

Edgar Filing: VICAL INC - Form 10-K

(Address of principal executive offices)

(Zip Code)

Registrant's telephone number, including area code: (858) 646-1100

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

Title of each class	Name of each exchange on which registered
Common Stock, \$0.01 par value	The Nasdaq Capital Market

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

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer Accelerated filer

Non-accelerated filer Smaller reporting company
Emerging growth company

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

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

The aggregate market value of the voting stock held by non-affiliates of the registrant, based upon the last sale price of the registrant's common stock reported on the Nasdaq Capital Market on June 30, 2018, was approximately \$19,828,148.

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The number of shares of common stock outstanding as of January 31, 2019, was 21,820,195.

Documents Incorporated by Reference:

Document	Part of Form 10-K
Proxy Statement for the Annual Meeting of	Part III
Stockholders to be held May 23, 2019	

VICAL INCORPORATED

FORM 10-K

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FORWARD-LOOKING STATEMENTS

In addition to historical information, this Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, including statements regarding our business, our financial position, our ongoing evaluation of strategic alternatives, the research and development of biopharmaceutical products, the timing of clinical trial activities and other statements describing our goals, expectations, intentions or beliefs. Such statements reflect our current views and assumptions and are subject to risks and uncertainties, particularly those inherent in the process of developing and commercializing biopharmaceutical products. Actual results could differ materially from those discussed in this Annual Report on Form 10-K. Factors that could cause or contribute to such differences include, but are not limited to, those identified in Item 1A entitled “Risk Factors” beginning on page 11 of this report, as well as those discussed in our other filings with the Securities and Exchange Commission, or SEC, including our Quarterly Reports on Form 10-Q. As a result, you are cautioned not to unduly rely on these forward-looking statements. We disclaim any duty to update any forward-looking statement to reflect events or circumstances that occur after the date on which such statement is made.

PART I

ITEM 1. BUSINESS

Overview

Until recently, we were focused on developing our novel antifungal VL-2397, for the treatment of patients with invasive aspergillosis. VL-2397 was being evaluated in a multicenter, open label randomized Phase 2 clinical study, designed to compare the efficacy and safety of VL-2397 to standard treatment for invasive aspergillosis in acute leukemia patients and recipients of allogeneic hematopoietic cell transplant (HCT). In February 2019, we decided to discontinue the Phase 2 clinical trial of VL-2397 in order to conserve our cash resources while we pursue our strategic alternative review process.

Our board of directors is conducting a review of strategic alternatives, including, but are not limited to, merger or acquisition transactions, issuing or transferring shares of our common stock, or the license, purchase or sale of specific assets, in addition to other potential actions aimed at maximizing stockholder value. There can be no assurance that the review of strategic alternatives will result in the identification or consummation of any transaction or that our board of directors will determine that continuing our current business operations is in the best interests of our stockholders.

Our Current Strategy

In the third quarter of 2018, we announced plans to explore a range of strategic options to enhance stockholder value. We retained MTS Health Partners, L.P. to assist in the strategic review process. Given our decision to discontinue the Phase 2 clinical trial of VL-2397, we will focus on concluding the strategic review process.

We expect to devote substantial time and resources to concluding the review of strategic alternatives. Despite devoting significant efforts to identify and evaluate potential strategic transactions, we may not be successful in completing a transaction. Further, even if a strategic transaction is completed, it ultimately may not deliver the anticipated benefits or enhance stockholder value.

Corporate Information

We were incorporated in Delaware in 1987. Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to these reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, are available free of charge on our website at www.vical.com as soon as reasonably practicable after such reports and amendments are electronically filed with or furnished to the SEC. We also make available copies of our news releases and other financial information about us on our website.

Product Development

VL-2397 represents a potential new class of antifungal compound to address invasive aspergillus infections, which are major causes of morbidity and mortality in immunocompromised patients, including transplant recipients. In preclinical studies to date, it has demonstrated faster fungicidal activity than marketed drugs and activity against azole-resistant fungal pathogens. Current treatment options have limited efficacy, as approximately 50-60% of allogeneic hematopoietic stem cell transplant recipients with invasive aspergillosis infections die within 12 weeks. Over the past 30 years, only one new class of antifungal drugs (echinocandins) has been introduced.

The U.S. FDA has advised that VL-2397 would be eligible for a Limited Use Indication (LUI) approval assuming a successful outcome of a single Phase 2 trial carried out in accordance with a protocol and statistical analysis plan consistent with the Agency's advice. The final determination whether the drug is approvable will be made by FDA after review of all relevant data. The LUI is a provision of the Limited Population Pathway established under the 21st

Century Cures Act of 2016. In the case of VL-2397, the LUI approval would be for patients for whom alternative regimens are not available to treat their invasive aspergillosis. A Phase 3 trial would be required to support full approval of VL-2397 for the treatment of invasive aspergillosis in a broader population. The FDA has granted Vical Qualified Infectious Disease Product (QIDP), Orphan Drug and Fast Track designations for VL-2397 in the treatment of invasive aspergillosis.

About Invasive Aspergillosis

Invasive aspergillosis is a life-threatening infection that typically affects immunocompromised patients, including those with acute leukemia and recipients of allogeneic HCT or lung transplants. Infection typically starts in the lungs and rapidly disseminates to other tissues. An estimated 200,000 cases of invasive aspergillosis are diagnosed annually worldwide.

Adjuvant Development

DNA Vaccines with Vaxfectin®

Vaxfectin® is our proprietary, cationic lipid formulation optimized to increase the immune response to vaccines. Vaxfectin® formulations have demonstrated safety and adjuvant activity in DNA vaccine applications in multiple animal models, including nonhuman primates. Studies of Vaxfectin®-formulated DNA vaccines against CMV and measles have shown enhanced immunogenicity in rodents and nonhuman primates. Vaxfectin®-formulated DNA vaccines have also been tested in approximately 400 healthy human subjects receiving influenza, dengue, or HSV-2 vaccines, and collectively, these Phase 1 trials indicate favorable safety profiles of these vaccines. We believe Vaxfectin® is an important potentiator of both antibody and T-cell mediated immune responses to DNA vaccines.

Other Vaxfectin® Applications

In 2013, we entered into a nonexclusive license with Bristol-Myers Squibb Company, or BMS, for our patented platform DNA immunization technology and our Vaxfectin® adjuvant for use in the production of antibodies. Under the agreement, BMS is using our technology to generate antibodies with potential therapeutic uses in humans. We also agreed to provide specified quantities of our Vaxfectin® adjuvant to BMS from time to time.

Collaboration and Licensing Agreements

We have entered into various arrangements with corporate, academic, and government collaborators, licensors, licensees, and others. In addition to the agreements summarized below, we conduct ongoing discussions with potential collaborators, licensors and licensees.

In-licensing

Astellas. In March 2015, we entered into a license agreement with Astellas, granting us exclusive worldwide license to develop and commercialize our novel antifungal candidate, VL-2397. As consideration for the rights under the license, we issued 86,121 shares of our common stock to Astellas and made an up-front payment of \$250,000 in cash. The license agreement provides for potential development, regulatory and sales milestone payments totaling up to \$99.0 million, as well as tiered single-digit royalty payments based on net sales of licensed products. The royalty payments are subject to reduction on a country-by-country basis in certain circumstances where there is not exclusivity in the country. We are responsible for the worldwide development, manufacturing and commercialization of licensed products, at our cost, and we are required to use commercially reasonable efforts with respect to such development and commercialization activities.

The license agreement, unless terminated earlier, will continue until expiration of our royalty obligations with respect to licensed products. Either party may terminate the license agreement earlier if the other party materially breaches the agreement and does not cure the breach within a specified notice period, or upon the other party's insolvency. Astellas may terminate the license agreement earlier if we or any of our affiliates or sublicensees oppose or challenge any of the licensed patents. We may terminate the license agreement on a country-by-country basis for reasonable scientific, regulatory, commercial, financial, ethical or other reasons.

As of December 31, 2018, the aggregate potential milestone payments that we could be obligated to pay under our active in-license agreements total approximately \$99.0 million. These amounts assume that all remaining milestones associated with the milestone payments are met. We may also be obligated to pay royalties based on net sales of any products which incorporate the in-licensed technology.

Intellectual Property

Patents and other proprietary rights are essential to our business. We file patent applications to protect our technologies, inventions, and improvements to our inventions that we consider important to the development of our

business. We believe we have a comprehensive patent portfolio in the United States and in key foreign markets. We also rely upon trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position.

We are the sole assignee of issued U.S. patents covering numerous examples of cationic lipid compounds that are used to facilitate delivery of plasmids to some tissues. Our Vaxfectin® adjuvant are protected in-part by lipid technology and/or lipid compound patents that extend up to March 24, 2020. Patent protection of these key lipids also has been obtained in Europe, Canada and Japan. Under the Hatch-Waxman Act, a U.S. patent term extension for up to 5 years may be available under certain conditions.

We have been granted the exclusive right to Astellas patents which claim the composition of matter of, and methods of making or using, VL-2397. All of these issued U.S. patents and foreign counterparts will expire on March 13, 2029.

As of December 31, 2018, we were the assignee or co-assignee of 30 issued U.S. and foreign patents. We maintain our issued patents by paying maintenance fees to the patent office in each country when due. Where appropriate, we participate in legal proceedings to vigorously defend against the revocation or withdrawal of our patents. The scope and nature of these proceedings generally differ depending on the country in which they are initiated.

See “Risk Factors—Our patents and proprietary rights may not provide us with any benefit and the patents of others may prevent us from commercializing our products,” and “The legal proceedings to obtain and defend patents, and litigation of third-party claims of intellectual property infringement, could require us to spend money and could impair our operations.”

Commercialization and Manufacturing

We intend to develop and commercialize products both on our own and through collaborators. We intend to develop and commercialize products in well-defined specialty markets, including infectious diseases. Where appropriate, we intend to rely on strategic marketing and distribution alliances.

Competition

We are aware of several development-stage and established enterprises, including major pharmaceutical and biotechnology firms, which are actively engaged in invasive fungal infection research and development. These include Amplyx Pharmaceuticals, F2G Ltd, Cidara Therapeutics and Scynexis, Inc. We may also experience competition from companies that have acquired or may acquire technologies from companies, universities and other research institutions. These companies may develop proprietary technologies which may materially and adversely affect our business. If these or any other companies develop products with efficacy or safety profiles significantly better than our products, we may not be able to commercialize our products, and sales of any of our commercialized products could be harmed.

Some of our competitors and potential competitors have substantially greater product development capabilities and financial, scientific, marketing and human resources than we do. Competitors may develop products earlier, obtain FDA approvals for products more rapidly, or develop products that are more effective than those under development by us. We will seek to expand our technological capabilities to remain competitive; however, research and development by others may render our technologies or products obsolete or noncompetitive, or result in treatments or cures superior to ours.

Our competitive position will be affected by the disease indications addressed by our product candidates and those of our competitors, the timing of market introduction for these products and the stage of development of other technologies to address these disease indications. For us and our competitors, proprietary technologies, the ability to complete clinical trials on a timely basis and with the desired results, and the ability to obtain timely regulatory approvals to market these product candidates are likely to be significant competitive factors. Other important competitive factors will include the efficacy, safety, ease of use, reliability, availability and price of products and the ability to fund operations during the period between technological conception and commercial sales.

Government Regulation

FDA Review and Approval

Any products we develop will require regulatory clearances prior to conducting clinical trials and additional regulatory approvals prior to commercialization. In the United States, the Federal Food, Drug and Cosmetic Act and the Public Health Service Act and their implementing regulations govern, among other things, biopharmaceutical testing, manufacturing, safety, efficacy, labeling, storage, record keeping, advertising, and other promotional practices.

Obtaining FDA approval is a costly and time-consuming process. Generally, FDA approval requires that preclinical studies be conducted in the laboratory and in animal model systems to gain preliminary information on efficacy and to identify any major safety concerns. The results of these studies are submitted as a part of an IND which the FDA must review and allow before human clinical trials can start. The IND includes a detailed description of the proposed clinical investigations.

A company must submit an IND for each proposed product and must conduct clinical studies to demonstrate the safety and efficacy of the product necessary to obtain FDA approval. The FDA receives reports on the progress of each phase of clinical testing and may require the modification, suspension, or termination of clinical trials if an unwarranted risk is presented to patients.

To obtain FDA approval prior to marketing a biopharmaceutical product in the United States typically requires several phases of clinical trials to demonstrate the safety and efficacy of the product candidate. Clinical trials are the means by which experimental treatments are tested in humans, and are conducted following preclinical testing. Clinical trials may be conducted within the United States or in foreign countries. If clinical trials are conducted in foreign countries, the products under development as well as the trials are subject to regulations of the FDA and/or its regulatory counterparts in the other countries. Upon successful completion of clinical trials, approval to market the treatment for a particular patient population may be requested from the FDA in the United States and/or its counterparts in other countries.

Clinical trials for therapeutic products are normally done in three phases. Phase 1 clinical trials are typically conducted with a small number of patients or healthy subjects to evaluate safety, determine a safe dosage range, identify side effects, and, if possible, gain early evidence of effectiveness. Phase 2 clinical trials are conducted with a larger group of patients to evaluate effectiveness of an investigational product for a defined patient population, and to determine common short-term side effects and risks associated with the drug. Phase 3 clinical trials involve large scale, multi-center, comparative trials that are conducted to evaluate the overall benefit-risk relationship of the investigational product and to provide an adequate basis for product labeling. In some special cases where the efficacy testing of a product may present a special challenge to testing in humans, such as in the case of a vaccine to protect healthy humans from a life-threatening disease that is not a naturally occurring threat, effectiveness testing may be required in animals.

After completion of clinical trials of a new product, FDA marketing approval must be obtained. If the product is regulated as a biologic, a Biologics License Application, or BLA, is required. If the product is classified as a new

drug, a New Drug Application, or NDA is required. The NDA or BLA must include results of product development activities, preclinical studies, and clinical trials in addition to detailed chemistry, manufacturing and control information.

Applications submitted to the FDA are subject to an unpredictable and potentially prolonged approval process. Despite good-faith communication and collaboration between the applicant and the FDA during the development process, the FDA may ultimately decide, upon final review of the data, that the application does not satisfy its criteria for approval or requires additional product development or further preclinical or clinical studies. Even if FDA regulatory clearances are obtained, a marketed product is subject to continual review, and later discovery of previously unknown problems or failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions.

Before marketing clearance for a product can be secured, the facility in which the product is manufactured must be inspected by the FDA and must comply with the FDA's current Good Manufacturing Practices, or cGMP, regulations. In addition, after marketing clearance is secured, the manufacturing facility must be inspected periodically for cGMP compliance by FDA inspectors, and, if the facility is located in California, by inspectors from the Food and Drug Branch of the California Department of Health Services.

Sponsors of clinical trials are required to register, and report results for, all controlled, clinical investigations, other than Phase 1 investigations, of a product subject to FDA regulation. Trial registration may require public disclosure of confidential commercial development data resulting in the loss of competitive secrets, which could be commercially detrimental.

Under the Orphan Drug Act, the FDA may grant orphan designation to a product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a product available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan designation must be requested before submitting an NDA or BLA. Orphan designation does not convey any advantage in or shorten the duration of the regulatory review and approval process. If a product that has orphan designation subsequently receives the first FDA approval for such product for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. Competitors, however, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. If a product designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan product exclusivity.

We received QIDP, Orphan Drug, and Fast Track designation for VL-2397 for the treatment of invasive aspergillosis. With Qualified Infectious Disease Product designation, if VL-2397 for the treatment of invasive aspergillosis is approved by FDA, the FDA will extend by an additional five years any non-patent marketing exclusivity period awarded. FDA's Fast Track Drug Development Program is a process designed to facilitate the development and expeditious review of drugs to treat serious conditions and fill an unmet medical need. These designations allow for companies to interact with the FDA review team frequently to discuss critical development issues such as study design, required safety data necessary to support approval, and structure and content of an application. Additionally, should the FDA determine that a Fast Track product may be effective after their preliminary evaluation of clinical data submitted by a sponsor, the FDA may also consider reviewing portions of a marketing application before the sponsor submits the complete application, known as a "rolling" submission.

Fraud and Abuse, Data Privacy and Security, and Transparency Laws and Regulations

We may also be subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which we conduct our business. These additional healthcare regulations could affect our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors. Such laws potentially applicable to our operations include:

• The federal Anti Kickback Statute makes it illegal for any person or entity, including a prescription drug manufacturer (or a party acting on its behalf), to knowingly and willfully, directly or indirectly, overtly or covertly, solicit, receive, offer, or pay any remuneration that is intended to induce the referral of business, including the purchase, order, or lease of any good, facility, item or service for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. The term "remuneration" has been broadly interpreted to include anything of value. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the

Anti Kickback Statute has been violated. The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act, collectively the Affordable Care Act or ACA, among other things, amended the intent requirement of the federal Anti-Kickback Statute such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate, in order to commit a violation.

Federal false claims and false statement laws, including the federal civil False Claims Act, which may be enforced through whistleblower or qui tam actions, prohibit, among other things, any person or entity from

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knowingly presenting, or causing to be presented, for payment to, or approval by, federal programs, including Medicare and Medicaid, claims for items or services, including drugs, that are false or fraudulent or not provided as claimed. Entities can be held liable under these laws if they are deemed to “cause” the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers, promoting a product off label, or for providing medically unnecessary services or items.

•The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

•HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, require certain types of individuals and entities to protect the privacy, security, and electronic exchange of certain patient data.

•The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments or other transfers of value made to physicians and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by the physicians and their immediate family members.

•Analogous state and foreign laws and regulations, such as state anti kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by third party payors, including private insurers. Additionally, we may be subject to state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government. Further, we may be subject to state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians, other healthcare providers and healthcare entities, or marketing expenditures, as well as state and foreign laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

If our operations are found to be in violation of any of these federal, state, local or foreign laws or regulations, we may be subject to penalties, including without limitation, administrative or civil penalties, imprisonment, damages, fines, disgorgement, individual imprisonment, exclusion from participation in government healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional integrity obligations, or the curtailment or restructuring of our operations.

