and officer liability insurance as a risk management measure.

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AUDIT COMMITTEE REPORT

The information contained in this report shall not be deemed to be soliciting material, filed with the SEC or incorporated by reference into any filing under the Securities Act or the Exchange Act, or subject to the liabilities of Section 18 of the Exchange Act, except to the extent that the Company specifically incorporates it by reference into a document filed under the Securities Act or the Exchange Act.

The Audit Committee s primary purpose is to act on behalf of the Board in fulfilling the Board s oversight responsibilities with respect to the Company s corporate accounting and financial reporting practices, systems of internal control over financial reporting and audits of financial statements, as well as the quality and integrity of the Company s financial statements, reports and internal controls, the qualifications, independence and performance of the Company s independent registered public accounting firm, the performance of the Company s internal audit function and the Company s processes for monitoring compliance with legal and regulatory requirements and the Company s Global Code of Business Conduct. The Audit Committee operates under a written charter adopted by the Board, a current copy of which is available on the Company s website at *www.interceptpharma.com* in the Investors & Media section under Corporate Governance.

The Audit Committee has:

reviewed and discussed the audited financial statements for the year ended December 31, 2017 with the Company s management;
discussed with the Company s independent registered public accounting firm, KPMG LLP, the matters required to be discussed by Auditing Standard No. 1301, *Communications with Audit Committees*, as adopted by the Public Company Accounting Oversight Board (PCAOB); and
received the written disclosures and the letter from KPMG LLP required by applicable requirements of the PCAOB regarding KPMG LLP s communications with the Audit Committee concerning independence, and has discussed with KPMG LLP such firm s independence.

Based on the foregoing review and discussions, the Audit Committee has recommended to the Board that the audited financial statements be included in the Company s Annual Report on Form 10-K for the year ended December 31, 2017.

The Audit Committee is responsible for the appointment, compensation, retention and oversight of the work of the Company s independent registered public accounting firm. After reviewing the past services provided by, and performance of, KPMG LLP, the Audit Committee appointed KPMG LLP as the Company s independent registered public accounting firm for the year ending December 31, 2018. The Audit Committee recommends that the Company s stockholders ratify such appointment at the Annual Meeting.

By the Audit Committee of the Board of Directors of Intercept Pharmaceuticals, Inc.,

Glenn Sblendorio, *Chairperson*
Daniel Bradbury
Gino Santini

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INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Audit Committee has appointed KPMG LLP as the Company s independent registered public accounting firm for the year ending December 31, 2018. KPMG LLP has audited the Company s financial statements since 2008.

Fees Paid to KPMG LLP

The following table sets forth the aggregate fees billed to the Company for the years ended December 31, 2017 and 2016 by KPMG LLP.

	Year Ended December 31,	
	2017	2016
	(in thousands)	
Audit Fees	$ 1,415	$ 1,061
Audit-Related Fees		
Tax Fees	$ 127	$ 128
All Other Fees		
Total Fees	$ 1,542	$ 1,189

Audit fees include fees associated with the annual integrated audit of our financial statements and internal control over financial reporting, reviews of our interim financial information, the issuance of consents in connection with filings with the SEC, statutory audits and KPMG LLP s work in connection with our financing activities. Tax fees include fees associated with tax compliance services, preparation of federal and state income tax returns, preparation of sales tax returns and certain other tax consulting services.

We did not incur any audit-related fees or other fees in 2017 and 2016. All fees described above were approved by the Audit Committee.

The Audit Committee has determined that the provision of services rendered above is compatible with maintaining KPMG LLP s independence.

Pre-Approval Policy and Procedures

The Audit Committee has adopted a policy and procedures for the pre-approval of audit and non-audit services rendered by the Company s independent registered public accounting firm, KPMG LLP. On an annual basis, management submits to the Audit Committee for pre-approval specified services expected to be rendered by the Company s independent registered public accounting firm in the defined categories of audit, audit-related, tax and other services up to specified amounts. Prior to engagement, the Audit Committee pre-approves these services by category of service. In the event that circumstances arise where it may become necessary to engage the Company s independent registered public accounting firm for additional services not contemplated in the original pre-approval, pre-approval may also be given on an individual, case-by-case basis before the Company s independent registered public accounting firm is engaged to provide such services. The Audit Committee may delegate pre-approval authority to one or more of its members. The member or members to whom such authority is delegated must report, for informational purposes only, any pre-approval decisions to the full Audit Committee at its next scheduled meeting.

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SECTION 16(a) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

Section 16(a) of the Exchange Act requires the Company s directors and executive officers, and persons who own more than ten percent of a registered class of the Company s equity securities, to file with the SEC initial reports of ownership and reports of changes in ownership of common stock and other equity securities of the Company. Officers, directors and greater than ten percent stockholders are required by SEC regulation to furnish the Company with copies of all Section 16(a) forms they file.