Reimbursement and Health Reform

Significant uncertainty exists as to the coverage and reimbursement status of any product candidate that receives regulatory approval. In the United States and markets in other countries, sales of our product candidates, if approved, will depend, in part, on the extent to which third party payors provide coverage and establish adequate reimbursement levels.

In the United States, third party payors include federal and state healthcare programs, government authorities, private managed care providers, private health insurers and other organizations. Third party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost effectiveness of medical drug products and medical services, in addition to questioning their safety and efficacy. Such payors may limit coverage to specific drug products on an approved list, also known as a formulary, which might not include all of the FDA approved drugs for a particular indication.

Moreover, the process for determining whether a third party payor will provide coverage for a drug product may be separate from the process for setting the price of a drug product or for establishing the reimbursement rate that such a payor will pay for the drug product. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage for the drug product.

There are ongoing efforts by governmental and third-party payers to contain or reduce the costs of healthcare through various reform measures. For example, in the United States, the Federal government passed comprehensive healthcare reform legislation, the Affordable Care Act, or ACA, in 2010. With respect to pharmaceutical products, the ACA, among other things, expanded and increased industry rebates for drugs covered by Medicaid and made changes to the coverage requirements under Medicare Part D, Medicare's prescription drug benefits program. Since its enactment there have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of any certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law, including the repeal, effective January 1, 2019, of the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain fees mandated by the ACA, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Moreover, the Bipartisan Budget Act of 2018, among other things, amends the ACA, effective January 1, 2019, to increase from 50% to 70% the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". Congress may consider other legislation to repeal or replace elements of the ACA. We continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business.

In addition, drug pricing by pharmaceutical companies has recently come under increased scrutiny. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the out-of-pocket cost of prescription drugs, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies. At the federal level, the Trump administration's budget proposal for fiscal year 2019 contains additional drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid and to eliminate cost sharing for generic drugs for low-income patients. While any proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our current product candidates and those for which we may receive regulatory approval in the future.

Further, third-party payers are increasingly challenging the price of medical products and services. If purchasers or users of our products are not able to obtain adequate reimbursement for the cost of using our products, they may forego or reduce their use. Significant uncertainty exists as to the reimbursement status of newly approved healthcare products, and whether adequate third-party coverage will be available.

We also are subject to various federal, state and local laws, regulations, and recommendations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals, and the use and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents, used in connection with our research. The extent of government regulation that might result from any future legislation or administrative action cannot be accurately predicted.

Employees

As of December 31, 2018, we had 30 full-time employees, including five with doctorate degrees and one medical doctor. Of these full-time employees, 19 were engaged in, or directly supporting, research and development and manufacturing activities, and 11 were in general and administrative positions. A significant number of our management and other employees have prior experience with pharmaceutical and/or biotechnology companies. None of our employees is covered by collective bargaining agreements, and our management considers relations with our employees to be good. In

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February 2019, we made the decision to discontinue the Phase 2 clinical trial of our novel antifungal VL-2397. As a result, we plan to undertake a restructuring, including an appropriate reduction in staff.

Executive Officers of the Registrant

Our executive officers are as follows:

Name	Age ¹	Position
Vijay B. Samant	66	President, Chief Executive Officer and Director
Mammen P. Mammen, Jr., M.D. ²	55	Sr. Vice President, Clinical Development
Anthony A. Ramos	52	Vice President, Chief Financial Officer
Larry R. Smith, Ph.D.	58	Sr. Vice President, Research

¹As of December 31, 2018.

²On February 19, 2019, Dr. Mammen departed the Company and will no longer serve as our Sr. Vice President, Clinical Development.

Vijay B. Samant joined us as President and Chief Executive Officer in November 2000. Previously, he held various positions at Merck from 1977 to 2000. From 1998 to 2000, he was Chief Operating Officer of the Merck Vaccine Division. From 1990 to 1998, he served in the Merck Manufacturing Division as Vice President of Vaccine Operations, Vice President of Business Affairs and Executive Director of Materials Management. From 1977 to 1990, Mr. Samant held a variety of positions of increasing responsibility in manufacturing, process engineering, production planning and control, business development and loss prevention in several Merck operating divisions. Mr. Samant holds a bachelor's degree in chemical engineering from the University of Bombay, India, an M.S. degree in chemical engineering from Columbia University and an S.M. degree from the Sloan School of Management at MIT. Mr. Samant currently serves on the Board of Directors for AmpliPhi Biosciences and was a member of the board of directors of Raptor Pharmaceutical Corporation from 2011 to 2014. Mr. Samant was a member of the Board of Trustees for the National Foundation for Infectious Diseases and the International Vaccine Institute in Seoul, South Korea from 2008 to 2012. Mr. Samant was also a Director of the Aeras Global TB Vaccine Foundation from 2001 to 2010.

Mammen P. Mammen, Jr., M.D., joined us as Vice President, Clinical Vaccines, in November 2012 and was named Senior Vice President, Clinical Development in May 2017. Prior to joining us, he served as Infectious Disease Consultant and Chief, Pandemic Warning Team, U.S. Department of Defense, Fort Detrick, Maryland. From 2006 to 2010, he served as the Army's Product Manager for vaccines in Advanced Development against dengue, hepatitis E, and HIV viruses for the U.S. Army Medical Research and Materiel Command, Fort Detrick, Maryland. As Chief, Department of Virology, the Armed Forces Research Institute of Medical Sciences, Thailand, from 2001 to 2006, Dr. Mammen managed a number of the Army's FDA-regulated vaccine studies. Dr. Mammen received his M.D. degree from the Pennsylvania State University College of Medicine and is Board-certified in Infectious Diseases. He has been elected as Fellow by the Infectious Disease Society of America and the American College of Physicians. He received his Internal Medicine and Infectious Disease clinical training from the Walter Reed Army Medical Center. He earned a B.A. degree in mathematics from Williams College. Dr. Mammen has authored or co-authored nearly 50 scientific publications spanning multiple emerging and re-emerging infectious diseases.

Anthony A. Ramos joined us as Corporate Controller in February 2005 and was named Chief Accounting Officer in July 2010, Vice President of Finance in December 2013 and Chief Financial Officer in May 2017. From January 1999 until joining Vical, Mr. Ramos held various positions at Copper Mountain Networks, Inc., a publicly held network communications company, most recently as Vice President of Finance with broad responsibilities in finance, accounting, treasury, risk management and corporate governance. From April 1996 until joining Copper Mountain

Networks, Mr. Ramos was Accounting Manager at Viasat, Inc., a publicly held digital communications company, where he held accounting and financial reporting responsibilities. From January 1990 until joining Viasat, Mr. Ramos served as an audit manager at PricewaterhouseCoopers LLP, where his clients included life sciences, computer software and telecommunications companies as well as government contractors. Mr. Ramos received his bachelor's degree in business administration and accounting from San Diego State University and is a Certified Public Accountant.

Larry R. Smith, Ph.D., joined us as Executive Director, Vaccinology in September 2003, and was named Vice President, Vaccine Research in October 2006 and Senior Vice President, Research in May 2017. Prior to joining Vical, Dr. Smith was Director of Viral Vaccines Research at Wyeth Vaccines, where he oversaw the immunogenicity testing of various viral vaccines including a number of recombinant viral vectors. Prior to joining Wyeth in 1996, Dr. Smith was a

Scientific Investigator at Immune Response, where he identified autoreactive T-cell targets in psoriasis and multiple sclerosis which led to the clinical testing of several therapeutic vaccine candidates. Dr. Smith received a B.S. degree in biology from Purdue University, a Ph.D. in microbiology and immunology from the University of Texas Medical Branch, and was a postdoctoral fellow in the Immunology Department at Scripps Clinic and Research Foundation.

ITEM 1A. RISK FACTORS

You should consider carefully the risks described below, together with all of the other information included in this Annual Report on Form 10-K, and in our other filings with the SEC, before deciding whether to invest in or continue to hold our common stock. The risks described below are all material risks currently known, expected or reasonably foreseeable by us. If any of these risks actually occur, our business, financial condition, results of operations or cash flow could be seriously harmed. This could cause the trading price of our common stock to decline, resulting in a loss of all or part of your investment.

We are reviewing strategic alternatives and there can be no assurance that we will be successful in identifying or completing any strategic transaction, that any such strategic transaction will result in additional value for our stockholders or that the process will not have an adverse impact on our business.

We have announced that our board of directors is conducting a review of strategic alternatives and we have retained MTS Health Partners, L.P. as our financial advisor to assist in the review process. These alternatives could include, but are not limited to, merger or acquisition transactions, issuing or transferring shares of our common stock, or the license, purchase or sale of specific assets, in addition to other potential actions aimed at increasing stockholder value. There can be no assurance that the review of strategic alternatives will result in the identification or consummation of any transaction. Our board of directors may also determine that our most effective strategy is to continue to execute on our current development strategy or to cease our current drug development activities altogether. The process of reviewing strategic alternatives may be time consuming and disruptive to our business operations and, if we are unable to effectively manage the process, our business, financial condition and results of operations could be adversely affected. We could incur substantial expenses associated with identifying, evaluating and negotiating potential strategic alternatives. There can be no assurance that any potential transaction or other strategic alternative, if consummated, will provide greater value to our stockholders than that reflected in the current price of our common stock. Until the review process is concluded, perceived uncertainties related to our future may result in the loss of potential business opportunities and volatility in the market price of our common stock and may make it more difficult for us to attract and retain qualified personnel and business partners.

If we do not successfully consummate a strategic transaction, our board of directors may decide to pursue a dissolution and liquidation of our company. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.

There can be no assurance that the process to identify a strategic transaction will result in a successfully consummated transaction. If no transaction is completed, our board of directors may decide to pursue a dissolution and liquidation of our company. In such an event, the amount of cash available for distribution to our stockholders, if any, will depend heavily on the timing of such decision and, ultimately, such liquidation, since the amount of cash available for distribution continues to decrease as we fund our operations and evaluate our strategic alternatives. In addition, if our board of directors were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation of our company, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. As a result of this requirement, a portion of our assets may need to be reserved

pending the resolution of such obligations. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation of our company. If a dissolution and liquidation were pursued, our board of directors, in consultation with its advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of a liquidation, dissolution or winding up of our company.

If we are successful in completing a strategic transaction, we may be exposed to other operational and financial risks.

Although there can be no assurance that a strategic transaction will result from the process we have undertaken to identify and evaluate strategic alternatives, the negotiation and consummation of any such transaction will require significant time on the part of our management, and the diversion of management's attention may disrupt our business.

The negotiation and consummation of any such transaction may also require more time or greater cash resources than we anticipate and expose us to other operational and financial risks, including:

- increased near-term and long-term expenditures;
- exposure to unknown liabilities;
- higher than expected acquisition or integration costs;
- incurrence of substantial debt or dilutive issuances of equity securities to fund future operations;
- write-downs of assets or goodwill or incurrence of non-recurring, impairment or other charges;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired business with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired business due to changes in management and ownership; and
- inability to retain key employees of our company or any acquired business.

Any of the foregoing risks could have a material adverse effect on our business, financial condition and prospects.

None of our product candidates has been approved for sale, and we have a limited number of product candidates in development. If we do not develop commercially successful products, we may be forced to curtail or cease operations.

We must conduct a substantial amount of additional research and development before any U.S. or foreign regulatory authority will approve any of our product candidates. Results of our research and development activities may indicate that our product candidates are unsafe or ineffective. In this case, we may stop development and regulatory authorities will not approve them. For example, we have previously terminated numerous development programs following negative results from preclinical studies or clinical trials.

Even if we complete clinical development, the results of clinical trials may not support approval by the FDA or comparable foreign agencies or, if approved, our products may not be commercially successful, particularly if they do not gain market acceptance among physicians, patients, healthcare payers and relevant medical communities. If we fail to develop and commercialize our product candidates, we may be forced to curtail or cease operations.

Our clinical trials may fail to demonstrate adequately the safety and efficacy of our product candidate, which would prevent or delay regulatory approval and commercialization.

Before obtaining regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. We and our licensees have in the past suffered significant setbacks in advanced clinical trials due to lack of efficacy, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never approved as products.

There are a number of factors that could cause a clinical study to fail or be delayed, including:

- the clinical study may not be designed properly or may produce negative or inconclusive results;
- regulators, monitoring boards or other entities may not grant permission to start a clinical study or require that we hold, suspend or terminate clinical research for safety, ethical or regulatory reasons, including adverse events, or AEs, reported during the trial;

- we may encounter delays in reaching agreement with regulators on final clinical study design;
- we may decide, or regulators may require us, to conduct additional preclinical testing or clinical studies;

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- enrollment in our clinical studies may be slower than we anticipate;
- we may encounter delays in engaging prospective clinical research organizations and clinical trial sites to conduct our clinical studies or may have disagreements with these entities;
- the cost of our clinical studies may be greater than we anticipate;
- we may not be able to raise funding necessary to initiate or complete our clinical studies; and
- the supply or quality of our product candidates or other materials necessary to conduct our clinical studies may be insufficient, inadequate or delayed.

If initiation or completion of our clinical studies or those of our collaborators are delayed, our development costs may increase, the approval process for our product candidates would be delayed, any periods during which we may have the exclusive right to commercialize our product candidates may be reduced and our competitors may have more time to bring products to market or establish market positions.

In addition, even if clinical trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as sufficient to demonstrate that a product is safe and efficacious, and more trials could be required before we submit our product candidates for approval. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, approval of our product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates.

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

There is risk that our product candidates may induce AEs, many of which may be unknown at this time. If an unacceptable frequency and/or severity of AEs are reported in clinical studies for our product candidates, our ability to obtain regulatory approval for may be negatively impacted. Even if we receive regulatory approval, AEs associated with any approved products could have significant negative consequences, including:

- regulatory authorities may approve the product only with a risk evaluation and mitigation strategy (REMS), potentially with restrictions on distribution and other elements to assure safe use (ETASU);
- regulatory authorities may withdraw their approval of the product or impose restrictions on its distribution in a form of a modified REMS;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- we may be required to change the way the product is administered or to conduct additional clinical studies;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining regulatory approvals or market acceptance of the affected product candidate and could substantially increase the costs of commercializing our product candidates.

Our revenues have depended on the development and commercialization of products in collaboration with others to whom we have licensed our technologies. If we are unable to find additional collaborators or licensees, or if future collaborators or licensees do not successfully develop and commercialize products covered by such arrangements, we may not be able to derive collaboration and licensing revenues, we may lose opportunities to validate our technologies, or we may be forced to curtail our development and commercialization efforts in these areas.

We have licensed, and may continue to license, our technologies to corporate collaborators and licensees for the research, development and commercialization of specified product candidates. Our revenues have partially depended upon the ability of these collaborators and licensees to successfully develop and commercialize products covered by these arrangements. For example, we previously entered into license agreements with Astellas related to ASP0113, an investigational CMV therapeutic vaccine, and these agreements were subsequently terminated following negative

results from a Phase 3 clinical trial. Prior to the termination, the revenue received by us under this collaboration accounted for a significant amount of our revenue generated over the prior two years. During the years ended December 31, 2018, 2017 and

2016, we recognized \$0.0 million, \$0.3 million and \$1.5 million, respectively, of revenue related to license fees, and \$1.2 million, \$12.9 million and \$12.5 million, respectively, of revenue related to contract services and product supply. If we are unable to enter into new collaboration or licensing arrangements with third parties, we will not receive additional revenues from these sources and our financial results will be negatively impacted. The development and commercialization efforts of our collaborators and licensees are subject to the same risks and uncertainties described above with respect to our independently developed product candidates.

Some collaborators or licensees may not succeed in their product development efforts. It is possible that our collaborators or licensees may be unable to obtain regulatory approval of product candidates using our technologies or successfully market and commercialize any such products for which regulatory approval is obtained. Other collaborators or licensees may not devote sufficient time or resources to the programs covered by these arrangements, and we may have limited or no control over the time or resources allocated by these collaborators or licensees to these programs. The occurrence of any of these events may cause us to derive little or no revenue from these arrangements, lose opportunities to validate our technologies, or force us to curtail or cease our development and commercialization efforts in these areas.

Our collaborators and licensees may breach or terminate their agreements with us, including some that may terminate their agreements without cause at any time subject to certain prior written notice requirements, and we may be unsuccessful in entering into and maintaining other collaborative arrangements for the development and commercialization of products using our technologies. If we are unable to maintain existing collaboration arrangements or enter into new ones, our ability to generate licensing, milestone or royalty revenues would be materially impaired.

Some of our independent product candidates and some of those under development by our sublicensees incorporate technologies we have licensed from others. If we are unable to retain rights to use these technologies, we or our sublicensees may not be able to market products incorporating these technologies on a commercially feasible basis, if at all.

We have licensed certain technologies from corporate collaborators and research institutions, and sublicensed certain of such technologies to others, for use in the research, development and commercialization of product candidates. Our product development efforts and those of our sublicensees partially depend upon continued access to these technologies. For example, we or our licensors may breach or terminate our agreements, or disagree on interpretations of those agreements, which could prevent continued access to these technologies. If we were unable to resolve such matters on satisfactory terms, or at all, we or our sublicensees may be unable to develop and commercialize our products, and we may be forced to curtail or cease operations.

We licensed rights to patents and know-how for VL-2397 from Astellas pursuant to an in-license agreement that contains obligations to pay Astellas regulatory and sales milestone payments relating to VL-2397, as well as royalties on net sales of VL-2397. If we fail to make a required payment to Astellas or otherwise materially breach our in-license agreement with Astellas, including our obligation to use commercially reasonable efforts to advance development of VL-2397, and do not cure the failure within the required time period, Astellas may be able to terminate the license to the VL-2397 patents and know-how, which could have a material adverse effect on our business, financial condition and results of operations.

We have a history of net losses. We expect to continue to incur net losses and we may not achieve or maintain profitability.

To date, we have not sold, or received approval to sell, any pharmaceutical products. We do not expect to sell any pharmaceutical products for at least the next several years. Our net losses were approximately \$16.3 million, \$13.0 million and \$9.0 million for the years ended December 31, 2018, 2017 and 2016, respectively. As of December 31, 2018, we had incurred cumulative net losses totaling approximately \$442.1 million. Moreover, we expect that our

net losses will continue and may increase for the foreseeable future. We may not be able to achieve projected results if we generate lower revenues or receive lower investment income than expected, or we incur greater expenses than expected, or all of the above. Over the past several years our revenues were largely dependent on manufacturing and research services performed under our license agreement with Astellas. In February 2018, Astellas exercised its rights to terminate the ASP0113 license agreements, and we will therefore not receive any further payments under these agreements. We may never generate sufficient product revenue to become profitable. We also expect to have quarter-to-quarter fluctuations in revenues, expenses, and losses, some of which could be significant.

We may need additional capital in the future. If additional capital is not available, we may have to curtail or cease operations.

We may need to raise more money to continue the research and development necessary to bring our products to market and to establish marketing and additional manufacturing capabilities. We may seek additional funds through public and private stock offerings, government contracts and grants, arrangements with corporate collaborators, borrowings under lines of credit or other sources. We currently have on file a shelf registration statement that allows us to raise up to an aggregate of \$40.0 million from the sale of common stock, preferred stock, debt securities and/or warrants, subject to limitations on the amount of securities we may sell under the registration statement in any 12-month period. However, we may not be able to raise additional funds on favorable terms, or at all. Conditions in the credit markets and the financial services industry may make equity and debt financing more difficult to obtain, and may negatively impact our ability to complete financing transactions. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants, such as limitations on our ability to incur additional indebtedness and other operating restrictions that could adversely impact our ability to conduct our business.

If we are unable to obtain additional funds, we may have to scale back our development of new products, reduce our workforce or license to others products or technologies that we otherwise would seek to commercialize ourselves. The amount of money we may need would depend on many factors, including:

- The progress of our research and development programs;
- The scope and results of our preclinical studies and clinical trials;
- The amount of our legal expenses and any settlement or damages payments associated with litigation; and
- The time and costs involved in: obtaining necessary regulatory approvals; filing, prosecuting and enforcing patent claims; scaling up our manufacturing capabilities; and the commercial arrangements we may establish.

If we do not realize the expected benefits and successfully manage the transition from our restructuring our operations and financial condition may be negatively impacted.

In January 2018, we implemented a restructuring designed to conserve capital and focus our efforts on our VL-2397 antifungal drug product candidate. In addition, in July 2018, we entered into an agreement with Genopis, Inc., or Genopis, to sell our idle manufacturing assets and sublease our manufacturing facilities space. In February 2019, in light of our decision to discontinue the Phase 2 clinical trial of our novel antifungal VL-2397, we plan to restructure our operations to conserve capital. If we are unable to realize the expected operational efficiencies and cost savings from our restructuring activities and sale of our manufacturing assets, our operating results and financial condition would be adversely affected. We cannot guarantee that we will not have to undertake additional restructuring activities or that any of our restructuring efforts will be successful.

We will also need to effectively manage our operations and facilities in order to advance our drug development programs and support our collaboration arrangements. Following our January 2018 restructuring and July 2018 sale of our manufacturing assets, it is possible that our infrastructure may be inadequate to support our future efforts and business strategy or to maintain effective operational, financial and management controls and reporting systems and procedures. If we cannot successfully manage the transition of our restructured operations, we may be unsuccessful in executing our business strategy.

The regulatory approval process is expensive, time consuming and uncertain, which may prevent us and our collaborators and licensees from obtaining required approvals for the commercialization of our products.

Our product candidates under development and those of our collaborators and licensees are subject to extensive and rigorous regulations by numerous governmental authorities in the United States and other countries. The regulatory approval process takes many years and will require us to expend substantial resources.

U.S. or foreign regulations evolve and could prevent or delay regulatory approval of our products or limit our and our collaborators and licensees' ability to develop and commercialize our products. Delays could:

- Impose costly procedures on our activities and those of our collaborators and licensees;
- Delay or prevent our receipt of developmental or commercial milestones from our collaborators and licensees;

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- Diminish any competitive advantages that we or our products attain; or

◊ Otherwise negatively affect our results of operations and cash flows.

We have no experience in submitting a BLA or an NDA to the FDA. Because these applications must be submitted to and approved by the FDA before any of our product candidates may be commercialized, our lack of experience may impede our ability to obtain FDA approval in a timely manner, if at all, which in turn would delay or prevent us from commercializing those products. Similarly, our lack of experience with respect to obtaining regulatory approvals in countries other than the United States may impede our ability to commercialize our products in those countries.

Presently, to commercialize any product we and our collaborators and licensees must file a regulatory application for each proposed use. We and our collaborators and licensees must conduct clinical studies to demonstrate the safety and efficacy of the product necessary to obtain FDA or foreign regulatory authority approval. The results obtained so far in our clinical trials and those of our collaborators and licensees may not be replicated in ongoing or future trials, or the results may be subject to varying interpretation on whether they are sufficient to support approval for commercialization. This may prevent any of our product candidates from receiving approval for commercial sale.

If any of our product candidates receive regulatory approval, the FDA or other foreign regulatory agencies may still impose significant restrictions on the indicated uses or marketing of our product candidates or impose ongoing requirements for potentially costly post-approval studies. In addition, regulatory agencies subject a product, its manufacturer and the manufacturer's facilities to continual review and periodic inspections. If a regulatory agency discovers previously unknown problems with a product or a product class, including AEs of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product or product class, our collaborators and licensees or us, including requiring withdrawal of a product from the market. Our product candidates will also be subject to ongoing FDA and other foreign regulatory agency requirements for the labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information on the product. If we or our collaborators and licensees fail to maintain regulatory compliance after receiving marketing approval, we or our collaborators and licensees may be unable to market our products and our business could suffer.

Adverse events or the perception of adverse events in the biotechnology industry, or with respect to our product candidates, may negatively impact regulatory approval or public perception of our products.

Future AEs in the biotechnology industry could result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approval of our potential products. Any increased scrutiny could delay or increase the costs of our product development efforts or clinical trials. In addition, any AEs that may occur in our clinical trials and any resulting publicity may cause regulatory delays or otherwise affect our product development efforts or clinical trials.

Some of our potential products may be administered to patients who are suffering from, or are vulnerable to, serious diseases or other conditions which can themselves be life-threatening and often result in the death of the patient. Patient deaths in our clinical trials, even if caused by pre-existing diseases or conditions, could negatively affect the perception of our product candidates. In addition, although we do not believe our potential product candidates could cause the diseases they are designed to protect against, a temporal relationship between the potential product and the disease onset could be perceived as causal.

Our patents and proprietary rights may not provide us with any benefit and the patents of others may prevent us from commercializing our products.

As of December 31, 2018, we were the assignee or co-assignee of 30 issued U.S. and foreign patents. We maintain our issued patents by paying maintenance fees to the patent office in each country when due. Where appropriate, we participate in legal proceedings to vigorously defend against the revocation or withdrawal of our patents. The scope

and nature of these proceedings generally differ depending on the country in which they are initiated. If we are not successful in defending our patents, we may lose all or part of our proprietary rights related to those patents in these geographic regions.

We may not receive any patents from our current patent applications. Issued patents provide exclusivity for only a limited time period, after which they no longer serve to protect proprietary technologies or to provide any commercial advantage. Moreover, if patents are issued to us, governmental authorities may not allow claims sufficient to protect our technologies and products. Others may also challenge or seek to circumvent or invalidate our patents. In that event, the

rights granted under our patents may be inadequate to protect our proprietary technologies or to provide any commercial advantage.

An inability to obtain, enforce, and defend patents covering our proprietary technologies would materially and adversely affect our business prospects and financial condition.

Some components of our product candidates are, or may become, patented by others. As a result, we may be required to obtain licenses to conduct research, to manufacture, or to market such products. Licenses may not be available on commercially reasonable terms, or at all, which may impede our ability to commercialize our products.

The legal proceedings to obtain and defend patents, and litigation of third-party claims of intellectual property infringement, could require us to spend money and could impair our operations.

Our and our collaborators' success will depend in part on our, or our collaborators', ability to obtain patent protection for our products and processes, both in the United States and in other countries. The patent positions of biotechnology and pharmaceutical companies, however, can be highly uncertain and involve complex legal and factual questions. Therefore, it is difficult to predict the breadth of claims allowed in the biotechnology and pharmaceutical fields.

We also rely on confidentiality agreements with our corporate collaborators, employees, consultants and certain contractors to protect our proprietary technologies. However, these agreements may be breached and we may not have adequate remedies for such breaches. In addition, our trade secrets may otherwise become known or independently discovered by our competitors.

Protecting intellectual property rights can be very expensive. Litigation may be necessary to enforce patents issued to us or to determine the scope and validity of third-party proprietary rights. If we or, as applicable, our commercialization partners, including Astellas pursuant to its first right to enforce patents licensed to it under our license agreements, choose to go to court to stop someone else from using our inventions, that individual or company has the right to ask the court to rule that the underlying patents are invalid and/or should not be enforced against that third party. Moreover, if a competitor were to file a patent application claiming technology also invented by us or our collaborators or licensees, we would have to participate in an interference proceeding before the U.S. Patent and Trademark Office to determine the priority of the invention. We or our collaborators or licensees may be drawn into interferences with third parties or may have to provoke interferences ourselves to unblock third-party patent rights to allow us or our collaborators or licensees to commercialize products based on our technologies. Litigation could result in substantial costs and the diversion of management's efforts regardless of the results of the litigation. An unfavorable result in litigation could subject us to significant liabilities to third parties, require disputed rights to be licensed or require us to cease using some technologies.

Our products and processes may infringe, or be found to infringe, patents not owned or controlled by us. Patents held by others may require us to alter our products or processes, obtain licenses, or stop activities. If relevant claims of third-party patents are upheld as valid and enforceable, we or our collaborators or licensees could be prevented from practicing the subject matter claimed in the patents, or may be required to obtain licenses or redesign our products or processes to avoid infringement. In addition, we or our collaborators or licensees could be required to pay money damages. A number of genetic sequences or proteins encoded by genetic sequences that we are investigating are, or may become, patented by others. As a result, we or our collaborators or licensees may have to obtain licenses to test, use or market these products. Our business will suffer if we or our collaborators or licensees are not able to obtain licenses at all or on terms commercially reasonable to us or them and we or they are not able to redesign our products or processes to avoid infringement.

We have incurred costs in several legal proceedings involving our intellectual property rights in Europe, Japan and Canada. We may continue to incur costs to defend and prosecute patents and patent applications in these and other regions.

Competition and technological change may make our product candidates and technologies less attractive or obsolete.

We compete with companies, including major pharmaceutical and biotechnology firms that are pursuing other forms of treatment or prevention for diseases that we target. We also may experience competition from companies that have acquired or may acquire technologies from universities and other research institutions. As these companies develop their technologies, they may develop proprietary positions which may prevent us from successfully commercializing products.

Some of our competitors are established companies with greater financial and other resources than we have. Other companies may succeed in developing products and obtaining regulatory approval from the FDA or comparable foreign agencies faster than we do, or in developing products that are more effective than ours. Research and development by others may seek to render our technologies or products obsolete or noncompetitive or result in treatments or cures superior to any therapeutics developed by us.

The internet site ClinicalTrials.gov provides public access to information on clinical trials and their results for a wide range of diseases and conditions. Future disclosures of such confidential commercial information may result in loss of advantage of competitive secrets.

If we conduct clinical trials or manufacture our product candidates, we expect to depend on third parties.

If we conduct clinical trials, we expect to rely on third parties, including clinical research organizations, medical institutions and contract laboratories, to perform critical services for us in connection with such clinical trials. These third parties would be responsible for many aspects of the trials, including finding and enrolling subjects for testing and administering the trials. Even if we rely on third parties to conduct our clinical trials, we will be responsible for ensuring that each of our clinical trials is conducted in accordance with its protocol and applicable regulations, including good clinical practices established by the FDA and foreign regulatory authorities, which govern the conduct, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that trial subjects are adequately informed of the potential risks associated with participating in clinical trials. Even if we rely on third parties, this will not relieve us of the responsibility to ensure these requirements are met. It is possible that these third parties will not comply with all regulatory and contractual requirements or will not otherwise perform their services in a timely or acceptable manner, and we may need to enter into new arrangements with alternative third parties and our clinical trials may be extended, delayed or terminated. In addition, if such third parties fail to perform their obligations in compliance with our clinical trial protocols or applicable good clinical practice regulations, our clinical trials may not meet regulatory requirements or may need to be repeated, and we may not be able to obtain regulatory approval for or commercialize the product candidate being tested in such trials. These risks also apply to the development activities of our collaborators and licensees, and we do not control our collaborators' and licensees' research and development, clinical trials or regulatory activities.

If we manufacture our product candidates, we expect to depend on collaborators, licensees or other third parties to manufacture our product candidates, and this reliance has increased following the sale of our manufacturing assets in July 2018. There are a limited number of third parties that could manufacture our product candidates. We may be unable to enter into any arrangement for the manufacture of our product candidates, and any arrangement we secure may not meet our requirements for manufacturing quality or quantity. If we manufacture our product candidates, we expect that our dependence on third parties for the manufacture of our product candidates may also reduce our profit margins and our ability to develop and deliver products in a timely manner.

We have no marketing or sales experience, and if we are unable to develop our own sales and marketing capability, we may not be successful in commercializing our products.

Our current strategy is to market our proprietary products directly in the United States, but we currently do not possess pharmaceutical marketing or sales capabilities. To market and sell our proprietary products, we will need to develop a sales force and a marketing group with relevant pharmaceutical industry experience, or make appropriate arrangements with strategic partners to market and sell these products. Developing a marketing and sales force is expensive and time-consuming and could delay any product launch. If we are unable to successfully employ qualified marketing and sales personnel or develop other sales and marketing capabilities, we may not be able to generate sufficient product revenue to become profitable.

If we fail to comply with federal and state healthcare laws, including fraud and abuse, transparency, and health information privacy and security laws, we could face substantial penalties and our business, results of operations, financial condition and prospects could be adversely affected.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute any product for which we obtain marketing approval. Such laws include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under a federal healthcare program, such as Medicare or Medicaid;
- the federal false claims and civil monetary penalties laws, including the civil False Claims Act and its qui tam or whistleblower provisions, which impose criminal and civil penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, which imposes obligations, including mandatory contractual terms, on certain types of individuals and entities and their respective business associates with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments or other transfers of value made to physicians and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by the physicians and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by third-party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians, other healthcare providers, and healthcare entities, or marketing expenditures; and state and foreign laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable healthcare laws. If our operations are found to be in violation of any of these or any other health regulatory laws that may apply to us, we may be subject to significant penalties, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional integrity obligations, such as additional reporting and/or oversight requirements if we become subject to a corporate integrity agreement or

similar agreement with a governmental authority, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

Healthcare reform and restrictions on reimbursement may limit our returns on potential products.

Our ability to earn sufficient returns on our products will depend in part on how much, if any, reimbursement for our products and related treatments will be available from:

- Government health administration authorities;
- Government agencies procuring biodefense products for military or public use, including some for which we may become a sole-source vendor;
- Private health coverage insurers;
- Managed care organizations; and
- Other organizations.

Such third-party payers decide which drugs and treatments they will cover and the amount of reimbursement, and no uniform policy exists. Therefore, coverage and reimbursement for products can differ significantly from payer to payer. Further, the coverage determination process is a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payer separately. Patients rely on third-party payers to reimburse all or part of the cost associated with treatment. If we fail to obtain adequate reimbursement, we could be prevented from successfully commercializing our potential products.

There are ongoing efforts by governmental and third-party payers to contain or reduce the costs of healthcare through various reform measures. For example, in the United States, the Federal government passed comprehensive healthcare reform legislation, the ACA, in 2010. With respect to pharmaceutical products, the ACA, among other things, expanded and increased industry rebates for drugs covered by Medicaid and made changes to the coverage requirements under Medicare Part D, Medicare's prescription drug benefits program. Since its enactment there have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of any certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law, including the repeal, effective January 1, 2019, of the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain fees mandated by the ACA, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Moreover, the Bipartisan Budget Act of 2018, among other things, amends the ACA, effective January 1, 2019, to increase from 50% to 70% the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". Congress may consider other legislation to repeal or repeal and replace elements of the ACA. We continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business.

In addition, drug pricing by pharmaceutical companies has recently come under increased scrutiny. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the out-of-pocket cost of prescription drugs, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies. At the federal level, the Trump administration's budget proposal for fiscal year 2019 contains additional drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid and to eliminate cost sharing for generic drugs for low-income patients. While any proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each

indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate

revenue, attain profitability, or commercialize our current product candidates and those for which we may receive regulatory approval in the future.

Further, third-party payers are increasingly challenging the price of medical products and services. If purchasers or users of our products are not able to obtain adequate reimbursement for the cost of using our products, they may forego or reduce their use. Significant uncertainty exists as to the reimbursement status of newly approved healthcare products, and whether adequate third-party coverage will be available.

Our internal computer systems, or those used by our contractors or consultants, may fail or suffer security breaches.

We are dependent upon our own or third-party information technology systems, infrastructure and data, including mobile technologies, to operate our business. The multitude and complexity of our computer systems may make them vulnerable to service interruption or destruction, malicious intrusion, or random attack. Likewise, data privacy or security breaches by employees or others may pose a risk that sensitive data, including our clinical trial data, intellectual property, trade secrets or personal information of our employees, patients, customers or other business partners may be exposed to unauthorized persons or to the public. Cyber-attacks are increasing in their frequency, sophistication and intensity. Cyber-attacks could include the deployment of harmful malware, denial-of-service, social engineering and other means to affect service reliability and threaten data confidentiality, integrity and availability. Third party sites that take part in clinical trials we or our collaborators sponsor face similar risks and any security breach of their systems could adversely affect us. A security breach or privacy violation that leads to disclosure or modification of or prevents access to patient information, including personally identifiable information or protected health information, could harm our reputation, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, require us to verify the correctness of database contents and otherwise subject us to litigation or other liability under laws and regulations that protect personal data, any of which could disrupt our business and/or result in increased costs or loss of revenue. Moreover, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information, trade secrets or other intellectual property. While we have invested, and continue to invest, in the protection of our data and information technology infrastructure, there can be no assurance that our efforts will prevent service interruptions, or identify breaches in our systems, that could adversely affect our business and operations and/or result in the loss of critical or sensitive information, which could result in financial, legal, business or reputational harm to us. In addition, our liability insurance may not be sufficient in type or amount to cover us against claims related to security breaches, cyber-attacks and other related breaches.