To the Company s knowledge, based solely on a review of the copies of such reports furnished to the Company, during the year ended December 31, 2017, all Section 16(a) filing requirements applicable to the Company s officers, directors and greater than ten percent beneficial owners were complied with, except that (i) a Form 4 reporting the vesting of restricted stock held by Lisa Bright on August 1, 2017 and December 18, 2017 was filed late on January 26, 2018, (ii) a Form 4 reporting the grants of restricted stock and stock options to Christian Weyer on November 27, 2017 was filed late on December 11, 2017 and (iii) a Form 4 reporting the vesting and subsequent partial sale of restricted stock held by Lisa Bright on May 2, 2017 was filed late on May 10, 2017.

STOCKHOLDERS PROPOSALS

Stockholder Proposals in the Proxy Statement

Rule 14a-8 under the Exchange Act addresses when a company must include a stockholder s proposal in its proxy statement and identify the proposal in its form of proxy card when the company holds an annual or special meeting of stockholders. Under Rule 14a-8, in order for your proposals to be considered for inclusion in the proxy statement and proxy card relating to the 2019 Annual Meeting of Stockholders (the 2019 Annual Meeting), your proposals must be sent to Intercept Pharmaceuticals, Inc., 10 Hudson Yards, 37th Floor, New York, NY 10001, Attention: Company Secretary, not less than 120 days prior to the anniversary of the date on which the Company s proxy statement was released to stockholders in connection with the 2018 Annual Meeting of Stockholders (the 2018 Annual Meeting). Therefore, the deadline is expected to be December 28, 2018 for the 2019 Annual Meeting. However, if the date of the 2019 Annual Meeting changes by more than 30 days from the anniversary of the 2018 Annual Meeting, the deadline is a reasonable time before we begin to print and mail our proxy materials. We will notify you of any change in this deadline in a quarterly report on Form 10-Q or in another communication to you. Stockholder proposals must also be otherwise eligible for inclusion.

Stockholder Proposals and Nominations for Directors to Be Presented at Meetings

If you desire to bring a matter before an Annual Meeting of Stockholders outside the process of Rule 14a-8, you may do so by following the procedures set forth in the Company s Restated Bylaws. To be timely, written notice must be delivered to Intercept Pharmaceuticals, Inc., 10 Hudson Yards, 37th Floor, New York, NY 10001, Attention: Company Secretary not less than 90 days nor more than 120 days prior to the first anniversary of the 2018 Annual Meeting; provided, however, that in the event that the date of the 2019 Annual Meeting is more than 30 days before or more than 30 days after such anniversary date, then such notice to be timely must be delivered to the Company Secretary not more than 120 days prior to the 2019 Annual Meeting and not less than the later of (i) 90 days prior to such annual

meeting or (ii) 10 days following the date of the first public announcement of the scheduled date of the 2019 Annual Meeting. As a result, in the event the 2019 Annual Meeting is not held more than 30 days before nor more than 30 days after the first anniversary of the 2018 Annual Meeting, notice of nominations or other business submitted pursuant to the Company s Restated Bylaws must be received no later than the close of business on March 22, 2019 and no earlier than February 20, 2019. Any such notice to the Company Secretary must include all of the information specified in the Company s Restated Bylaws.

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EXPENSES AND SOLICITATION

The cost of solicitation will be borne by the Company, and in addition to directly soliciting stockholders by mail, the Company may request brokers, dealers, banks, trustees or other nominees to solicit their customers who have shares of the Company registered in the name of the nominee and, if so, will reimburse such brokers, dealers, banks, trustees or other nominees for their reasonable out-of-pocket costs. Solicitation by officers and employees of the Company may also be made of some stockholders in person or by mail, email or telephone following the original solicitation. The Company has retained Innisfree M&A Incorporated to assist in the solicitation of proxies for a fee of approximately $17,500, plus out-of-pocket expenses.

HOUSEHOLDING

Our Annual Report, including our audited financial statements for the year ended December 31, 2017, is being mailed to you along with this proxy statement. In order to reduce printing and postage costs, only one Annual Report and one proxy statement will be mailed to multiple stockholders sharing an address unless the Company receives contrary instructions from one or more of the stockholders sharing an address. If your household has received only one Annual Report and one proxy statement and you wish to receive separate copies of these documents, we will deliver promptly a separate copy of such documents to any requesting stockholder who contacts our transfer agent, VStock Transfer, LLC, by telephone at 1-855-9VSTOCK or in writing to VStock Transfer, LLC, 18 Lafayette Place, Woodmere, NY 11598. If your household is receiving multiple copies of the Company s annual reports or proxy statements and you wish to request delivery of a single copy, you may send a written request to our transfer agent at VStock Transfer, LLC, 18 Lafayette Place, Woodmere, NY 11598.

OTHER BUSINESS

Management does not know of any other matters to be brought before the Annual Meeting except those set forth in the notice thereof. If other business is properly presented for consideration at the Annual Meeting, it is intended that the proxies will be voted by the persons named therein in accordance with their judgment on such matters.

We will mail without charge, upon written request, a copy of our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, including the consolidated financial statements, schedules and list of exhibits, and any particular exhibit specifically requested. Requests should be sent to: Intercept Pharmaceuticals, Inc., 10 Hudson Yards, 37th Floor, New York, NY 10001, Attention: Company Secretary.

BY ORDER OF THE BOARD OF DIRECTORS

/s/ RYAN T. SULLIVAN
Ryan T. Sullivan
General Counsel and Secretary

New York, New York
April 27, 2018

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