We use hazardous materials in our business. Any claims relating to improper handling, storage or disposal of these materials could be time consuming and costly.

Our research and development processes involve the controlled storage, use and disposal of hazardous materials and biological materials. Our hazardous materials include certain compressed gases, flammable liquids, acids and bases, and other toxic compounds. We are subject to federal, state and local regulations governing the use, manufacture, storage, handling and disposal of materials and waste products. Although we believe that our safety procedures for handling and disposing of these hazardous materials comply with the standards prescribed by law and regulation, the risk of accidental contamination or injury from hazardous materials cannot be completely eliminated. In the event of an accident, we could be held liable for any damages that result. We could incur significant costs to comply with current or future environmental laws and regulations.

We may have significant product liability exposure.

We face an inherent business risk of exposure to product liability and other claims in the event that our technologies or products are alleged to have caused harm. We also have potential liability for products manufactured by us on a contract basis for third parties. Although we currently maintain product liability insurance in the amount of \$10 million in the aggregate plus additional coverage specific to the foreign countries where our clinical trials are being

conducted, this insurance coverage may not be sufficient, and we may not be able to obtain sufficient coverage in the future at a reasonable cost. Our inability to obtain product liability insurance at an acceptable cost or to otherwise protect against potential product liability claims could prevent or inhibit the commercialization of any products developed by us or our collaborators, or our ability to manufacture products for third parties. If we are sued for any injury caused by our technologies or products, or by third-party products that we manufacture, our liability could exceed our insurance coverage and total assets.

The recently passed comprehensive tax reform bill could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law new legislation that significantly revises the Internal Revenue Code of 1986, as amended. The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the newly enacted federal tax law. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

Our stock price could continue to be highly volatile and you may not be able to resell your shares at or above the price you pay for them.

The market price of our common stock, like that of many other life sciences companies, has been and is likely to continue to be highly volatile. From January 1, 2016, to December 31, 2018, our stock price has ranged from \$1.00 to \$4.80. The following factors, among others, could have a significant impact on the market price of our common stock:

- The results of our on-going review of strategic alternatives;
- The results of our preclinical studies and clinical trials or announcements regarding our plans for future studies or trials, or those of our collaborators, licensees or competitors;
- Evidence or lack of evidence of the safety or efficacy of our potential products or those of our collaborators, licensees or competitors;
- Our ability to enter into new collaboration and licensing agreements and the success of any collaborators and licensees in the development or commercialization of our product candidates;
- The announcement by us or our collaborators, licensees or competitors of technological innovations or new products;
- Developments concerning our patent or other proprietary rights or those of our collaborators, licensees or competitors, including litigation and challenges to our proprietary rights;
- Other developments with our collaborators or licensees, including our entry into new collaborative or licensing arrangements;
- Geopolitical developments, natural or man-made disease threats, or other events beyond our control;
- U.S. and foreign governmental regulatory actions;
- Changes or announcements in reimbursement policies;
- Period-to-period fluctuations in our operating results;
- Market conditions for life science stocks in general;
- Changes in the collective short interest in our stock;
- Changes in estimates of our performance by securities analysts; and
- Our cash balances, need for additional capital, and access to capital.

We are at risk of future securities class action litigation due to our past and expected stock price volatility.

In the past, stockholders have brought securities class action litigation against a company following a decline in the market price of its securities. This risk is especially acute for us because life science companies have experienced greater than average stock price volatility in recent years and, as a result, have been subject to, on average, a greater number of securities class action claims than companies in other industries. Even if such claims are not successful, any litigation could

result in substantial costs and divert our management's attention and resources, which could have a material adverse effect on our business, operating results or financial condition.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Our certificate of incorporation and bylaws include anti-takeover provisions, such as a classified board of directors, a prohibition on stockholder actions by written consent, the authority of our board of directors to issue preferred stock without stockholder approval, and supermajority voting requirements for specified actions. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally prohibits stockholders owning in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years. These provisions may delay or prevent an acquisition of us, even if the acquisition may be considered beneficial by some stockholders. In addition, they may discourage or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management.

In addition, in August 2016, we completed a private placement of 1,841,420 shares of common stock to AnGes. In connection with the private placement, AnGes agreed to vote all of its shares in accordance with the recommendations of our board of directors on any matter brought before our stockholders for a vote, subject to certain limitations. This voting provision may also discourage or prevent attempts by other stockholders to replace members of our board of directors or engage in acquisition activities that our board of directors does not determine to be in the best interests of our stockholders.

The issuance of preferred stock could adversely affect our common stockholders.

We currently have on file a shelf registration statement that allows us to raise up to an aggregate of \$40.0 million from the sale of common stock, preferred stock, debt securities and/or warrants (subject to limitations on the amount of securities that we may sell under the registration statement in any 12-month period) and our restated certificate of incorporation authorizes us to issue up to 5,000,000 shares of preferred stock. The issuance of preferred stock could adversely affect the voting power of holders of our common stock, and reduce the likelihood that our common stockholders will receive dividend payments and payments upon liquidation. The issuance of preferred stock could also decrease the market price of our common stock, or have terms and conditions that could discourage a takeover or other transaction that might involve a premium price for our shares or that our stockholders might believe to be in their best interests.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

We occupy approximately 17,000 square feet of research laboratory and office space at a single site in San Diego, California through a sublease with Genopis, Inc. ending on December 31, 2019.

ITEM 3. LEGAL PROCEEDINGS

We prosecute our intellectual property estate vigorously to obtain the broadest valid scope for our patents. Due to uncertainty of the ultimate outcome of these matters, the impact on future operating results or our financial condition is not subject to reasonable estimates.

In the ordinary course of business, we may become a party to additional lawsuits involving various matters. We are unaware of any such lawsuits presently pending against us which, individually or in the aggregate, are deemed to be material to our financial condition or results of operations.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Our common stock is listed on the Nasdaq Capital Market under the symbol VICL and until January 25, 2016 was listed on the Nasdaq Global Market.

As of January 31, 2019, there were approximately 128 stockholders of record of our common stock and 21,820,195 shares of our common stock outstanding. We did not repurchase any of our common stock in the fourth quarter of 2018.

Performance Graph

The following performance graph and related information shall not be deemed "soliciting material" or to be "filed" with the SEC, nor shall such information be incorporated by reference into any future filing under the Securities Act or Exchange Act, except to the extent that we specifically incorporate it by reference into such filing.

The following table compares total stockholder returns for Vical over the last five years to the Nasdaq U.S. and Foreign Index and the Nasdaq Pharmaceutical Stocks Index assuming a \$100 investment made on December 31, 2013. Each of the two comparative measures of cumulative total return assumes reinvestment of dividends. The stock performance shown on the graph below is not necessarily indicative of future price performance.

ITEM 6. SELECTED FINANCIAL DATA

The following table summarizes certain selected financial data derived from our audited financial statements. The information presented should be read in conjunction with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our audited financial statements and notes thereto appearing elsewhere in this Annual Report on Form 10-K.

	Year Ended December 31,				
	2018	2017	2016	2015	2014
	(in thousands, except per share amounts)				
Statement of Operations Data:					
Revenues:					
Contract revenue	\$ 1,582	\$ 13,401	\$ 12,804	\$ 18,860	\$ 13,304
License and royalty revenue	40	418	1,727	2,090	1,913
Total revenues	1,622	13,819	14,531	20,950	15,217
Operating expenses:					
Research and development	12,327	14,391	10,355	11,061	11,467
Manufacturing and production	1,436	6,479	6,291	10,927	10,824
General and administrative	7,505	6,335	7,062	8,366	9,552
Total operating expenses	21,268	27,205	23,708	30,354	31,843
Loss from operations	(19,646)	(13,386)	(9,177)	(9,404)	(16,626)
Investment and other income, net	3,392	426	204	166	134
Net loss	(16,254)	(12,960)	(8,973)	(9,238)	(16,492)
Net loss per share (basic and diluted)	\$(0.74)	\$(1.01)	\$(0.90)	\$(1.01)	\$(1.86)
Weighted average shares used in per share calculation	21,842	12,888	10,019	9,175	8,879
Balance Sheet Data (at end of period):					
Cash, cash equivalents, marketable securities, long-term investments, including restricted					
	\$50,457	\$62,900	\$40,978	\$42,006	\$49,123
Working capital	45,618	59,400	40,722	40,336	46,129
Total assets	52,344	80,494	52,284	49,914	57,979
Long-term obligations, less current portion	—	—	—	359	856
Total stockholders’ equity	48,763	63,577	45,139	45,393	51,922

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Overview

Until recently, we were focused on developing our novel antifungal VL-2397, for the treatment of patients with invasive aspergillosis. VL-2397 was being evaluated in a multicenter, open label randomized Phase 2 clinical study, designed to compare the efficacy and safety of VL-2397 to standard treatment for invasive aspergillosis in acute leukemia patients and recipients of allogeneic hematopoietic cell transplant (HCT). In February 2019, we decided to discontinue the Phase 2 clinical trial in order to conserve our cash resources while we complete our review of strategic alternatives.

Our board of directors is conducting a review of strategic alternatives, including, but not limited to, merger or acquisition transactions, issuing or transferring shares of our common stock, or the license, purchase or sale of specific assets, in addition to other potential actions aimed at maximizing stockholder value. There can be no assurance that the review of strategic alternatives will result in the identification or consummation of any transaction or that our board of directors will determine that continuing our current business operations is in the best interests of our stockholders.

Research, Development and Manufacturing Programs

To date, we have not received revenues from the sale of our independently developed pharmaceutical products and have received minimal revenues from the sale of commercially marketed products by our licensees. We have previously earned revenues by performing services under research and development contracts, grants, manufacturing contracts, and from licensing access to our proprietary technologies. Since our inception, we have received approximately \$289.6 million in revenues from these sources. Revenues by source for each of the three years ended December 31, 2018, were as follows (in millions):

Source	2018	2017	2016
Astellas contract	\$ 1.2	\$ 12.9	\$ 12.5
Other contracts	0.4	0.5	0.3
Total contract revenue	1.6	13.4	12.8
Astellas license	—	0.3	1.5
Other royalties and licenses	—	0.1	0.2
Total royalty and license revenues	—	0.4	1.7
Total revenues	\$ 1.6	\$ 13.8	\$ 14.5

In January 2018, we and Astellas announced that ASP0113 did not meet its primary endpoint in a Phase 3 clinical study in HCT recipients, after which Astellas informed us that it was terminating further development. As a result, we do not expect additional collaboration or license revenue absent new agreements with third parties.

Research, development, manufacturing and production costs by major program, as well as other expenses for each of the three years ended December 31, 2018, were as follows (in millions):

Program	2018	2017	2016
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CMV	\$1.5	\$9.4	\$9.2
HSV-2	1.6	5.3	3.6
VL-2397	8.5	4.3	3.4
Other research, development, manufacturing and production	2.2	1.9	0.4
Total research, development, manufacturing and production	\$13.8	\$20.9	\$16.6

From inception through December 31, 2018, we had spent approximately \$19.6 million on our VL-2397 program. The development of our CMV and HSV-2 vaccine programs has been terminated following negative trial results and we do not expect additional material spending on these programs going forward.

As a result, we expect to incur substantial operating losses for at least the next several years, due primarily to the advancement of our research and development programs, the cost of preclinical studies and clinical trials, spending for outside services, costs related to maintaining our intellectual property portfolio, costs due to manufacturing activities, costs related to our facilities, and possible advancement toward commercialization activities.

Critical Accounting Policies and Estimates

The preparation and presentation of financial statements in accordance with accounting principles generally accepted in the United States requires that management make a number of assumptions and informed estimates that affect the reported amounts of assets, liabilities, revenues and expenses in our financial statements and accompanying notes. Management bases its estimates on historical information and assumptions believed to be reasonable. Although these estimates are based on management's best knowledge of current events and circumstances that may impact us in the future, they are inherently uncertain and actual results may differ materially from these estimates.

Our critical accounting policies are those that affect our financial statements materially and involve a significant level of judgment by management. Our critical accounting policies regarding revenue recognition are in the following areas: license and royalty agreements, manufacturing contracts, contract services and grant revenues. Our critical accounting policies also include recognition of research and development expenses and the valuation of long-lived and intangible assets.

Revenue Recognition

The Company recognizes revenue when control of its products and services is transferred to its customers in an amount that reflects the consideration the Company expects to receive from its customers in exchange for those products and services. This process involves identifying the contract with a customer, determining the performance obligations in the contract, determining the contract price, allocating the contract price to the distinct performance obligations in the contract, and recognizing revenue when the performance obligations have been satisfied. A performance obligation is considered distinct from other obligations in a contract when it provides a benefit to the customer either on its own or together with other resources that are readily available to the customer and is separately identified in the contract. The Company considers a performance obligation satisfied once it has transferred control of a good or service to the customer, meaning the customer has the ability to use and obtain the benefit of the good or service. The Company recognizes revenue for satisfied performance obligations only when it determines there are no uncertainties regarding payment terms or transfer of control.

Research and Development Expenses

Research and development expenses consist of expenses incurred in performing research and development activities including salaries and personnel-related costs, supplies and materials, outside services, costs of conducting preclinical and clinical trials, facilities costs and amortization of intangible assets. Research and development expenses are charged to operations as they are incurred.

We assess our obligations to make milestone payments that may become due for licensed or acquired technology to determine whether the payments should be expensed or capitalized. We charge milestone payments to research and development expense when:

- The technology is in the early stage of development and has no alternative uses;
- There is substantial uncertainty of the technology or product being successful;
- There will be difficulty in completing the remaining development; and
- There is substantial cost to complete the work.

Capitalization and Valuation of Long-Lived Assets

Intangible assets with finite useful lives consist of capitalized costs incurred in connection with patents, patent applications pending and technology license agreements. Payments to acquire a license to use a proprietary technology are capitalized if the technology is expected to have alternative future use in research and development projects. We amortize costs of approved patents, patent applications pending and license agreements over their estimated useful lives, or terms of the agreements, whichever are shorter.

For patents pending, we amortize the costs over the shorter of a period of twenty years from the date of filing the application or, if licensed, the term of the license agreement. We re-assess the useful lives of patents when they are issued, or whenever events or changes in circumstances indicate the useful lives may have changed. For patents and patent applications pending that we abandon, we charge the remaining unamortized accumulated costs to research and development expense.

Intangible assets and long-lived assets are evaluated for impairment at least annually or whenever events or changes in circumstances indicate that their carrying value may not be recoverable. If the review indicates that intangible assets or long-lived assets are not recoverable, their carrying amount would be reduced to fair value. Factors we consider important that could trigger an impairment review include the following:

- A significant change in the manner of our use of the acquired asset or the strategy for our overall business; and/or
- A significant negative industry or economic trend.

In the event we determine that the carrying value of intangible assets or long-lived assets is not recoverable based upon the existence of one or more of the above indicators of impairment, we may be required to record impairment charges for these assets.

Recent Accounting Pronouncements

For information on the recent accounting pronouncements which may impact our business, see Note 1 of the Notes to Financial Statements included in this Annual Report on Form 10-K.

Results of Operations

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

Total Revenues. Total revenues decreased \$12.2 million, or 88.3%, to \$1.6 million in 2018 from \$13.8 million in 2017. This decrease was primarily due to a decrease in Astellas contract revenues due to the termination of the ASP0113 program following negative results from a Phase 3 clinical trial. The revenue received by us under this collaboration accounted for a significant amount of our revenue generated over the prior two years. During the years ended December 31, 2018, 2017 and 2016, we recognized \$0.0 million, \$0.3 million and \$1.5 million, respectively, related to license fees, and \$1.2 million, \$12.9 million and \$12.5 million, respectively, of revenue related to contract services and product supply.

Research and Development Expenses. Research and development expenses decreased \$2.1 million, or 14.3%, to \$12.3 million for 2018 from \$14.4 million for 2017. This decrease was primarily due to lower HSV-2 clinical trial costs and scientific supplies, offset by higher clinical trial costs associated with the VL-2397 Phase 2 trial.

Manufacturing and Production Expenses. Manufacturing and production expenses decreased \$5.1 million, or 77.8%, to \$1.4 million for 2018 from \$6.5 million for 2017. This decrease was primarily due to a decrease in salaries and benefits and allocated overhead due to the termination of the ASP0113 program and the closure of our manufacturing facility. These decreases were partially offset by a net decrease in deferred costs capitalized during the twelve months ended December 31, 2018 related to materials manufactured under our supply agreement with Astellas. We have discontinued all manufacturing and production activities and, as a result, we do not expect to incur any future manufacturing or production expenses.

General and Administrative Expenses. General and administrative expenses increased \$1.2 million, or 18.5%, to \$7.5 million for 2018 from \$6.3 million for 2017. This increase was primarily due to the allocation of additional overhead to general and administrative expenses as a result of the closure of our manufacturing facility.

Investment and Other Income. Investment and other income increased \$3.0 million, or 696.2%, to \$3.4 million for 2018 from \$0.4 million for 2017. This increase was primarily due to a \$2.3 million gain on the sale of assets to Genopis, and higher interest income due to a larger investment balance as a result of the November 2017 stock offering.

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

Total Revenues. Total revenues decreased \$0.7 million, or 4.9%, to \$13.8 million in 2017 from \$14.5 million in 2016. Our license revenue decreased \$1.3 million which was the result of the recognition of \$0.3 million of revenue related to our ASP0113 license agreement with Astellas in 2017, compared to \$1.5 million in license revenue recognized in 2016. This was offset by an increase in our contract revenue of \$0.6 million which was primarily the result of a \$0.4 million increase in contract revenue recognized under our ASP0113 agreement with Astellas and a \$0.2 million increase in contract revenue recognized relating to our research collaboration agreement with AnGes.

In February 2018, Astellas exercised its rights to terminate the ASP0113 license agreements following negative results from a Phase 3 clinical trial. The revenue received by us under this collaboration accounted for a significant amount of our

revenue generated over the past three years. During the years ended December 31, 2017, 2016 and 2015, we recognized \$0.3 million, \$1.5 million and \$1.8 million, respectively, related to license fees, and \$12.9 million, \$12.5 million and \$14.7 million, respectively, of revenue related to contract services and product supply.

Research and Development Expenses. Research and development expenses increased \$4.0 million, or 39.0%, to \$14.4 million for 2017 from \$10.4 million for 2016. This increase was primarily due to an increase in clinical trial expenses relating to our HSV-2 and VL-2397 trials.

Manufacturing and Production Expenses. Manufacturing and production expenses increased \$0.2 million, or 3.0%, to \$6.5 million for 2017 from \$6.3 million for 2016. This increase was primarily due to an increase in wages of \$0.4 million and a \$0.5 million net decrease in deferred contract costs capitalized, which was offset by a decrease in scientific supplies of \$0.8 million.

General and Administrative Expenses. General and administrative expenses decreased \$0.7 million, or 10.3%, to \$6.3 million for 2017 from \$7.1 million for 2016. This decrease was primarily due to a decrease in audit fees and miscellaneous operating expenses.

Investment and Other Income. Investment and other income increased \$0.2 million, or 108.8%, to \$0.4 million for 2017 from \$0.2 million for 2016. This increase was primarily the result of an increase in yields realized on short-term investments during the year ended December 31, 2016.

Liquidity and Capital Resources

Since our inception, we have financed our operations primarily through private placements and public offerings of equity securities, and revenues from our operations. From our inception through December 31, 2018, we have received approximately \$289.6 million in revenues from performing services under research and development and manufacturing contracts, from grants and from licensing access to our proprietary technologies, and we have raised net proceeds of approximately \$463.8 million from the sale of equity securities. Cash, cash equivalents, marketable securities, and long-term investments, including restricted cash, totaled \$50.5 million at December 31, 2018, compared with \$63.0 million at December 31, 2017. The decrease in our cash, cash equivalents and marketable securities for the year ended December 31, 2018, was due primarily to the use of cash to fund our operations, offset by proceeds from the sale of property and equipment to Genopis. In February 2019, we decided to discontinue the Phase 2 trial of our novel antifungal VL-2397. As a result, we plan to undertake a restructuring, including an appropriate reduction in staff.

Net cash used in operating activities was \$14.4 million and \$8.6 million for the years ended December 31, 2018 and 2017, respectively. The increase in net cash used in operating activities for the year ended December 31, 2018, compared with the prior year period, was primarily the result of a decrease in cash receipts from Astellas due to the termination of the ASP0113 program, offset in part by lower salaries and benefits as a result of the closure of our manufacturing facility and lower HSV-2 clinical trial costs.

Net cash provided by (used in) investing activities was \$1.3 million and \$(5.3) million for the years ended December 31, 2018 and 2017, respectively. The increase in net cash provided by investing activities for the year ended December 31, 2018, compared with the prior year, was primarily the result of a reduction in the purchases of marketable securities and proceeds from the sale of property and equipment to Genopis.

Net cash provided by financing activities was \$0.0 million and \$30.5 million for the years ended December 31, 2018 and 2017, respectively. The decrease in net cash provided by financing activities for the year ended December 31, 2018, compared with the prior year period, was the result of \$26.4 million in net proceeds received from the public offering of common stock and pre-funded warrants and \$4.2 million in net proceeds from the sale of common stock under our ATM Agreement in 2017, with no corresponding financing proceeds in 2018.

A discussion of our exposure to auction rate securities is included in Part II, Item 7A of this Annual Report on Form 10-K under the heading “Quantitative and Qualitative Disclosures About Market Risk.”

In the long-term, we expect to incur substantial additional research and development expenses and general and administrative expenses, including increases in costs related to personnel, preclinical and clinical testing, outside services, facilities, intellectual property and possible commercialization. Our future capital requirements will depend on many factors, including continued scientific progress in our research and development programs, the scope and results of preclinical

testing and clinical trials, the time and costs involved in obtaining regulatory approvals, the costs involved in filing, prosecuting, enforcing and defending patent claims, the impact of competing technological and market developments, the cost of manufacturing scale-up and validation, and possible commercialization activities and arrangements. We may seek additional funding through research and development relationships with suitable potential corporate collaborators. We may also seek additional funding through public or private financings. For example, in November 2017, we sold 9,194,286 shares of our common stock and pre-funded warrants to purchase 7,234,285 shares of our common stock in a public offering for gross proceeds of approximately \$28.7 million.

We currently have on file an effective shelf registration statement that allows us to raise up to \$40.0 million from the sale of common stock, preferred stock, debt securities and/or warrants, subject to limitations on the amount of securities that we may sell under the registration statement in any 12-month period. In October 2016, we entered into an At-The-Market Issuance Sales Agreement, or the ATM Agreement, with IFS Securities, Inc. (doing business as Brinson Patrick, a division of IFS Securities, Inc.), or BP, under which we could issue and sell up to \$10.0 million of shares of our common stock from time to time. The ATM expired in October 2018. For the 12 months ended December 31, 2017, we sold 1,509,370 shares under the ATM Agreement and received gross proceeds of \$4.3 million. We sold no shares under the agreement in 2018.

Despite our current shelf registration statement, additional financing through this or other means may not be available on favorable terms or at all. If additional financing is not available, we anticipate that our available cash and existing sources of funding will be adequate to satisfy our cash needs at least through December 31, 2020.

Contractual Obligations and Off-Balance Sheet Arrangements

The following table sets forth our contractual obligations, including all off-balance sheet arrangements, as of December 31, 2018 (in thousands):

	Payment Due by Period								
	Less than	1	2-3	4-5	After 5				
						Total Year	Years	Years	Years
Contractual Obligations									
Unconditional purchase obligations ¹	98	98	—	—	—				
Total contractual obligations	\$98	\$98	\$ —	\$ —	\$ —				

¹Unconditional purchase obligations represent contractual commitments entered into for goods and services in the normal course of our business. The purchase obligations do not include potential severance payment obligations to our executive officers. For information regarding these severance arrangements, refer to the final paragraph in this Item 7.

We may be required to make future payments to our licensors based on the achievement of milestones set forth in various in-licensing agreements. In most cases, these milestone payments are based on the achievement of development or regulatory milestones, including the exercise of options to obtain licenses related to specific disease targets, commencement of various phases of clinical trials, filing of product license applications, approval of product licenses from the FDA or a foreign regulatory agency, and the first commercial sale of a related product. Payment for the achievement of milestones under our in-license agreements is highly speculative and subject to a number of contingencies.

The aggregate amount of additional milestone payments that we could be required to pay under our active in-license agreements in place at December 31, 2018, is approximately \$99.0 million. These amounts assume that all remaining milestones associated with the milestone payments are met. In the event that product license approval for any of the related products is obtained, we may be required to make royalty payments in addition to these milestone payments. Although we believe that some of the milestones contained in our in-license agreements may be achieved, it is highly unlikely that a significant number of them will be achieved. Because the milestones are contingent, we are not in a position to reasonably estimate how much, if any, of the potential milestone payments will ultimately be paid, or when. Additionally, under the in-license agreements, many of the milestone events are related to progress in clinical trials which will take several years to achieve.

In addition, under the indemnification agreements with our officers and directors, we have agreed to indemnify those individuals for any expenses and liabilities in the event of a threatened, pending or actual investigation, lawsuit, or criminal or investigative proceeding.

We have an employment agreement that contains severance arrangements with our chief executive officer, or CEO, and severance agreements with six of our other employees. Under the agreement with our CEO, we are obligated to pay severance if we terminate the CEO's employment without "cause," or if the CEO resigns for "good reason," as defined in the agreement, within the periods set forth therein. The severance for the CEO consists of continued base salary payments at the then-current rate, including the payment of health insurance premiums for 18 months, plus a payment equal to one and one-half times the CEO's cash bonus in the previous year. In addition, the CEO receives accelerated vesting on all his unvested stock awards as if he had remained employed by us for 18 months from the date of termination. In the event that the termination occurs within 24 months of a "change in control," as defined in the agreement, the severance for the CEO consists of a lump sum payment equal to 24 months of base salary at the then-current rate, the payment of health insurance premiums for 18 months, plus a payment equal to one and one-half times the CEO's cash bonus in the previous year. In addition, all outstanding unvested stock awards will vest immediately. Under the agreements with our other six executives, we are obligated to pay severance if we terminate the executive's employment without "cause," or if the executive resigns for "good reason," as defined in the agreements, within the periods set forth therein. The severance for three of these executives consists of a lump-sum payment equal to 12 months of base salary at the then-current rate, including the payment of health insurance premiums for 12 months, plus a payment equal to the executive's cash bonus in the previous year. In addition, the executive receives accelerated vesting on all unvested stock awards as if the executive had remained employed by us for 12 months from the date of termination. In the event that the termination occurs within 12 months of a "change in control," as defined in the agreements, the severance consists of a lump sum payment equal to 18 months of base salary at the then-current rate, the payment of health insurance premiums for 12 months, plus a payment equal to the executive's cash bonus in the previous year. In addition, all outstanding unvested stock awards will vest immediately. The severance for the remaining three employees consists of a lump-sum payment equal to six months of base salary at the then-current rate, including the payment of health insurance premiums for six months, plus a bonus payment of \$75,000. The maximum payments due under these agreements would have been \$4.1 million if each such employee had been terminated at December 31, 2018.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are subject to interest rate risk. Our investment portfolio is maintained in accordance with our investment policy which defines allowable investments, specifies credit quality standards and limits the credit exposure of any single issuer. Our investment portfolio consists of cash equivalents, both restricted and non-restricted, marketable securities and long-term investments. The average maturity of our investments, excluding our auction rate securities, is approximately five months. Our investments are classified as available-for-sale securities.

To assess our interest rate risk, we performed a sensitivity analysis projecting an ending fair value of our cash equivalents and current marketable securities using the following assumptions: a 12-month time horizon, a five-month average maturity and a 150-basis-point increase in interest rates. This pro forma fair value would have been \$300,000 lower than the reported fair value of our investments at December 31, 2018.

Our investment securities consist of auction rate securities, corporate debt securities and government agency securities. As of December 31, 2018, our long-term investments included a (at par value) \$2.5 million auction rate security secured by municipal bonds. At December 31, 2018, the auction rate security we held maintained a Standard and Poor's credit rating of BBB. Our auction rate security is a debt instrument with a long-term maturity and with an interest rate that is reset in short intervals through auctions. The conditions in the global credit markets have prevented some investors from liquidating their holdings of auction rate securities because the amount of securities submitted for sale has exceeded the amount of purchase orders for such securities. If there is insufficient demand for the securities at the time of an auction, the auction may not be completed and the interest rates may be reset to predetermined higher rates. When auctions for these securities fail, the investments may not be readily convertible to cash until a future

auction of these investments is successful or they are redeemed or mature.

Our auction rate security has not experienced a successful auction since the liquidity issues experienced in the global credit and capital markets in 2008, as a result we could be required to sell it at less than par value, hold it until it is redeemed by the issuer or hold it to maturity in 2038. We do not anticipate a need to access these funds for operational purposes for the foreseeable future. We will continue to monitor and evaluate this investment on an ongoing basis for impairment. Based on our ability to access our cash and other short-term investments, our expected operating cash flows, and our other sources of cash, we do not anticipate that the potential illiquidity of these investments will affect our ability to execute our current business plan.

As of December 31, 2018, we had recognized \$0.4 million of losses related to the auction rate security by adjusting its carrying value. The market value of the security has partially recovered from the lows that created the losses. As of December 31, 2018, we had recorded cumulative unrealized gains of \$0.6 million. Any future decline in market value may result in additional losses being recognized.

The valuation of our auction rate security is subject to uncertainties that are difficult to predict. The fair value of the security is estimated utilizing a discounted cash flow analysis or other type of valuation model as of December 31, 2018. The key drivers of the valuation model include the expected term, collateralization underlying the security investments, the creditworthiness of the counterparty, the timing of expected future cash flows, discount rates, and the expected holding period. The security was also compared, when possible, to other observable market data for securities with similar characteristics.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Vical Incorporated

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Vical Incorporated (the Company) as of December 31, 2018 and 2017, the related statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2018, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with U.S. generally accepted accounting principles.

Adoption of ASU No. 2014-09

As discussed in Note 1 to the financial statements, the Company changed its method of accounting for revenue recognition in 2018 due to the adoption of ASU No. 2014-09, Revenue from Contracts with Customers, as amended.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2006.

San Diego, California
March 1, 2019

VICAL INCORPORATED

BALANCE SHEETS

(in thousands, except per share data)

	December 31,	
	2018	2017
ASSETS		
Current assets:		
Cash and cash equivalents	\$11,870	\$24,841
Marketable securities, available-for-sale	36,201	35,658
Restricted cash	—	192
Deferred contract costs	—	10,502
Receivables and other assets	1,128	5,124
Total current assets	49,199	76,317
Long-term investments	2,386	2,209
Property and equipment, net	100	606
Intangible assets, net	—	703
Other assets	659	659
Total assets	\$52,344	\$80,494
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	\$3,551	\$5,217
Deferred revenue	30	11,700
Total current liabilities	3,581	16,917
Long-term liabilities:		
Commitments and contingencies (Notes 6 and 7)		
Stockholders' equity:		
Preferred stock, \$0.01 par value, 5,000 shares authorized, none issued and outstanding	—	—
Common stock, \$0.01 par value, 50,000 shares authorized, 21,817 and 21,802 shares issued and outstanding at December 31, 2018 and 2017, respectively	218	218
Additional paid-in capital	490,337	489,975
Accumulated deficit	(442,064)	(426,738)
Accumulated other comprehensive income	272	122
Total stockholders' equity	48,763	63,577
Total liabilities and stockholders' equity	\$52,344	\$80,494

See accompanying notes to financial statements

VICAL INCORPORATED

STATEMENTS OF OPERATIONS

(in thousands, except per share data)

	Year Ended December 31,		
	2018	2017	2016
Revenues:			
Contract revenue	\$1,582	\$13,401	\$12,804
License and royalty revenue	40	418	1,727
Total revenues	1,622	13,819	14,531
Operating expenses:			
Research and development	12,327	14,391	10,355
Manufacturing and production	1,436	6,479	6,291
General and administrative	7,505	6,335	7,062
Total operating expenses	21,268	27,205	23,708
Loss from operations	(19,646)	(13,386)	(9,177)
Other income:			
Investment and other income, net	3,392	426	204
Net loss	\$(16,254)	\$(12,960)	\$(8,973)
Basic and diluted net loss per share	\$(0.74)	\$(1.01)	\$(0.90)
Weighted average shares used in computing basic and diluted net loss			
per share	21,842	12,888	10,019

See accompanying notes to financial statements

VICAL INCORPORATED

STATEMENTS OF COMPREHENSIVE LOSS

(in thousands)

	Year Ended December 31,		
	2018	2017	2016
Net loss	\$(16,254)	\$(12,960)	\$(8,973)
Other comprehensive gain (loss):			
Unrealized gain (loss) on available-for-sale and long-term marketable securities:			
Unrealized gain (loss) arising during holding period, net of tax benefit of \$37, \$56 and \$0 for years ended December 31, 2018, 2017 and 2016, respectively	150	97	(15)
Other comprehensive gain (loss)	150	97	(15)
Total comprehensive loss	\$(16,104)	\$(12,863)	\$(8,988)

See accompanying notes to financial statements

VICAL INCORPORATED

STATEMENTS OF STOCKHOLDERS' EQUITY

FOR EACH OF THE THREE YEARS IN THE PERIOD ENDED DECEMBER 31, 2018

(in thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Comprehensive Income/(Loss)	Other Equity	Total Stockholders'
	Number of Shares	Amount					
Balance at January 1, 2016	9,154	\$ 92	\$ 450,166	\$ (404,905)	\$ 40		\$ 45,393
Net loss	—	—	—	(8,973)	—		(8,973)
Other comprehensive income	—	—	—	—	(15)		(15)
Issuance of common stock	1,841	18	7,735	—	—		7,753
Issuance of common stock underlying restricted stock units net of shares withheld to settle withholding taxes	57	1	(10)	—	—		(9)
Non-cash compensation expense related to grant of equity based compensation	—	—	990	—	—		990
Balance at December 31, 2016	11,052	\$ 111	\$ 458,881	\$ (413,878)	\$ 25		\$ 45,139
Net loss	—	—	—	(12,960)	—		(12,960)
Other comprehensive loss	—	—	(100)	100	97		97
Issuance of common stock	10,704	107	17,849	—	—		17,956
Issuance of pre-funded warrants	—	—	12,588	—	—		12,588
Issuance of common stock underlying restricted stock units net of shares withheld to settle withholding taxes	46	—	1	—	—		1
Non-cash compensation expense related to grant of equity based compensation	—	—	756	—	—		756
Balance at December 31, 2017	21,802	\$ 218	\$ 489,975	\$ (426,738)	\$ 122		\$ 63,577
Net loss	—	—	—	(16,254)	—		(16,254)
Retained earnings adjustment upon adoption of	—	—	—	928	—		928

ASU 2014-09							
Other comprehensive loss	—	—	—	—	150	150	
Issuance of common stock	—	—	—	—	—	—	
Issuance of common stock underlying restricted							
stock units net of shares withheld to settle							
withholding taxes	15	—	1	—	—	1	
Non-cash compensation expense related to grant							
of equity based compensation	—	—	361	—	—	361	
Balance at December 31, 2018	21,817	\$ 218	\$ 490,337	\$ (442,064)	\$ 272	\$ 48,763	

See accompanying notes to financial statements

VICAL INCORPORATED

STATEMENTS OF CASH FLOWS

(in thousands)

	Year Ended December 31,		
	2018	2017	2016
Cash flows from operating activities:			
Net loss	\$(16,254)	\$(12,960)	\$(8,973)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	151	793	1,117
Accretion of discount on short-term investments	(249)	—	—
Write-off of abandoned patents	673	—	374
Gain on sale of property and equipment	(2,286)	—	—
Compensation expense related to stock options and awards	361	756	990
Changes in operating assets and liabilities:			
Deferred contract costs	—	(4,989)	(5,428)
Receivables and other assets	5,064	(1,973)	840
Accounts payable and accrued expenses	(1,666)	1,313	557
Deferred revenue	(239)	8,682	2,768
Deferred rent	—	(223)	(633)
Net cash used in operating activities	(14,445)	(8,601)	(8,388)
Cash flows from investing activities:			
Maturities of marketable securities	44,688	31,429	30,652
Purchases of marketable securities	(45,009)	(36,640)	(38,069)
Purchases of property and equipment	(36)	(80)	(255)
Proceeds from the sale of property and equipment	1,639	—	—
Net cash provided by (used in) investing activities	1,282	(5,291)	(7,672)
Cash flows from financing activities:			
Net proceeds from issuance of common stock and pre-funded warrants	1	30,549	7,758
Payment of withholding taxes for net settlement of restricted stock units	(1)	(4)	(14)
Net cash provided by financing activities	—	30,545	7,744
Net (decrease) increase in cash, cash equivalents and restricted cash	(13,163)	16,653	(8,316)
Cash, cash equivalents and restricted cash at beginning of year	25,033	8,380	16,696
Cash, cash equivalents and restricted cash at end of year	\$11,870	\$25,033	\$8,380
Supplemental disclosure of noncash investing and financing activities:			
Gain related to deferred rent	\$1,067	\$—	\$—

See accompanying notes to financial statements

VICAL INCORPORATED

NOTES TO FINANCIAL STATEMENTS

1. Organization and Summary of Significant Accounting Policies

Organization and Business Activity

Vical Incorporated, or the Company, a Delaware corporation, was incorporated in April 1987 and has devoted substantially all of its resources since that time to its research and development programs. The Company researches and develops biopharmaceutical products, including those based on its patented DNA delivery technologies for the prevention and treatment of serious or life-threatening diseases.

All of the Company's potential products are in research and development phases. No revenues have been generated from the sale of any such products, nor are any such revenues expected for at least the next several years. The Company earns revenue from research and development agreements with pharmaceutical collaborators and from contract manufacturing agreements. Most of the Company's product candidates will require significant additional research and development efforts, including extensive preclinical and clinical testing. All product candidates that advance to clinical testing will require regulatory approval prior to commercial use, and will require significant costs for commercialization. There can be no assurance that the Company's research and development efforts, or those of its collaborators, will be successful. The Company expects to continue to incur substantial losses and not generate positive cash flows from operations for at least the next several years. No assurance can be given that the Company can generate sufficient product revenue to become profitable or generate positive cash flows from operations.

Basis of Presentation

These financial statements are prepared in conformity with accounting principles generally accepted in the United States of America.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make informed estimates and assumptions that affect the amounts reported in the financial statements and disclosures made in the accompanying notes. Actual results could differ materially from those estimates.

Cash, Cash Equivalents and Marketable Securities

Cash and cash equivalents consist of cash and highly liquid securities with original maturities at the date of acquisition of ninety days or less and can be liquidated without prior notice or penalty. Investments with an original maturity of more than ninety days are considered marketable securities and have been classified by management as available-for-sale. These investments are classified as current assets, even though the stated maturity date may be one year or more beyond the current balance sheet date which reflects management's intention to use the proceeds from sales of these securities to fund its operations, as necessary. Such investments are carried at fair value, with unrealized gains and losses included as a separate component of stockholders' equity. Realized gains and losses from the sale of available-for-sale securities or the amounts, net of tax, reclassified out of accumulated other comprehensive income (loss), if any, are determined on a specific identification basis.

Restricted Cash

The Company was required to maintain a letter of credit securing an amount equal to twelve months of the then current monthly installment of base rent for the original term of the lease for its facilities, which ended on August 31, 2017. In July 2016, the term of the lease was extended for 16 months through December 2018. During the extended term, the Company was required to maintain a letter of credit securing an amount equal to \$0.2 million. At December 31, 2017, restricted cash of \$0.2 million was pledged as collateral for the letter of credit. The letter of credit expired on December 31, 2018 and, therefore, no cash was pledged as collateral as of that date.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash equivalents, marketable securities and receivables. The Company invests its excess cash in debt instruments of financial institutions and of corporations with above average credit ratings, in U.S. government obligations, and in money market funds and certificates of deposits at financial institutions.

Property and Equipment

Property and equipment is recorded at cost and depreciation is computed using the straight-line method over the estimated useful lives of the assets. Assets acquired pursuant to capital lease arrangements and leasehold improvements are amortized using the straight-line method over the shorter of the life of the remaining lease term or the remaining useful life of the asset. Manufacturing equipment has estimated useful lives of 5 to 10 years. All other property and equipment have estimated useful lives of 3 to 5 years. Maintenance and repairs of property and equipment are expensed as incurred.

Intangible Assets

Intangible assets include certain costs related to patent applications. The Company capitalizes license fees paid to acquire access to proprietary technology if the technology is expected to have alternative future use in multiple research and development projects. The cost of licensed technology rights is amortized using the straight-line method over the estimated useful life of the technology. Certain costs related to patent applications are amortized over the estimated economic lives of the patents, which is generally 20 years and typically commences at the time the patent application is filed. As of December 31, 2018, the Company had no capitalized patent costs. Amortization expense for licensed technology and capitalized patent cost is included in research and development expenses.

Impairment of Long-lived Assets

The Company reviews long-lived assets for impairment at least annually, quarterly for intangible assets, and whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Should an impairment exist, the impairment loss would be measured based on the excess of the carrying amount of the asset over the asset's estimated fair value and the loss recognized in current earnings. The Company recognized research and development expense of approximately \$0.7 million, \$0.0 million and \$0.4 million for the years ended December 31, 2018, 2017 and 2016, respectively, related to patents for which the value was deemed to be impaired.

Revenue Recognition

The Company recognizes revenue when control of its products and services is transferred to its customers in an amount that reflects the consideration the Company expects to receive from its customers in exchange for those products and services. This process involves identifying the contract with a customer, determining the performance obligations in the contract, determining the contract price, allocating the contract price to the distinct performance obligations in the contract, and recognizing revenue when the performance obligations have been satisfied. A performance obligation is considered distinct from other obligations in a contract when it provides a benefit to the customer either on its own or together with other resources that are readily available to the customer and is separately identified in the contract. The Company considers a performance obligation satisfied once it has transferred control of a good or service to the customer, meaning the customer has the ability to use and obtain the benefit of the good or service. The Company recognizes revenue for satisfied performance obligations only when it determines there are no uncertainties regarding payment terms or transfer of control.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development costs include salaries and personnel-related costs, supplies and materials, outside services, costs of conducting preclinical and clinical trials, facilities costs and amortization of intangible assets. The Company accounts for its clinical trial costs by estimating the total cost to treat a patient in each clinical trial, and accruing this total cost for the patient over the estimated treatment period, which corresponds with the period over which the services are performed, beginning when the patient enrolls in the clinical trial. This estimated cost includes payments to the site conducting the trial, and patient-related lab and other costs related to the conduct of the trial. Cost per patient varies based on the type of clinical trial, the site of the clinical trial, the method of administration of the treatment, and the number of treatments that a patient receives. Treatment periods vary depending on the clinical trial. The Company makes revisions to the clinical trial cost estimates in the current period, as clinical trials progress.

Manufacturing and Production Costs

Manufacturing and production costs include expenses related to manufacturing contracts and expenses for the production of plasmid DNA for use in the Company's research and development efforts. Manufacturing expenses related to manufacturing contracts are deferred and expensed when the related revenue is recognized. Deferred contract costs at December 31, 2018 and 2017 were \$0.0 million and \$10.5 million, respectively. Production expenses related to the Company's research and development efforts are expensed as incurred.

Net Loss Per Share

Basic and diluted net loss per share has been computed using the weighted-average number of shares of common stock outstanding during the period. The weighted-average number of shares used to compute diluted loss per share excludes any assumed exercise of stock options, and the assumed issuance of common stock under RSUs, as the effect would be antidilutive. Common stock equivalents of 7.2 million, 1.8 million and 7,350 for the years ended December 31, 2018, 2017 and 2016, respectively, were excluded from the calculation because of their antidilutive effect.

Fair Value of Financial Instruments

The carrying amounts of cash, cash equivalents, restricted cash, marketable securities, receivables, accounts payable and accrued expenses at December 31, 2018 and 2017, are considered to approximate fair value because of the short term nature of those items.

Income Taxes

The impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. There were no unrecognized tax benefits recorded by the Company as of the date of adoption in 2007. There are no unrecognized tax benefits included in the balance sheets that would, if recognized, affect the effective tax rate.

Deferred income taxes result primarily from temporary differences between financial and tax reporting. Deferred tax assets and liabilities are determined based on the difference between the financial statement bases and the tax bases of assets and liabilities using enacted tax rates. A valuation allowance is established to reduce a deferred tax asset to the amount that is expected more likely than not to be realized.

The Tax Cuts and Jobs Act ("the Act") was enacted on December 22, 2017. The Act reduces the U.S. federal corporate tax rate from 35% to 21%. Pursuant to the Securities and Exchange Commission Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act (SAB 118), we have finalized the accounting for the income tax effects of the Tax Legislation and believe the disclosures made in the financial statements as of December 31, 2017 are still accurate.

Comprehensive Loss

Comprehensive loss consists of net loss and certain changes in equity that are excluded from net loss. Comprehensive loss for the years ended December 31, 2018, 2017 and 2016, has been reflected in the accompanying Statements of Comprehensive Loss. Accumulated other comprehensive income (loss), which is included in stockholders' equity, represents unrealized gains and losses on marketable securities.

Business Segments

The Company operates in one business segment, which is within the United States, and is dedicated to research and development of biopharmaceutical products.

Stock-Based Compensation

The Company records its compensation expense associated with stock options and other forms of equity compensation based on their fair value at the date of grant using the Black-Scholes-Merton option pricing model. Stock-based compensation expense includes amortization related to stock option awards based on the estimated grant date fair

value. The compensation expense related to stock options is recognized ratably over the vesting period of the options. In addition, the Company records expense related to RSUs granted based on the fair value of those awards on the grant date. The fair value related to the RSUs is amortized to expense over the vesting term of those awards. Stock-based compensation expense related to stock options and RSUs for the year ended December 31, 2016 includes an estimate of 8.75% for forfeitures. Effective January 1, 2017, the Company adopted ASU No. 2016-09, “Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting” which allowed the Company to change its methodology for recording forfeitures from estimated forfeitures to actual forfeitures and recorded an adjustment to beginning retained earnings of \$0.1 million.

The fair value of each option award is estimated on the date of grant using the Black-Scholes-Merton valuation model using the assumptions noted in the following table. The expected life of options is based on the Company’s observed historical exercise patterns. The expected volatility of stock options is based upon the historical volatility of the Company’s stock commensurate with the expected life of the option. The risk-free interest rate is based on the implied yield on a U.S. Treasury zero-coupon issue with a remaining term equal to the expected term of the option. The dividend yield reflects that the Company has not paid any cash dividends since inception and does not intend to pay any cash dividends in the foreseeable future.

	Year Ended December 31,		
	2018	2017	2016
Assumptions:			
Assumed risk-free interest rate	2.34%	1.86%	1.44%
Assumed volatility	60%	72%	72%
	4.5	4.5	4.5
Average expected option life	years	years	years
Expected dividend yield	—	—	—

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (the “FASB”) issued ASU No. 2014-09, “Revenue from Contracts with Customers” which outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers. The Company adopted the new standard effective January 1, 2018 using the modified retrospective method applied to contracts not completed as of December 31, 2017. As it relates to process validation lots and stock piling lots completed but not delivered as of December 31, 2017 at the request of a customer, the Company concluded that, under ASC 606, the criteria for transfer of control were met prior to January 1, 2018 and as a result, the Company recorded an adjustment as of January 1, 2018 to recognize previously deferred revenue of \$11.4 million and previously deferred contract costs of \$10.5 million, with an adjustment to retained earnings of \$0.9 million. There was no tax impact, as the effect of the implementation for tax purposes was offset by the valuation allowance. The impact of adoption on the Company’s income statement and balance sheet as of December 31, 2018 and for the 12 months then ended was as follows (in thousands):

	As Reported	Balances Without Adoption of ASC 606	Effect of Change Increase/(Decrease)
Income Statement			

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Revenues			
Contract revenue	\$ 1,582	\$ 13,012	\$ (11,430)
Operating expenses			
Manufacturing and production	1,436	11,938	(10,502)
Net loss	(16,254)	(15,326)	928

Balance Sheet	As Reported	Balances Without Adoption of ASC 606	Effect of Change Increase/(Decrease)
Assets			
Deferred contract costs	\$—	\$—	\$ —
Liabilities			
Deferred revenue	30	30	—
Equity			
Accumulated deficit	(442,064)	(442,064)	—

In February 2016, the FASB issued ASU No. 2016-02, “Leases (Topic 842).” The new standard requires a lessee to record on the balance sheet the assets and liabilities for the rights and obligations created by leases with lease terms of more

than 12 months and will require both lessees and lessors to disclose certain key information about lease transactions. The standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The Company will adopt the new standard in the first quarter of 2019. While the Company is continuing to assess the potential impacts of the new standard, the Company estimates that the adoption of ASU No. 2016-02 will have no significant impact on its financial statements.

2. Short-Term Marketable Securities

The following is a summary of short-term marketable securities classified as available-for-sale (in thousands):

	Amortized	Unrealized	Unrealized	Market
December 31, 2018	Cost	Gain	Loss	Value
U.S. treasuries	\$ 36,219	\$ —	\$ 18	\$36,201
	\$ 36,219	\$ —	\$ 18	\$36,201

	Amortized	Unrealized	Unrealized	Market
December 31, 2017	Cost	Gain	Loss	Value
U.S. treasuries	\$ 34,462	\$ —	\$ 29	\$34,433
Certificates of deposit	1,225	—	—	1,225
	\$ 35,687	\$ —	\$ 29	\$35,658

At December 31, 2018, none of these securities were scheduled to mature outside of one year. There were no net realized gains (losses) on sales of available-for-sale securities for the years ended December 31, 2018, 2017 and 2016. None of these investments have been in a continuous unrealized loss position for more than 12 months as of December 31, 2018 and 2017.

3. Long-Term Investments

As of December 31, 2018, the Company held an auction rate security with a par value of \$2.5 million. This auction rate security has not experienced a successful auction since the liquidity issues experienced in the global credit and capital markets in 2008. As a result the security is classified as a long-term investment as it is scheduled to mature in 2038. The security was rated BBB by Standard and Poor's as of December 31, 2018. The security continues to pay interest according to its stated terms.

The valuation of the Company's auction rate security is subject to uncertainties that are difficult to predict. The fair value of the security is estimated utilizing a discounted cash flow analysis. The key drivers of the valuation model include the expected term, collateral underlying the security investment, the creditworthiness of the counterparty, the

timing of expected future cash flows, discount rates, liquidity and the expected holding period. The security was also compared, when possible, to other observable market data for securities with similar characteristics. As of December 31, 2018, the inputs used in the Company's discounted cash flow analysis assumed an interest rate of 6.71%, an estimated redemption period of five years and a discount rate of 1.0%. Based on the valuation of the security, the Company has recognized cumulative losses of \$0.4 million as of December 31, 2018, none of which were realized during the year ended December 31, 2018. The losses, when recognized, are included in investment and other income. The market value of the security has partially recovered. Included in other comprehensive (loss) income are unrealized gains (losses) of \$139,000, \$108,000 and \$(6,000) for the years ended December 31, 2018, 2017 and 2016, respectively. As of December 31, 2018, the Company had recorded cumulative unrealized gains of \$0.6 million. The resulting carrying value of the auction rate security at December 31, 2018, was \$2.4 million. Any future decline in market value may result in additional losses being recognized.

4. Fair Value Measurements

The Company measures fair value as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. Fair value measurements are based on a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets;

Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and

Level 3: Unobservable inputs for which there is little or no market data, which require the reporting entity to develop its own assumptions.

Cash equivalents, marketable securities and long-term investments measured at fair value are classified in the table below in one of the three categories described above (in thousands):

December 31, 2018	Fair Value Measurements			Total
	Level 1	Level 2	Level 3	
Money market funds	\$ 11,523	\$ —	\$ —	\$ 11,523
U.S. treasuries	36,201	—	—	36,201
Auction rate securities	—	—	2,386	2,386
	\$47,724	\$ —	\$2,386	\$50,110

December 31, 2017	Fair Value Measurements			Total
	Level 1	Level 2	Level 3	
Certificates of deposit	\$ 1,225	\$ —	\$ —	\$ 1,225
Money market funds	21,760	—	—	21,760
U.S. treasuries	34,433	—	—	34,433
Auction rate securities	—	—	2,209	2,209
	\$57,418	\$ —	\$2,209	\$59,627

The Company's investments in U.S. treasury securities, certificates of deposit and money market funds are valued based on publicly available quoted market prices for identical securities as of December 31, 2018. The Company determines the fair value of other government-sponsored enterprise related securities with the aid of valuations provided by third parties using proprietary valuation models and analytical tools. These valuation models and analytical tools use market pricing or similar instruments that are both objective and publicly available, including matrix pricing or reported trades, benchmark yields, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids and/or offers. The Company validates the valuations received from its primary pricing vendors for its level 2 securities by examining the inputs used in that vendor's pricing process and determines whether they are reasonable and observable. The Company also compares those valuations to recent reported trades for those securities. The Company did not adjust any of the valuations received from these third parties with respect to any of its level 2 securities at December 31, 2018. The valuation of the Company's investment in auction rate securities is more fully described in Note 3.

Activity for assets measured at fair value using significant unobservable inputs (Level 3) is presented in the table below (in thousands):

Balance at December 31, 2017	\$2,209
Total net realized gains included in earnings	—
Total net unrealized gains included in other comprehensive income	177
Net transfers in and/out of Level 3	—
Balance at December 31, 2018	\$2,386
Amount of total losses for the period included in net loss attributable to the change in unrealized gains or losses relating to assets still held at December 31, 2018	\$—

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Total cumulative unrealized losses of \$0.1 million relate to Level 3 assets still held as of December 31, 2018, none of which were recognized during the years ended December 31, 2018, 2017 and 2016. The losses, when recognized, are included in investment and other income.

5. Other Balance Sheet Accounts

Property and equipment consisted of the following at December 31 (in thousands):

	2018	2017
Equipment	\$3,270	\$16,908
Leasehold improvements	—	8,144
	3,270	25,052
Less accumulated depreciation and amortization	(3,170)	(24,446)
	\$100	\$606

Depreciation and amortization of equipment and leasehold improvements for the years ended December 31, 2018, 2017 and 2016, was \$0.1 million, \$0.6 million and \$0.9 million, respectively.

Intangible assets consisted of the following at December 31 (in thousands):

	2018	2017
Patent application costs	\$ —	\$1,500
Accumulated amortization patent costs	—	(797)
	\$ —	\$703

Amortization of licensed technology rights and patent application costs was \$0.1 million for each of the years ended December 31, 2018, 2017 and 2016.

Accounts payable and accrued expenses consisted of the following at December 31 (in thousands):

	2018	2017
Employee compensation	\$1,768	\$2,654
Clinical trial accruals	1,000	1,017
Accounts payable	412	1,213
Other accrued liabilities	371	333
	\$3,551	\$5,217

6. Significant Contract, License and Royalty Agreements

Contracts

Astellas

In July 2011, the Company entered into license agreements with Astellas, granting Astellas exclusive, worldwide, royalty-bearing licenses under certain of the Company's know-how and intellectual property to develop and commercialize certain products containing plasmids encoding certain forms of glycoprotein B and/or phosphoprotein 65. Under the terms of the license agreements, Astellas paid a nonrefundable upfront license fee of \$25.0 million. In 2012, the Company received a \$10.0 million milestone payment upon finalization of the trial design for a Phase 3 registration trial of ASP0113 in hematopoietic stem cell transplant recipients.

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The Company identified the deliverables at the inception of the agreements. The Company determined that the license and related know-how, the development and regulatory services and the drug product supply individually represent separate units of accounting, because each deliverable has standalone value. The best estimated selling prices for these units of accounting was determined based on market conditions, the terms of comparable collaborative arrangements for similar technology in the pharmaceutical and biotechnology industry and entity-specific factors, such as the terms of the Company's previous collaborative agreements, the Company's pricing practices and pricing objectives and the nature of the research and development services to be performed for the partner. The arrangement consideration was allocated to the deliverables based on the relative selling price method.

The amount of allocable arrangement consideration is limited to amounts that are fixed or determinable; therefore, the amount allocated to the licenses was limited to the extent of cash received. As a result, during the years ended December 31, 2018, 2017 and 2016, the Company recognized \$0.0 million, \$0.3 million and \$1.5 million, respectively, related to the license fee and know-how. The Company recognized the amounts allocated to research and development services as revenues under the agreements as the related services were delivered and as reimbursements were received. During the years ended December 31, 2018, 2017 and 2016, the Company recognized \$1.2 million, \$12.9 million and \$10.1 million, respectively, of revenue related to contract services delivered. The Company recognized as revenue the amounts allocated to the sales of drug product when the sale of that drug product had met all required specifications and the related title and risk of loss and damages passed to Astellas. During the years ended December 31, 2018, 2017 and 2016, the Company recognized \$0.0 million, \$0.0 million and \$2.4 million, respectively, of revenue related to drug product delivered.

In January 2018, Astellas announced the results from a Phase 3 trial of ASP0113 in approximately 515 CMV seropositive subjects undergoing HCT procedures. Top-line results from the Phase 3 study demonstrated that the trial did not meet its primary endpoint in CMV end organ disease. Based on these results, Astellas determined to cease further clinical development of ASP0113 and has terminated the license agreement.

In-licensing Agreements

Astellas

In March 2015, the Company entered into a license agreement with Astellas which grants to the Company exclusive worldwide license to develop and commercialize a novel antifungal, VL-2397. As consideration for the rights under the license, the Company issued 86,121 shares of our common stock to Astellas and made an up-front payment of \$250,000 in cash. The License Agreement provides for potential development, regulatory and sales milestone payments totaling up to \$99.0 million, the vast majority of which are payable upon achievement of commercial and sales milestones, and single-digit royalties on net sales of commercial products. The Company is responsible for the worldwide development, manufacturing and commercialization of licensed products, at the Company's cost, and we are required to use commercially reasonable efforts with respect to such development and commercialization activities.

The license agreement, unless terminated earlier, will continue until expiration of Vical's royalty obligations with respect to licensed products. Either party may terminate the license agreement earlier if the other party materially breaches the agreement and does not cure the breach within a specified notice period, or upon the other party's insolvency. Astellas may terminate the license agreement earlier if Vical or any of its affiliates or sublicensees oppose or challenge any of the licensed patents. Vical may terminate the license agreement on a country-by-country basis for reasonable scientific, regulatory, commercial, financial, ethical or other reasons.

Milestone Payments

The Company may be required to make future payments to its licensors based on the achievement of milestones set forth in various in-licensing agreements. In most cases, these milestone payments are based on the achievement of

development or regulatory milestones, including the exercise of options to obtain licenses related to specific disease targets, commencement of various phases of clinical trials, filing of product license applications, approval of product licenses from the FDA or a foreign regulatory agency, and the first commercial sale of a related product. Payment for the achievement of milestones under the Company's in-license agreements is highly speculative and subject to a number of contingencies.

The aggregate amount of additional milestone payments that the Company could be required to pay under its active in-license agreements in place at December 31, 2018, is approximately \$99.0 million. These amounts assume that all remaining milestones associated with the milestone payments are met. In the event that product license approval for any of the related products is obtained, the Company may be required to make royalty payments in addition to these milestone payments. Although the Company believes that some of the milestones contained in its in-license agreements may be

achieved, it is highly unlikely that a significant number of them will be achieved. Because the milestones are contingent the Company is not in a position to reasonably estimate how much, if any, of the potential milestone payments will ultimately be paid. Additionally, under the in-license agreements, many of the milestone events are related to progress in clinical trials which the Company estimates will take several years to achieve.

7. Commitments and Contingencies

Facility Leases

The Company occupied approximately 68,400 square feet of manufacturing, research laboratory and office space until July 2018 when the Company entered into an agreement with Genopis, Inc. (“Genopis”) to sell the Company’s idle manufacturing assets for \$1.7 million. As part of the agreement, Genopis agreed to sublease 51,400 square feet of the Company’s facility through the remaining term of the Company’s lease which expired on December 31, 2018. Genopis was also required to sign a long-term lease with the facility’s landlord beginning on January 1, 2019. Genopis agreed to sublease 17,000 square feet of the facility to the Company at no cost for the one-year period ending on December 31, 2019. A gain on the sale of assets of \$2.3 million was recorded, with \$1.1 million attributable to the fair value of rent for the space that the Company is occupying at no cost. The amount was recorded to deferred rent expense in Receivables and Other Assets and is being amortized as rent expense through December 31, 2019.

Rent expense for the years ended December 31, 2018, 2017 and 2016 was \$1.5 million, \$2.4 million, and \$2.6 million, respectively.

At December 31, 2018, there were no future minimum rental payments due by the Company.

Other Contingencies

In the ordinary course of business, the Company may become a party to additional lawsuits involving various matters. The Company is unaware of any such lawsuits presently pending against it which, individually or in the aggregate, are deemed to be material to the Company’s financial condition or results of operations.

The Company prosecutes its intellectual property vigorously to obtain the broadest valid scope for its patents. Due to uncertainty of the ultimate outcome of these matters, the impact on future operating results or the Company’s financial condition is not subject to reasonable estimates.

8. Stockholders’ Equity

As of the date of this filing the Company has on file a shelf registration statement that allows it to raise up to an additional \$40.0 million from the sale of common stock, preferred stock, debt securities and/or warrants. Specific terms of any offering under the shelf registration statements and the securities involved would be established at the time of sale.

In November 2017, the Company sold 9,194,286 shares of its common stock in a public offering at a price of \$1.75 per share, including an overallotment of 2,142,857 shares issued at a price of \$1.75 per share, and pre-funded warrants to purchase 7,234,285 shares of common stock at a purchase price of \$1.74 per share. Net proceeds from the offering, after deducting underwriting discounts and commissions and other offering expenses payable by the Company, totaled \$26.4 million. The pre-funded warrants have an exercise price of \$0.01 per share and are immediately exercisable and may be exercised at any time.

In October 2016, we entered into an At-The-Market Issuance Sales Agreement, or the ATM Agreement, with IFS Securities, Inc. (doing business as Brinson Patrick, a division of IFS Securities, Inc.), or BP, under which we could issue and sell up to \$10.0 million of shares of our common stock from time to time. The ATM expired in October 2018. For the 12 months ended December 31, 2017, we sold 1,509,370 shares under the ATM Agreement and received gross proceeds of \$4.3 million. We sold no shares under the agreement in 2018.

On August 1, 2016, the Company entered into a stock purchase agreement with AnGes, Inc., or AnGes, an existing stockholder, to purchase 1,841,420 shares of the Company's common stock in a private placement. The shares were sold at a price of \$4.24 per share. Gross proceeds totaled approximately \$7.8 million. The private placement closed on August 2, 2016. The shares are subject to a two-year lock-up period during which they may not be sold and AnGes has agreed to not increase its ownership position beyond 19.9% and to refrain from taking certain other actions with respect to the Company's

stock, subject to certain conditions. AnGes is entitled to have a representative attend meetings of the Company's Board of Directors in a non-voting capacity and may in the future be entitled to have a representative appointed to the Company's Board of Directors, subject to certain conditions. AnGes has also agreed to vote its shares in accordance with the recommendations of the Company's Board of Directors for so long as it continues to hold a specified percentage of the Company's outstanding common stock. The Company also agreed under certain circumstances in the future to register the private placement shares for resale by AnGes.

9. Stock Based Compensation

The Company has a stock-based compensation plan which is described below. Total stock-based compensation expense of \$0.4 million, \$0.8 million and \$1.0 million was recognized for the years ended December 31, 2018, 2017 and 2016, respectively. Total stock-based compensation expense was allocated to research and development, manufacturing and production and general and administrative expense as follows (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Research and development	\$154	\$239	\$290
Manufacturing and production	(67)	124	111
General and administrative	274	393	589
Total stock-based compensation expense	\$361	\$756	\$990
Cash received from RSU grants	\$—	\$—	\$1

Stock Incentive Plan

The Company has a stock incentive plan, under which 3,370,000 shares of common stock, subject to adjustment as provided in the plan, are reserved for issuance to employees, non-employee directors and consultants of the Company. As of December 31, 2018 there were 2,927,509 shares reserved for future issuance under the plan. The plan provides for the grant of incentive and nonstatutory stock options and the direct award or sale of shares, including restricted stock. The exercise price of stock options must equal at least the fair market value of the underlying common stock on the date of grant. The maximum term of options granted under the plan is ten years. Except for annual grants to non-employee directors which vest at the next annual meeting, options generally vest 25% on the first anniversary of the date of grant, with the balance vesting quarterly over the remaining three years. The plan also limits the number of options that may be granted to any plan participant in a single calendar year to 1,300,000 shares.

The Company has granted RSUs to executive officers, other executives, and employees under the stock incentive plan. There were no RSUs granted in the years ended December 31, 2018, 2017 or 2016. These RSUs generally vest 25% on the first anniversary date of the grant, with the remaining rights vesting quarterly over the remaining three years and, once vested, allow the participants to acquire the underlying shares of common stock at par value. The participants are not entitled to sell or transfer any unvested RSUs and are not entitled to vote or receive dividends on any shares of common stock covered by the RSUs prior to the acquisition of such shares. Granted but unvested RSUs are forfeited at termination of employment. Compensation expense related to the RSUs for the years ended December 31, 2018, 2017, and 2016 was approximately \$23,000, \$95,000 and \$316,000, respectively.

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The following table summarizes stock option transactions under the Company's stock incentive plans for the years ended December 31, 2018, 2017 and 2016:

	Weighted Average	
	Shares	Exercise Price
Outstanding December 31, 2015	945,584	\$ 23.27
Granted	339,975	\$ 3.51
Exercised	—	\$ —
Forfeited	(82,758)	\$ 24.37
Outstanding December 31, 2016	1,202,801	\$ 17.61
Granted	590,200	\$ 2.30
Exercised	—	\$ —
Forfeited	(68,330)	\$ 22.17
Outstanding December 31, 2017	1,724,671	\$ 12.19
Granted	547,701	\$ 1.77
Exercised	—	\$ —
Forfeited	(376,816)	\$ 10.00
Outstanding December 31, 2018	1,895,556	\$ 9.61
Vested and unvested options expected to vest as of December 31, 2018	1,895,556	\$ 9.61

The number of underlying shares and weighted average exercise price of options exercisable at December 31, 2018, 2017 and 2016, were 1,222,876 shares at \$13.71, 1,005,400 shares at \$18.72, and 808,639 shares at \$23.43, respectively. The weighted average remaining contractual term of options outstanding and options exercisable at December 31, 2018, was 6.6 years and 5.5 years, respectively. The weighted average remaining contractual term of vested and unvested options expected to vest at December 31, 2018, was 6.6 years. The aggregate intrinsic value of options outstanding and options exercisable at December 31, 2018 was \$0.0 million and \$0.0 million, respectively. As of December 31, 2018, the total unrecognized compensation cost related to unvested options was \$0.2 million, which is expected to be recognized over a weighted-average period of 1.39 years.

The weighted average grant-date fair value of options granted during the years ended December 31, 2018, 2017 and 2016, was \$0.81, \$1.21 and \$1.85 per share, respectively. There were no options exercised during the years ended December 31, 2018, 2017 or 2016. At December 31, 2018, there were 1,000,068 shares available for grant under the Company's stock incentive plans.

A summary of the outstanding RSUs as of December 31, 2018, and changes during the year then ended is presented below:

	Weighted Average	
	Shares	Value per Share
Unvested at December 31, 2017	21,204	\$ 10.43
Granted	—	\$ —
Vested	(16,187)	\$ 5.96

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Cancelled	(942)	\$ 10.30
Unvested at December 31, 2018	4,075	\$ 10.20

There were no RSUs granted in the years ended December 31, 2018, 2017 or 2016. As of December 31, 2018, the total unrecognized compensation cost related to unvested RSUs was \$1,000, which is expected to be recognized over a weighted average period of one year. The aggregate grant-date fair value of shares subject to RSUs vested during the years ended December 31, 2018, 2017 and 2016, was \$0.1 million, \$0.3 million and \$0.8 million, respectively. As of December 31, 2018, there were 27,809 shares of common stock underlying RSUs that were fully vested but the issuance of such shares has been deferred.

10. Related Party Transaction

On April 4, 2017, the Company entered into a research collaboration agreement with AnGes. As of the date of the transaction, AnGes held 18.6% of the outstanding stock of the Company. Pursuant to the collaboration agreement, AnGes

agreed to make a non-refundable payment to the Company of \$750,000 and the Company agreed to conduct certain research activities related to a development program targeting chronic hepatitis B. An amendment to the agreement was executed in September 2018 that added an additional non-refundable payment from AnGes to the Company of \$145,000. In exchange for the payments, AnGes received an option to negotiate exclusive rights in Japan related to the program. The parties also agreed to share the costs of prosecuting and maintaining intellectual property rights arising from the research program after such costs reach a specified limit. The decision to sell, license or sublicense rights is a contingent event within the Company's control. There are no guarantees for any outcomes of the research activities, no purchase obligations required by the Company and no debt or equity arrangements connected with the research activities. There are no other written or oral side agreements between the Company and AnGes that indicate that the funding of the research activities will be repaid. The Company is responsible for the conduct of the research activities. The upfront payments were deferred and recognized as contract revenue as the related research costs are incurred. Contract revenue relating to this collaboration of \$0.4 million and \$0.5 million was recognized in the years ended December 31, 2018 and 2017, respectively.

11. Restructuring Costs

In January 2018, the Company and Astellas announced that ASP0113 did not meet its primary endpoint in a Phase 3 clinical study in CMV end organ disease, after which Astellas informed the Company that it was terminating further development. As a result, the Company restructured its operations to conserve capital, which included a staff reduction of 40 employees and the write-off of certain intangible assets. The Company recorded charges for one-time employee termination benefits of \$1.1 million and for intangible asset impairments of \$0.3 million during the twelve months ended December 31, 2018. Overhead costs associated with the former manufacturing facility of \$1.2 million have been recognized as general and administrative expense during the twelve months ended December 31, 2018. The following table summarizes the components of the restructuring charges (in thousands):

	Employee Termination Benefits	Asset Impairments	Total
Research and development	\$ 272	\$ 267	\$539
Manufacturing and production	735	—	735
General and administrative	117	—	117
	\$ 1,124	\$ 267	\$1,391

The following table sets forth the accrual activity for employee termination benefits for the 12 months ended December 31, 2018 (in thousands). No additional charges are expected to be incurred.

Balance at December 31, 2017	\$—
Accruals	1,124
Payments	(1,124)
Balance at December 31, 2018	\$—

12. Sale of Manufacturing Assets

In July 2018, the Company entered into an agreement with Genopis to sell the Company's idle manufacturing assets for \$1.7 million. As part of the agreement, Genopis agreed to sublease 51,400 square feet of the Company's facility through the remaining term of the Company's lease, which expired on December 31, 2018. Genopis was also required to sign a long-term lease with the facility's landlord beginning on January 1, 2019. Genopis agreed to sublease 17,000 square feet of the facility (consisting of lab and office space) to the Company at no cost for the one-year period ending on December 31, 2019. A gain on the sale of assets of \$2.3 million was recorded and is included in Investment and Other Income, Net. The gain includes \$1.1 million for the fair value of rent for the lab and office space that the Company is occupying at no cost, with the offset recorded to deferred rent expense in Receivables and Other Assets.

13. Income Taxes

At December 31, 2018, the Company had deferred tax assets of \$87.4 million. Due to uncertainties surrounding the Company's ability to generate future taxable income to realize these assets, a full valuation allowance has been established

to offset the net deferred tax asset. Pursuant to Sections 382 and 383 of the Internal Revenue Code, or IRC, annual use of the Company's net operating loss and credit carryforwards may be limited in the event a cumulative change in ownership of more than 50% occurs within a three-year period. The Company determined that such an ownership change occurred on December 29, 2006, as defined in the provisions of Section 382 of the IRC as a result of various stock issuances used to finance the Company's operations. Such ownership change resulted in annual limitations on the utilization of tax attributes, including net operating loss carryforwards and tax credits. The Company estimates that \$94.6 million of its net operating loss carryforwards were effectively eliminated under Section 382 for federal tax purposes. A portion of the remaining net operating losses limited by Section 382 become available each year. The Company also estimates that \$11.8 million of its research and development credits and other tax credits were effectively eliminated under Section 383 for federal purposes. The Company's Section 382 analysis was completed through December 31, 2011. The Company has not, however, conducted a Section 382 study for any periods subsequent to December 31, 2011, and as such, the Company cannot provide any assurance that a change in ownership within the meaning of the IRC has not occurred since that date. There is a risk that additional changes in ownership could have occurred since that date. If a change in ownership were to have occurred, additional net operating loss and tax credit carryforwards could be eliminated or restricted. If eliminated, the related asset would be removed from the deferred tax asset schedule with a corresponding reduction in the valuation allowance.

Deferred income taxes result primarily from temporary differences between financial and tax reporting. Deferred tax assets and liabilities are determined based on the difference between the financial statement basis and the tax basis of assets and liabilities using enacted tax rates. A valuation allowance is established to reduce deferred tax assets to the amount that is expected more likely than not to be realized.

Significant components of the Company's deferred tax assets as of December 31, 2018 and 2017 are listed below. A valuation allowance of \$87.4 million and \$83.6 million at December 31, 2018 and 2017, respectively, has been recognized to offset the net deferred tax assets as realization of such assets is uncertain.

Amounts for the years ended December 31 were as follows (in thousands):

Deferred Tax Assets	2018	2017
Net operating losses	\$63,933	\$59,756
Credit carryovers	11,304	10,527
Depreciation and amortization	10,635	10,893
Deferred revenue	—	634
Accruals and reserves	275	450
Other	1,242	1,350
Total deferred tax assets	87,389	83,610
Less valuation allowance	(87,389)	(83,610)
Net deferred tax assets	\$—	\$—

The reconciliation between the provision for income taxes and income taxes computed using the U.S. federal statutory corporate tax rate were as follows for the years ended December 31 (in thousands):

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	2018	2017	2016
Computed “expected” tax benefit	\$(3,421)	\$(4,425)	\$(3,051)
State income taxes, net of federal benefit	(676)	(268)	(534)
Tax effect of:			
Change in valuation allowance	2,632	(31,665)	(6,030)
Impact of Tax Cuts and Jobs Act	—	34,439	—
Rate change	—	—	—
Expiration of prior year credits and net operating losses	1,386	1,256	692
Research and development and other tax credit carryovers	(1,320)	—	—
Stock compensation	121	458	491
Uncertain tax positions	1,357	276	9,010
Other	(79)	(71)	(578)
Provision for income taxes	\$—	\$—	\$—

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As of December 31, 2018 and 2017, the Company had available federal net operating loss carryforwards of approximately \$331.3 million and \$319.1 million, respectively. The net operating loss generated in 2018 of \$18.8 million will carry forward indefinitely and be available to offset up to 80% of future taxable income each year. Net operating losses generated prior to 2018 will expire from 2019 through 2038. In addition, the Company had federal research and development credit and orphan drug credit carryforwards of \$27.1 million and \$26.3 million as of December 31, 2018 and 2017, respectively, to reduce future federal income taxes, if any. These carryforwards expire from 2019 through 2038 and are subject to review and possible adjustment by the Internal Revenue Service. The Company also has available California state net operating loss carryforwards of approximately \$264.6 million and \$254.9 million as of December 31, 2018 and 2017, respectively, which expire from 2028 to 2038. In addition, the Company had California research and development credits of approximately \$9.3 million and \$8.8 million as of December 31, 2018 and 2017, respectively, to reduce future California income tax, if any. The California research and development credits do not expire. All federal and state net operating loss and credit carryforwards listed above are reflected before the reduction for amounts effectively eliminated under Sections 382 and 383. Based upon statute, federal and state losses and credits are expected to expire as follows (in millions):

Expiration Date			Federal		
	Federal NOLs	State NOLs	Federal R&D Credits	Orphan Drug Credits	State R&D Credits
2019	\$5.3	\$—	\$ 0.4	\$ 0.6	\$ —
2020	12.3	—	0.3	2.3	—
2021	7.5	—	0.3	2.0	—
2022	22.4	—	0.5	1.6	—
2023	22.4	—	0.3	0.9	—
2024 and thereafter	242.6	264.6	3.4	14.5	—
Indefinite	18.8	—	—	—	9.3
	\$331.3	\$264.6	\$ 5.2	\$ 21.9	\$ 9.3

In March 2016, the FASB issued Accounting Standards Update No. 2016-09, "Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting ("ASU 2016-09"). ASU 2016-09 simplifies how several aspects of share-based payments are accounted for and presented in the financial statements. ASU 2016-09 was effective for public companies for annual reporting periods beginning after December 15, 2016. Upon adoption of this ASU as of January 1, 2017, unrecognized excess tax benefits of approximately \$(0.2) million were recognized with the impact recorded to retained earnings including a corresponding change to the valuation allowance.

The Tax Cuts and Jobs Act (the "Act") was enacted on December 22, 2017. The Act reduced the U.S. federal corporate tax rate from 35% to 21% beginning in 2018. The Company applied the guidance in SAB 118 when accounting for the enactment-date effects of the Act in 2017 and throughout 2018. As of December 31, 2017, the Company remeasured certain deferred tax assets and liabilities based on the rates at which they were expected to reverse in the future (which is generally 21%), by recording a provisional amount of \$34.4 million, which was fully offset by the valuation allowance. Upon further analysis of certain aspects of the Act and refinement of our calculations during the twelve months ended December 31, 2018, the Company determined that no adjustment was necessary to the provisional amount.

The Company recognizes liabilities for uncertain tax positions based on a two-step process. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of

being realized upon settlement. While the Company believes that it has appropriate support for the positions taken on its tax returns, the Company regularly assesses the potential outcome of examinations by tax authorities in determining the adequacy of its provision for income taxes.

The following table summarizes the activity related to the Company's unrecognized tax benefits (in thousands):

	2018	2017	2016
Beginning balance	\$17,836	\$17,561	\$4,340
Increases (decreases) related to prior year tax positions	48	(140)	12,348
Increases related to current year tax positions	1,616	415	873
Ending balance	\$19,500	\$17,836	\$17,561

As of December 31, 2018 and 2017, the Company had gross unrecognized tax benefits of \$19.5 million and \$17.8 million, respectively, none of which would affect the effective tax rate. The Company does not anticipate any significant decreases in its unrecognized tax benefits over the next 12 months. The Company's policy is to recognize the interest expense and/or penalties related to income tax matters as a component of income tax expense. The Company had no accrual for interest or penalties on its balance sheets at December 31, 2018 or December 31, 2017, and has not recognized interest and/or penalties in its statements of operations for any of the years ended December 31, 2018, 2017 or 2016.

The Company is subject to taxation in the United States and state jurisdictions where applicable. The Company's tax years for 1998 and forward are subject to examination by the United States and California tax authorities due to the carryforward of unutilized net operating losses and R&D credits.

14. Employee Benefit Plan

The Company has a defined contribution savings plan under section 401(k) of the IRC. The plan covers substantially all employees. The Company matches employee contributions made to the plan according to a specified formula. The Company's matching contributions totaled approximately \$0.1 million, \$0.2 million and \$0.1 million for the years ended December 31, 2018, 2017 and 2016, respectively.

15. Summary of (Unaudited) Quarterly Financial Information

The following is a summary of the Company's (unaudited) quarterly results of operations for the years ended December 31 (in thousands, except per share amounts):

	March 31,	June 30,	Sept. 30,	Dec. 31,
2018:				
Total revenues	\$716	\$735	\$47	\$124
Total operating expenses	7,217	5,863	4,113	4,075
Net loss	(6,270)	(4,868)	(1,511)	(3,605)
Basic and diluted net loss per share (1)	(0.29)	(0.22)	(0.07)	(0.17)

	March 31,	June 30,	Sept. 30,	Dec. 31,
2017:				
Total revenues	\$3,205	\$3,421	\$3,240	\$3,953
Total operating expenses	6,118	6,832	6,421	7,834
Net income (loss)	(2,824)	(3,320)	(3,088)	(3,728)
Basic and diluted net loss per share (1)	(0.25)	(0.30)	(0.27)	(0.21)

(1) Net income (loss) per share is computed independently for each quarter and the full year based upon respective shares outstanding. Therefore, the sum of the quarterly loss per share amounts may not equal the annual amounts reported.

16. Subsequent Event

In February 2019, the Company decided to discontinue the Phase 2 clinical trial of VL-2397. As a result, the Company will be restructuring its operations to conserve capital, which will include a staff reduction and may include a write-off of certain assets. The Company will record these restructuring charges during the three months ended March 31, 2019.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of our disclosure controls and procedures, as such term is defined in Rule 13a-15(e) promulgated under the Exchange Act, as of the end of the period covered by this Annual Report on Form 10-K. The evaluation of our disclosure controls and procedures included a review of the disclosure controls' and procedures' objectives, design, implementation and the effect of the controls and procedures on the information generated for use in this report. In the course of our evaluation, we sought to identify data errors, control problems or acts of fraud and to confirm the appropriate corrective actions, including process improvements, were being undertaken. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this Annual Report on Form 10-K.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), as of December 31, 2018, the end of the period covered by this Annual Report on Form 10-K. Based on our evaluation under the framework in Internal Control – Integrated Framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2018.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. We were not required to have, nor have we, engaged our independent registered public accounting firm to perform an audit of internal control over financial reporting pursuant to SEC rules that permit us to provide only management's report in this Annual Report on Form 10-K.

Changes in Internal Controls

There has been no change in our internal control over financial reporting during the three months ended December 31, 2018, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item and not included in Part I, Item 1 of this Annual Report on Form 10-K is incorporated by reference from our Proxy Statement for our 2018 Annual Meeting of Stockholders, or our Proxy Statement.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference from our Proxy Statement.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item is incorporated by reference from our Proxy Statement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item is incorporated by reference from our Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item is incorporated by reference from our Proxy Statement.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)(1) Financial Statements

The following independent registered public accounting firms' reports and our financial statements are filed as part of this Annual Report:

Report of Independent Registered Public Accounting Firm

Balance Sheets as of December 31, 2018 and 2017

Statements of Operations for each of the three years in the period ended December 31, 2018

Statements of Comprehensive Loss for each of the three years in the period ended December 31, 2018

Statements of Stockholders' Equity for each of the three years in the period ended December 31, 2018

Statements of Cash Flows for each of the three years in the period ended December 31, 2018

Notes to Financial Statements

(2) Financial Statement Schedules

The schedules required to be filed by this item have been omitted because of the absence of conditions under which they are required, or because the required information is included in the financial statements or the notes thereto.

(3) Exhibits

See the list in paragraph (b) below. Each management contract or compensatory plan or arrangement required to be identified by this item is so designated in such list.

(b) Exhibits

Exhibit

Number Description of Document

3.1(i)(1) Restated Certificate of Incorporation. (P)

3.2(ii)(2) Amended and Restated Bylaws of the Company.

3.3(i)(3) Certificate of Amendment to Restated Certificate of Incorporation.

3.4(i)(4) Certificate of Amendment to Restated Certificate of Incorporation.

3.5(i)(5) Certificate of Amendment to Restated Certificate of Incorporation.

3.6(i)(6) Certificate of Amendment to Restated Certificate of Incorporation.

- 3.7(ii)(7) Amendment to Amended and Restated Bylaws of the Company.
- 4.1(1) Specimen Common Stock Certificate. (P)
- 10.1(8)^a Amended and Restated Stock Incentive Plan of Vical Incorporated.
- 10.2(9)^a Form of Indemnity Agreement between the Company and its directors and officers.
- 10.3(10)^a Vical Incorporated Non-Employee Director Compensation Policy.
- 10.4(11)^a Form of Delayed Issuance Stock Purchase Election Agreement, as amended, under the Amended and Restated Stock Incentive Plan (with deferral election).
- 10.5(12)^a Form of Delayed Issuance Stock Purchase Election Agreement, as amended, under the Amended and Restated Stock Incentive Plan.
- 10.6(13)^a Restated employment letter dated January 9, 2009, between the Company and Vijay B. Samant.
- 10.7(14)^a Employment Agreement dated January 14, 2005, between the Company and Anthony A. Ramos.
- 10.8(15)^a Severance Agreement dated January 23, 2015, between the Company and Anthony A. Ramos.

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Exhibit

Number Description of Document

- 10.9(16)^a Employment Agreement dated August 25, 2003, between the Company and Larry Smith.
- 10.10(17)^a Severance Agreement dated January 23, 2015, between the Company and Larry Smith.
- 10.11(18)^b License Agreement dated March 24, 2015, between the Company and Astellas Pharma Inc.
- 10.12(19)^b Amendment No. 1 dated August 31, 2015, to License Agreement dated March 24, 2015, between the Company and Astellas Pharma Inc.
- 10.13(20) Stock Purchase Agreement dated August 1, 2016, between the Company and AnGes MG, Inc.
- 23.1 Consent of Independent Registered Public Accounting Firm.
- 31.1 Certification of Vijay B. Samant, Chief Executive Officer, pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2 Certification of Anthony A. Ramos, Chief Financial Officer, pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1 Certification of Vijay B. Samant, Chief Executive Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2 Certification of Anthony A. Ramos, Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 101.INS XBRL Instance Document
- 101.SCH XBRL Taxonomy Extension Schema Document
- 101.CAL XBRL Taxonomy Extension Calculation Linkbase Document
- 101.DEF XBRL Taxonomy Extension Definition Linkbase Document
- 101.LAB XBRL Taxonomy Extension Label Linkbase Document
- 101.PRE XBRL Taxonomy Extension Presentation Linkbase Document

(P) Paper exhibit

- (1) Incorporated by reference to the exhibit of the same number filed with the Company's Registration Statement on Form S-3 (No. 33-95812) filed on August 15, 1995.
- (2) Incorporated by reference to the exhibit of the same number filed with the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2010.
- (3) Incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on June 1, 2017.
- (4) Incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on May 25, 2016.

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- (5) Incorporated by reference to Exhibit 3.3 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2010.
- (6) Incorporated by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-8 (No. 333-135266) filed on June 23, 2006.
- (7) Incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on November 29, 2018.
- (8) Incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K filed on June 7, 2018.
- (9) Incorporated by reference to Exhibit 10.3 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2002.
- (10) Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2014.
- (11) Incorporated by reference to Exhibit 10.58 to the Company's Annual Report on Form 10-K for the year ended December 31, 2009.
- (12) Incorporated by reference to Exhibit 10.59 to the Company's Annual Report on Form 10-K for the year ended December 31, 2009.
- (13) Incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K filed on January 15, 2009.
- (14) Incorporated by reference to Exhibit 10.7 to the Company's Annual Report on Form 10-K for the year ended December 31, 2013.
- (15) Incorporated by reference to Exhibit 10.8 to the Company's Annual Report on Form 10-K for the year ended December 31, 2014.

- (16) Incorporated by reference to Exhibit 10.11 to the Company's Annual Report on Form 10-K for the year ended December 31, 2013.
- (17) Incorporated by reference to Exhibit 10.12 to the Company's Annual Report on Form 10-K for the year ended December 31, 2014.
- (18) Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2015.
- (19) Incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015.
- (20) Incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2016.

aIndicates management contract or compensatory plan or arrangement.

bConfidential treatment of certain portions of this agreement has been requested and/or received and such portions have been omitted and filed separately with the SEC pursuant to Rule 24b-2 under the Securities Exchange Act of 1934.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: March 1, 2019

VICAL INCORPORATED

By: /S/ ANTHONY A. RAMOS

Anthony A. Ramos

Vice President, Chief Financial Officer (on behalf of the registrant and as the registrant's Principal Financial and Accounting Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

/S/ VIJAY B. SAMANT Vijay B. Samant	President, Chief Executive Officer and Director (Principal Executive Officer)	March 1, 2019
/S/ ANTHONY A. RAMOS Anthony A. Ramos	Vice President, Chief Financial Officer (Principal Financial and Accounting Officer)	March 1, 2019
/S/ R. GORDON DOUGLAS, M.D. R. Gordon Douglas, M.D.	Chairman of the Board of Directors	March 1, 2019
/S/ RICHARD M. BELESON Richard M. Beleson	Director	March 1, 2019
/S/ GARY A. LYONS Gary A. Lyons	Director	March 1, 2019
/S/ ROBERT C. MERTON, Ph.D. Robert C. Merton, Ph.D.	Director	March 1, 2019
/S/ GEORGE J. MORROW George J. Morrow	Director	March 1, 2019
/S/ Thomas E. Shenk, Ph.D. Thomas E. Shenk, Ph.D.	Director	March 1, 2019